



**U.S. FOOD & DRUG  
ADMINISTRATION**

# Investigations Operations Manual 2022



**Office of Regulatory Affairs  
Office of Operations**



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

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Office of Operations**

In August 2021, ORA published its five-year Strategic Plan covering FY2022 – 2025, which outlines ORA’s direction and approach to accomplish our mission and meet our vision.

### **Vision**

Public health is protected, promoted, and advanced.

### **Mission**

Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products.

### **Ultimate Outcome**

Protect consumers and patients from injury or illness from FDA-regulated products while ensuring timely access to safe and quality products.

### **Core Values**

ORA’s core values define the organization’s “character” and inform its actions and decisions.

*Accountability*

*Commitment to Public Health*

*Communication*

*Inclusion, Diversity, Equity, and Accessibility*

*Integrity and Respect*

*Quality*

Judith A. McMeekin, Pharm.D.

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs

## Foreword 2022

The *Investigations Operations Manual* (IOM) is the primary operational reference for FDA employees who perform field activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.

Other FDA manuals and field instructions supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of field activities. In such cases, your division management must be informed and concur with any significant departures from the IOM.

The 2022 version of the IOM contains important changes which clarify or present new information and procedures. As with each new edition of the IOM, please take time to review sections of the manual for changes which may apply to your work. Additions to the IOM are highlighted in light gray.

The IOM is also posted on ORA's Internet Website <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual>, with all graphics included.

The COVID-19 pandemic continues to be a paradigm-shifting public health event. In May 2021, FDA issued a report titled, "Resiliency Roadmap for FDA Inspectional Oversight," outlining the agency's inspectional activities during the COVID-19 pandemic and its detailed plan to move toward a more consistent state of operations. From the beginning of this public health emergency, ORA's innovation and resiliency in the face of challenges has highlighted our true commitment to fulfilling the agency's mission to protect and promote the public health. Additionally, 2021 marked the first milestone of the IOM Refresh Project, a cover to cover, all-inclusive review of the IOM, with completion of the Chapter 8 refresh in July and initiation of the Chapters 1 and 2 refresh. In 2022 we will continue to use the new tools and alternative inspectional activities developed in response to the public health emergency to support oversight of regulated industries and agency decision making. As these new tools continue to be developed and refined, we will capture the processes and procedures across programs in the IOM.

The IOM is published hard copy annually. Until the IOM Refresh Project is completed, future updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as ORA's official document of record.

ORA leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2023 edition of the IOM including recommended changes, deletions, and additions to the IOM may be sent via e-mail to [IOM@FDA.HHS.GOV](mailto:IOM@FDA.HHS.GOV). Suggestions are accepted from within the agency, our state and local partners, industry and consumers. All changes are reviewed by the IOM Committee, which is composed of a cross-functional group consisting of representatives from each commodity area in addition to imports, recalls, and policy.

Thank you for your continued exceptional work and commitment to protecting and promoting the health and well-being of the American people. It is an honor serving with you.



Judith A. McMeekin, Pharm.D.

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## SUBCHAPTER 1.1 - ENGLISH LANGUAGE REQUIREMENT FOR FDA DOCUMENTS

Records or Federal Records are defined in [44 U.S.C. 3301](#) as including “all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law ...” which includes regulatory notes, memoranda, inspection reports, emails, and official government forms e.g. SF-71, FDA-482-FDA-483, etc. made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the Government or because of the informational value of the data in them (44 U.S.C. 3301). (See also § 1222.10 of this part for an explanation of this definition).

All official FDA documents generated during your routine duties shall be completed in English. This requirement is necessary to facilitate efficiency in the workplace. For instance, many of your work products used in support of FDA’s regulatory process are subject to review and auditing by your supervisor, utilized by your co-workers, and others, including the public, in that they are releasable under the Freedom of Information Act (FOIA). The Agency does not have the resources to assure the accurate and timely English translation of documents written in a non-English language in order to facilitate their use in the conduct of official business. English is generally considered to be the common language of the U.S.; therefore it is necessary to standardize the language utilized in the production of official FDA documents.

Additionally, FDA imposes English only requirements on the public for information submitted to the Agency. For example 21 Code of Federal Regulations section 803.13(a) (English Reporting Requirement) states that all reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

## SUBCHAPTER 1.2 - TRAVEL

All official travel must be authorized and approved with a valid travel authorization (TA) using FDA’s Electronic Government Travel Services, Concur Government Edition (CGE). Emergency travel can be approved and the travel order prepared and authorized after the fact. "After the fact" TAs should be utilized on a very limited basis.

The [Federal Travel Regulations](#) (FTR) contained in [41 CFR 301](#), the [Department of Health and Human Services \(DHHS\) 2018 Travel Manual](#), the FDA supplements to the DHHS 2012 Travel Manual and the Collective Bargaining Agreement govern official travel. Article 42 of the Collective Bargaining Agreement is intended to be read in conjunction with the FTR and the HHS Travel Manual. If there is a conflict between the HHS Travel Manual and Article 42, Article 42 governs. Become familiar with these documents. All material contained in the Investigations Operations Manual (IOM) must be used in conjunction with, and subject to, federal travel regulations. Additional travel information

can be obtained from the Office of Financial Management (OFM) Intranet home page.

For foreign travel, be aware that there are differences in reporting requirements and reimbursable expenses. See the Guide to International Inspections and Travel, [Chapter 2, Subchapter 215.2](#) – Reimbursable Expenses, for specifics.

Federal employees must put most official travel-related charges on government-issued credit cards, with exceptions only for expenses that are either relatively minor or inconvenient for credit card usage such as parking, local transportation, tips, phone calls, and certain expenses for which credit cards are not accepted.

The FDA uses an Electronic Government Travel Services (ETS) as the Government Travel Service. The ETS is the Government-contracted, end-to-end travel management service that automates and consolidates the Federal travel process in a self-service Web-centric environment, covering all aspects of official travel, including travel planning, authorization, hotel and rental car reservations, ticketing, expense reimbursement, creating authorizations and vouchers (including local travel vouchers) and travel management reporting. In addition, the Electronic Government Travel Services (ETS) will interface with the Unified Financial Management System (UFMS) for obligation and payment of travel vouchers. Payments will include direct payment to the credit card company for expenses charged to the individual's official government travel credit card. The system incorporates Federal Government travel policies which include the city pair airfare contract program and Federal Travel Regulations and is structured to require justification if you want to deviate from General Services Administration's (GSA) regulations. A policy has been established with the FDA so that your government-issued credit card will be your primary method of billing and payment when you book flights, make hotel reservations, or reserve a rental car. Additional information can be obtained by contacting your Administrative Staff or visiting OFM's website.

## 1.2.1 - COMMON CARRIER

Request round-trip tickets when it can be expected you will use them. **Reserved tickets should be canceled through Omega if you will not be using them.** Do not assume if you cancel your travel authorization in CGE that it will automatically cancel your unused tickets. Failure to do so may result in unnecessary charges and could result in traveler being responsible for payment.

Employees are required to use a government individually billed travel charge card, CBA, or a Government Transportation Request (GTR) to pay for common carrier transportation services. Requirements which may authorize you to use cash payments for procurement of common carrier transportation and related expense, in lieu of your government-issued credit card or centrally billed account are specified in [41 CFR 301-72.200](#) and [301-51.100](#). Cash payments can be permitted to obtain passenger

transportation services in an emergency, for any amount when authorized by your Division Director (DD) and documented on your TA, but should happen on rare occasions only. Otherwise, cash and personal credit cards may not be used for transportation expenses exceeding \$100.00

Unauthorized purchases of common carrier transportation include:

1. Use of personal credit cards;
2. Cash withdrawals from an ATM using the Government travel charge card; and
3. Checks, both personal and Travelers.

If a new employee or an invitational or infrequent traveler, who is unaware of proper procedures, makes an unauthorized purchase of common carrier transportation using personal funds, reimbursement to the employee will be limited to the constructed cost of such transportation using the City Pair Fare (if no City Pair is available, the fare provided by the TMC will be used) and authorized method of payment. Employees who repeatedly use personal funds to pay for common carrier expenses may be subject to disciplinary action.

When cash is used, claim a reimbursement on your travel voucher and submit your ticket stubs or other appropriate receipts. You must also explain the circumstances for using cash on your travel vouchers. See IOM 1.2.7 for mandatory statements required on a travel voucher.

If emergency circumstances arise where the use of your government travel card is not possible contact your supervisor.

### 1.2.1.1 - Air

It is FDA's policy that you must always use a contract city-pair fare for scheduled air passenger transportation service, (an Internet list of city-pairs is available at <http://cpsearch.fas.gsa.gov/>), unless one or more of the following conditions exist(s):

1. Space or a scheduled contract flight is not available in time to accomplish the purpose of your travel, or use of contract service would require you to incur unnecessary overnight lodging costs which would increase the total cost of the trip; or
2. The contractor's flight schedule is inconsistent with explicit policies of your Federal department or agency with regard to scheduling travel during normal working hours; or
3. A non-contract carrier offers a lower fare available to the general public, the use of which will result in a lower total trip cost to the Government, to include the combined costs of transportation, lodging, meals, and related expenses.

Note: This exception does not apply if the contract carrier offers a comparable fare and has seats available at that fare, or if the lower fare offered by a non-contract carrier is restricted to Government and military travelers on official

business and may only be purchased with a GTR, contractor-issued charge card, or centrally billed account (e.g., YDG, MDG, ODG, VDG, and similar fares); or Note: the non-contract fare ticket must provide at least a 40 percent savings from the total cost of the contract fare.

4. Rail service is available and such service is cost effective and consistent with mission requirements; or
5. Smoking is permitted on the contract flight and the nonsmoking section of the aircraft for the contract flight is not acceptable to you.

Any additional costs or penalties incurred by you resulting from unauthorized use of non-contract service are borne by you. If the non-contract fare is non-refundable, restricted or has specific eligibility requirements, you must know or reasonably anticipate, based on your planned trip, that you will use the ticket and your Agency must determine that the proposed non-contract transportation is practical and cost effective for the Government.

Clear justifications are required and must be provided in the "Trip Details" section of your TA on why a Contract Carrier is not selected and must be approved on the travel authorization.

Refer to Federal Travel Regulation (FTR) [301-10.107](#) and [301-10.108](#) for additional information.

Other than Coach Class Travel accommodations must be requested by the traveler's office via memorandum to and approved by the Director, Office of Financial Management.

[The National Defense Authorization Act for Fiscal Year 2002](#), Section 1116 specifically states that federal employees may retain for personal use promotion items, including frequent flyer miles, earned on official travel. Normally it is the policy of the Government that employees generally must travel by coach class accommodations. However, you may upgrade your transportation class to premium service e.g. business class/first-class with your personal funds or your frequent flyer miles based on regulations found in [FTR 301-10.123](#) and [301-10.124](#).

Accommodations other than coach will be approved in accordance with the FTR and the NTEU-MOU for foreign inspections.

Consistent with [FTR 301-12.2](#), you may be reimbursed expenses related to baggage, but you should be prudent and only request reimbursement for reasonable excess baggage authorized and approved in advance on the travel authorization.

Please see the [FTR](#) on the GSA website for additional information.

### 1.2.1.2 - Auto Rental

GSA and the Department of Defense (DOD) both provide employees with a nationwide commercial auto rental program. The Federal Travel Directory contains a list of vehicle leasing companies participating in this program.

Agency policy dictates leasing the least expensive auto to satisfy the transportation requirements.

Commercial auto rental is available when specifically authorized and approved by your approving official on your travel authorization. Your agency must select the method most advantageous to the Government, when cost and other factors are considered. Under [5 U.S.C. 5733](#), travel must be by the most expeditious means of transportation practicable and commensurate with the nature and purpose of your duties.

In addition, your agency must consider energy conservation, total cost to the Government (including costs of per diem, overtime, lost work time, and actual transportation costs), total distance traveled, number of points visited, and number of travelers". If a rental vehicle is determined to be the most advantageous mode for travel, there must be specific written authorization or prior approval to obtain this service. See your Administrative Officer for additional information and necessary form to be uploaded into ETS.

Optional Collision Damage Insurance known as CDW will not be reimbursed for domestic travel. Participating rental companies have agreed to settle any claim for damages with the FDA. It is important to note that only damages incident to official travel will be covered by this agreement. If an investigation shows your vehicle damage or personal injury was the result of your unauthorized use of a rental vehicle, you may be personally liable for all related costs. See IOM 1.2.2.3 - Liability.

CDW is required for foreign travel and will be reimbursed. See the [Guide to International Inspections and Travel, 211.7 - Auto Rental](#).

The government will not pay or reimburse you for Personal Accident Insurance (PAI) for domestic or foreign travel. Travelers are covered while on official business by workmen's compensation insurance. See IOM 1.2.3.1

Travelers are required to adhere to the same rules and regulations covering government owned vehicles when using a rental car while on official business.

### 1.2.1.3 - Taxi

Reimbursements for the use of taxicabs will only be allowed when authorized on your TA. Allowable tips are 15% of the reimbursable fare. Receipts are required for fares over \$75.00.

You will be reimbursed for the usual cab and/or airport limousine fares plus tip from your home/office to the common carrier terminal on the day you depart on an official overnight trip, and upon your return. In lieu of cab, you may use your personal car at a mileage rate not to exceed the cab fare plus tip. See your administrative personnel for current mileage rates, the maximum allowable taxicab fares, and other pertinent details.



### 1.2.1.4 - Gainsharing

[The Government Employees Incentive Awards Act, 5 USC Paragraphs 4501-4507](#), authorizes an agency to pay a cash award for "efficiency" or "economy". FDA in conjunction with the National Treasury Employees Union (NTEU) implemented a Gainsharing Travel Savings Program which rewards you if you save the FDA money while you are on temporary travel (TDY). Your participation is optional. The Agency's gainsharing policy, filing instructions and frequently asked Questions/Answers for gainsharing claims can be found by accessing OFM's website.

## 1.2.2 – GOVERNMENT-OWNED/COMMERCIALY LEASED/RENTED VEHICLES

Government owned or commercially leased/rented vehicles may not be used for other than official business. Official business shall be interpreted strictly and shall not be construed to encompass the mingling of official business with non-official business. Official business is defined as those activities conducted during duty hours, which are considered an official part of the employee's assigned duties. Non-official business for which the use of Government owned or commercially leased/rented vehicles is illegal includes, but is not limited to such activities as:

- Attending to personal business
- Attendance at luncheons or other social engagements
- Pleasure trips; etc.

The distance involved in any such misuse is irrelevant.

You are responsible at all times for the proper care, operation, maintenance and protection of a GOV. Any employee of the Federal Government who willfully uses or authorizes the use of any Government-owned or commercially leased/rented vehicle for other than official purposes shall be suspended from duty by the office concerned, without compensation for not less than 30 days and shall be suspended for a longer period or summarily removed from office if circumstances warrant.

Operators of Government-owned and commercially leased vehicles shall become familiar with and obey all motor vehicle traffic laws of the State and local jurisdictions in which they operate. Fines imposed on a Government employee for an offense committed by him or her while in the performance of, but not as a part of the employee's official duties are imposed on the employee personally and payment thereof is his or her personal responsibility. This includes fines for parking violations, moving violations while operating a Government-owned/leased rented vehicle.

In accordance with EO 13513, **"No Texting While Driving"**, Federal employees shall not engage in text messaging (a) when driving GOV, or when driving POV while on official Government business, or (b) when using electronic equipment supplied by the Government. FDA's,

Daily Record of Government Vehicle, form, FDA-3369 is a required form which must be completed by each driver of a government-owned Commercially leased/rented vehicle. The form also bears acknowledgement of the ruling contained in the Executive Order. See: [Executive Order 13513](#),

The use of tobacco products is prohibited in Government-owned or commercially leased/rented vehicles. If this regulation is violated, an employee may be charged for the cost of cleaning the affected vehicle(s) beyond normal detailing procedures to remove tobacco odor or residue or repairing damage caused as a result of tobacco use.

FDA prohibits the use of hand-held phones while operating a government-owned, commercially leased/rented vehicle. Hands free devices such as Bluetooth devices are permitted unless otherwise stated in each states law.

The use of safety belts is mandatory for the operator and passengers in Government-owned or commercially leased/rented vehicles. It is the vehicle operator's responsibility to ensure all occupants are wearing their safety belts.

Parking Privately Owned Vehicles, (POV) in government reserved parking spaces is strictly intended for Government vehicles only. Staff Manual Guide 2560.2 the section on Parking, Section 8 line (J) informs all employees that all posted parking signs must be obeyed. Therefore, parking any vehicle in a government space is prohibited.

For additional information regarding [Federal Fleet Management](#), please visit:

<https://www.gsa.gov/buying-selling/products-services/transportation-logistics-services/vehicle-buying/federal-fleet-mgmt-system-fedfms>.

### 1.2.2.1 - Interagency Motor Pool

GOVs for District operations are furnished by the regional GSA motor pool. Be guided by the District operating procedures in effect for the appropriate GSA Motor pool.

Vehicle Operation - You are required to have a valid state, District of Columbia, or commonwealth operator's permit for the type vehicle to be operated, and a valid DHHS identification document (i.e., Agency ID card, credentials, building pass, etc.).

Each District has working arrangements for the repair and maintenance of vehicles, either with GSA contractors or the GSA motor pool. It is your responsibility to adhere to those safety and maintenance checks. Do not operate cars known to be mechanically unsafe. Handle emergency repairs in travel status in accordance with your District and GSA motor pool procedures.

Purchase fuel and oil for your GOV with GSA WEXCredit Cards. Make emergency purchases with cash only when the GSA Credit Card is refused. Your receipts are required

by the GSA Regional motor pool servicing your location. Provide for the safe and proper overnight storage of GOVs while you are in travel status, and put the charges on your travel voucher. Please note the dollar limit for maintenance purchases without prior GSA approval is \$100 except when purchasing tires, batteries or glass repair/replacement, GSA must be contacted first regardless of amount. Please consult your local Fleet Manager and supervisor for specific instructions and guidance.

You are responsible for all traffic violations, including parking fines, you incur during the use and operation of a GOV. See Staff Manual Guide 2173.1 Section 5.F.

While on official business, you may be reimbursed for parking fees or overnight storage charges. Put these charges on your travel voucher. Receipts are required when available.

Bridge, ferry and road tolls may be paid in cash. Put these charges on your travel voucher. Receipts are only required for amounts over \$75.00.

## 1.2.2.2 - Accidents

Immediate Action - Render first aid. If you are injured, obtain emergency treatment. Contact police.

### 1.2.2.2.1 - INFORMATION TO BE OBTAINED

Information to be obtained:

1. Description of vehicles involved, including license numbers
2. Name, address and other pertinent information about drivers and owners of other vehicles; exchange state driver license information if possible
3. Names, addresses and signed statements of witnesses
4. Names, official affiliation of investigating police officers
5. Photographs of the scene and the damage
6. Make no statements as to responsibility for the accident, except to your supervisor or investigating official.

### 1.2.2.2.2 - REPORTING

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor and the chief of the motor pool from which the vehicle is assigned, unless your supervisor advises you the district will handle it. Report the accident to the GSA Accident Management Control Center, Call (866) 400-0411, and select option 2.

1. Complete the following forms and submit as required:
  - a. "Motor Vehicle Accident Report" (SF-91) (A blank copy of this form should be kept in the glove compartment)
  - b. Copy of a traffic regulations or ordinance which was violated

- c. Results of any trial or disposition of summons if any arrests were made or charges preferred.
- d. "Claim for Damage, Injury or Death" (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.) To be completed by claimant or non-government employee.
- e. Investigation Reports and Policy Reports
- f. Statement of Witness (SF-94)
- g. Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
- h. Statement listing date of purchase, purchase price and salvage value where repair is not economical
- i. Photographs of damage and/or scene of accident if available

2. File reports to comply with all local and state laws dealing with accident reporting. Keep copies of all reports made and attach them to the federal accident report.
3. Check with your personal insurance carrier for their requirements.
4. Immediately submit to your supervisor any notice, summons, legal paper or claim, which may subsequently arise from the accident.
5. Check with your supervisor or administrative staff to determine if additional reports or information are needed.
6. Submit completed claims package electronically to the [FDATortClaims@fda.hhs.gov](mailto:FDATortClaims@fda.hhs.gov) e-mailbox or by inter-office mail or by the U.S. Post Office to the FDA Fleet Manager, Logistics and Transportation Management Branch, 10903 New Hampshire Ave, Bldg. 71, Room 2132, Silver Spring, MD 20993.

Mail (1) copy to: The Environment, Safety and Strategic Initiatives Staff, 10993 New Hampshire Ave., Bldg. 71, Room 2116, Silver Spring, MD 20993, and (1) copy to The ORA Safety Officer, 12420 Parklawn Dr., Room 3129, Rockville, MD. 20857. Tort claims must contain the completed Standard Form 91, Motor Vehicle Accident Report and the Standard Form 95, Claim for Damage, Injury, or Death.

## 1.2.2.3 - Liability

[The Federal Drivers Act \(28 U.S.C. 2679\(a\)-\(e\)\)](#) was enacted to protect government drivers from personal liability while driving within the scope of their employment. This means you must be on official business to be covered. It relieves you from the burden of acquiring private automobile liability insurance for driving while on the job.

The government's exclusive liability provided by this Act is predicated on its status as employer, without regard to whether the vehicle involved is government owned or privately owned.

[The Military Personnel and Civilian Employees' Claim Act of 1964](#) allows for claims against FDA by employees, provided the loss or damage was within the scope of their employment and the employee (claimant) is free of negligence regarding those losses (See IOM 1.2.2.3.1). [The Federal Tort Claims Act](#) provides for claims generally coming from outside the Agency where the activities of the Agency or specific individual employees are negligent and cause death, injuries, or property loss or damage (See IOM 1.2.2.3.2).

Claims should be submitted through your Administrative Office electronically to the [FDATortClaims@fda.hhs.gov](mailto:FDATortClaims@fda.hhs.gov) e-mailbox via the Outlook mailbox or through regular mail to the FDA Fleet Manager, Logistics and Transportation Management Branch, 10993 New Hampshire Ave., White Oak Bldg. 71, Room 2132, Silver Spring, MD. 20993. The claim will be reviewed and forwarded to the Office of the General Counsel, (OGC) for determination. The claimant will be notified by the OGC.

### 1.2.2.3.1 - MILITARY PERSONNEL AND CIVILIAN EMPLOYEES' CLAIM ACT OF 1964

Documentation and information is to be submitted as follows for military personnel and civilian employees' claims under the [Military Personnel and Civilian Employees' Claim Act of 1964](#).

Claims Involving Household Moves:

1. "Employee Claim for Loss or Damage to Personal Property" (HHS-481)
2. Schedule of Property
3. Household Inventory showing items claims
4. Other documents that may provide evidence of damage or loss
5. Proof of Ownership
6. Cost of Repair (if damage is over \$50.00 submit receipt of cost of repair or estimate of cost on company letterhead)
7. Photographs if available
8. Copies of private claims if applicable (claims must be filed seeking recovery from carrier before FDA claim can be filed.)
9. Personnel Order or Travel Authorization

Claims Involving Property Loss or Damage:

1. "Employee Claim for Loss or Damage to Personal Property" (HHS-481)
2. Schedule of Property
3. Proof of Ownership

4. Cost of Repair (if damage is over \$50.00 submit a receipt for the cost of repair or estimate of cost on company letterhead)
5. Photographs if available
6. Copies of private claims if applicable
7. Police report and/or other agency report and witness statements if appropriate

Motor Vehicle Accidents - See IOM 1.2.2.2

### 1.2.2.3.2 - TORT CLAIMS

Tort Claims can be filed by any individual who states that they have suffered personal injury or property damage or loss resulting from the action of an FDA employee or Commissioned Officer who was acting within the scope of employment.

Property Damage or Personal Injury

1. "Claim for Damage, Injury or Death" (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.)
2. Investigation Reports and Policy Reports
3. Statement of Witness (SF-94)
4. Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
5. Statement listing date of purchase, purchase price and salvage value where repair is not economical
6. Photographs of damage and/or scene of accident if available

### 1.2.2.3.3 - REFERENCES

FDA Staff Manual Guide 2260.1

Staff Manual Guide 2173.1 Section 5.F.

Military Personnel and Civilian Employees' Claims Act of 1964 Directive 495.1 - Claims Under The Military Personnel And Federal Tort Claims Act

### 1.2.2.4 - Use of a GOV between Your Residence and Place of Employment

Unless approved by the Secretary, DHHS, employees are not authorized the use of a Government-owned or commercially leased/rented vehicle between residence and place of employment. See [Staff Manual Guide 2173.1](#)

No employee shall use a government vehicle for transportation between their home and place of employment without the expressed written approval of the Secretary of Health and Human Services. Requests for Home-To-Work Authority must be submitted in writing by the Office Director/Center Director/ORR Headquarters to the FDA Fleet Manager.

Vehicles assigned to or purchased or leased by FDA are intended for official business as authorized by [Federal Management Regulation 102-34.220](#). FDA motor vehicles are not provided for the convenience of FDA employees. Government vehicles should only be used when it is: (1) the least costly method of transportation available (considering the value of employee time and actual transportation costs) or (2) when no other practical method of transportation is available considering the mission to be performed; the location; and any equipment needed to be transported to support the mission.

The Daily Log of Government Vehicle (Form FDA-3369) must be maintained by all approved persons using a GOV, assuring that all items indicated on the form are completed for each trip. The DHHS now requires that each person taking a GOV home, in order to perform Field work, must indicate in Column 10 on the FDA-3369, the location of their residence.

The Daily Log must be kept for at least period of three years and must be available for audit purposes.

### 1.2.2.5 - Care & Custody of U.S. Vehicles

GSA has issued instructions on the use and protection of U.S. Government vehicles, Government National Credit Cards, and car keys. The parts of these instructions applicable to you while the car is in your custody are:

1. The car should be locked when parked in public areas, in private lots, or in open government parking areas.
2. The operator is responsible for the keys and the credit card. They should be returned to the Administrative Officer/Program Fleet Manager and secured in a locked environment daily/nightly.
3. The keys and credit card are returned to the motor pool office when the vehicle is returned. These items should be kept in a safe place at the office if the vehicle is stored at other than a motor pool location.
4. The credit card must be removed when a vehicle is left at a garage or service station and the keys remain with the garage or station attendant.
5. The credit card may only be used to purchase fuel and lubricants or other items listed on the back of the card for the vehicle identified, and not used for other vehicles.
6. Before signing a service ticket, check for accuracy. Be sure the imprinted address is legible, and write the vehicle mileage (odometer reading) on the ticket and submit a copy or original to the Administrative Officer/Program Fleet Manager for monthly reporting requirements in the Motor Vehicle Management and Information System, (MVMIS).

The use of tobacco products is prohibited in government-owned or commercial, leased vehicles

### 1.2.3 - PRIVATELY OWNED VEHICLE (POV)

On official business, you may use your POV instead of a GOV, if authorized. However, reimbursement for mileage

will not exceed the cost of using a GOV. You should carry a set of government accident reporting forms whenever you use your POV for official business. See IOM 1.2.2.2 for accident reporting requirements.

In general, the mileage allowance is in lieu of all expenses of operating your POV, except tolls. Unless otherwise authorized, reimbursement is limited to the cost of travel by common carrier. Standard highway guide mileage may be used in lieu of odometer readings for direct travel from one town to another. Explain any extra mileage on your travel voucher.

According to HHS Logistics Management Manual, HHS employees and contractors may use their privately owned vehicles (POV) for official purposes when it is considered to be advantageous to HHS. Employees and contractors authorized to use POVs for official duties are entitled to reimbursement, per miles driven, based on GSA's annual rates.

**Please Note** - HHS employees and contractors who use POVs should inform their insurance companies that their vehicles are being used for official purposes. An HHS employee or contractor assumes full financial liability when using a POV for official purposes.

### 1.2.3.1 - Accidents

The [Federal Employees' Compensation Act](#) (Workmen's Compensation) protects employees against losses due to personal injuries received while operating POVs on official business.

Under the Federal Driver's Act [[28 U.S.C. 2679\(a\)-\(e\)](#)], you are immune from any civil liability to other parties for property damage, personal injury, or death resulting from operation of a vehicle within the scope of your employment. This immunity applies whether the vehicle involved is a GOV or POV. The government would defend any such claim or suit, and would pay any damage award to the injured party.

If an accident was caused by your negligent operation of a vehicle, and your vehicle is damaged, the cost of repairing your vehicle will not be paid for by the government. You should look to your own private insurance carrier for reimbursement, payable under the terms of your own automobile insurance policy. You are protected from liability by the Federal Drivers Act. See IOM 1.2.2.3 for further information on this.

If the accident is determined not to have been caused by your negligence, the provisions of the Military Personnel and Civilian Employees Claims Act (31 U.S.C. 240-243) would be applicable. Under this Act, you would be reimbursed for the deductible portion of the repair not covered by your own automobile insurance policy, up to a maximum of \$250.00 deductible. (You may also collect from the other party's insurance.) Form DHHS-481, Employee Claim for Loss or Damage to Personal Property, should be obtained from, completed, and submitted

electronically to the [FDATortClaims@fda.hhs.gov](mailto:FDATortClaims@fda.hhs.gov) Outlook e-mailbox or through regular mail to the FDA Fleet Manager, Logistics and Transportation Management, 10993 New Hampshire Ave., White Oak Bldg. 71, Room 2132 Silver Spring, MD. 20993 with evidence establishing that the use of a POV was authorized for official purposes and that the accident was not caused by your negligence.

Employee Liability - see IOM 1.2.2.3.

Reporting - Report vehicle accidents as instructed in IOM 1.2.2.2.2.

## 1.2.4 - PER DIEM AND SUBSISTENCE

Subsistence is the cost of lodging, meals, tips, and the miscellaneous expenses you incur while in travel status. Per Diem is based on the actual cost of lodging, plus a set amount for "Meals and Incidental Expenses" (M&IE), not to exceed the maximum rate for the prescribed city or area.

The FTR requires traveling employees to exercise care in incurring expenses which includes claiming a federal exemption from payment of state and/or local taxes on lodging whenever this option is available. Not all states and localities offer tax exemption, and some locations do not specify a particular form. Please view GSA's tax exempt state forms at <https://smartpay.gsa.gov/about-gsa-smartpay/tax-information/state-response-letter> to determine whether or not you can take advantage of the tax exemption.

For domestic travel if the hotel does not accept the tax exempt form, report lodging taxes separate from lodging expenses and claim them on your travel voucher. Foreign travel taxes still remain a part of your lodging expenses.

Lodging expenses should be paid using your government-issued credit card, when possible with direct payment to your government issued credit card (split disbursement) indicated on your travel voucher. It is your responsibility to pay the bill on time. The FDA will reimburse late charges on your bill only when you can show the late payment was due to late reimbursement of funds by the FDA.

Accurately record all of your expenditures. Document the date of your departure from each point where your duty is performed. Be guided by your Division's policy for where to record this information, e.g. in an administrative diary, etc.

Your regulatory notes (See IOM 2.1) should not contain notes of a purely administrative nature (documentation of travel, expenses [tolls, sample costs, etc.], fiscal data, mileage, etc.) These administrative notes can be documented in a separate section of the same bound notebook where your regulatory notes are kept or in a separate administrative diary. They do not need to be kept in a permanent record other than the completed Travel Voucher, Claim for Reimbursement for Expenditures on

Official Business, Receipt for Samples, etc. Follow your Division's requirements for maintaining this information.

### 1.2.4.1 - Per Diem Rates

Per Diem commences when you depart your home, office, or other point of departure, and terminates when you return to your home, office, or other point. This applies whether you are traveling by auto or by common carrier.

The M&IE Allowance is 3/4 of the daily rate on the first and last day of travel when overnight travel is involved, and the full daily rate for each intervening day.

M&IE may apply where there is no overnight lodging. However, M&IE will not be allowed for periods of time less than twelve hours.

Your work time plus your total commute time must be greater than twelve hours for you to be eligible for M&IE.

### 1.2.4.2 - Hospitalized In Travel Status

If, while you are in travel status, you become hospitalized by illness or injury not due to your own misconduct, your per diem continues (even if covered by your health insurance carrier) provided you do not receive hospitalization (or reimbursement therefore) under any Federal statute such as Workmen's Compensation, VA, or military hospital.

Your per diem is calculated on the lodgings-plus system, not to exceed the per diem rate allowed. Check with your Division supervisor or administrative personnel.

## 1.2.5 – RELOCATION SERVICES

Relocation services are provided by the Bureau of Public Debt which has been consolidated under the Administrative Resource Center (ARC), Bureau of the Fiscal Service. ([https://arc.fiscal.treasury.gov/travel\\_employee\\_relocation.htm](https://arc.fiscal.treasury.gov/travel_employee_relocation.htm).) The Bureau of Fiscal Service provides a fully automated, end-to-end relocation service to the FDA in processing all types of relocations including CONUS, OCONUS, New Appointee, Transfer and Commissioned Corps.

Relocation Services Include:

- Prepare and process pre-relocation documents
- Counsel employees about relocation allowances including Guaranteed Home Sale (when applicable)
- Manage the move, including packing and shipment of household goods
- Assist employee with travel arrangements
- Prepare and process employee vouchers
- Process third party real estate payments
- Make tax payments
- Prepare W-2s

## 1.2.6 - ADVANCE OF FUNDS

You will use your government-issued credit card to obtain a cash advance from an ATM machine, for official government business only. Ensure your Travel Authorization (TA) contains a statement that you are authorized to use an ATM to obtain cash advances and the maximum total amount authorized for your trip. Regardless of amounts indicated on your TA, ATM cash advances also may not exceed the weekly ATM withdrawal limit on your Travel Card account. This limit is established at the time that you apply for the travel card- based on a personal credit worthiness check.

ATM cash advance is to be used only to cover anticipated out-of-pocket incidental travel expenses which generally cannot be charged directly to the card. Excessive ATM cash advances not commensurate with travel are Travel Card misuse. Therefore, direct charge of the Travel Card must be utilized in lieu of ATM Cash whenever and wherever possible for approved, travel related expenses.

There are usually two fees associated with an ATM cash advance. The "Terminal Fee" assessed by the ATM terminal's owner/supplier and the "Cash Advance Fee" assessed by the bank. Currently, there are two formulas to calculate the reimbursable Cash Advance Fee using a 2.5% of the fee or a minimum of \$3.00. Percentage – 2.5% multiplied by (Cash advance amount + ATM Terminal Fee). Minimum payment - \$3 plus (Cash advance amount + ATM Terminal Fee). The Cash Advance Fee is described in your credit card agreement. These amounts should be included on the Travel Authorization/Voucher along with receipts before reimbursement is made.

If you do not have a government travel card and are required to travel, please see your administrative officer about receiving a travel advance. For further information, see Staff Manual Guide 2343.1 Government Travel Card and ATM Advance Programs.

## 1.2.7 - CLAIMS FOR REIMBURSEMENT

Within five days after each trip, submit your electronic claim for reimbursement (Travel Voucher) using ETS. Expenses for local travel for meetings and/or field work are also claimed using ETS. All travel vouchers are processed electronically.

Clerical procedures vary from Division to Division, so consult your supervisor or administrative officer for instructions. State all items in chronological order. Show your mode of transportation and if a POV/GOV is used and you are accompanied by other travelers, show their names as well.

Show your date of departure and return to your official duty station, and when periods of leave commence and end. Show all points where costs are incurred.

Mandatory Statements Required on Travel Voucher - See IOM Exhibit 1-1 for allowable expenses, receipts required, etc.

If you take any type of leave while in travel status, include a statement on your travel voucher that you apprised your timekeeper of the amount and type of leave taken.

Explain the necessity for unusual expenditures such as rental equipment, stenographic services and emergency charges (See IOM Exhibit 1-1). The following cash purchases are reimbursable when accompanied by necessary receipts (see Documentation below):

1. Travel costs such as road and bridge tolls, storage and parking for government cars, and handling of official (not personal) baggage.
2. Costs for samples and the necessary casual labor charges for their collection and packing. (See IOM 4.1.4.1(4) Official Samples.)
3. Telephone and telegraph expenses. Document that the use was for official purposes. See IOM 1.2.8 "Telephone Communication" for additional information.
4. Emergency purchases (flashlights, batteries, photographic film, jars, or dry ice for samples, etc.)
5. Coveralls or lab coat laundry while in travel status
6. Personal laundry while in travel status within continental U.S. (CONUS) for four or more consecutive nights

Documentation - Except for samples, all cash payments should be supported by itemized invoices or receipts signed by vendor, if possible. If you are unable to furnish receipts when submitting your voucher, explain that on the voucher.

Receipts for registration fees at meetings are required regardless of the amount. See Exhibit 1-1.

## 1.2.8 - TELEPHONE COMMUNICATIONS

### Business Calls

It is HHS policy that all necessary and reasonable charges for official business calls incurred while on official TDY travel must be reimbursed as a miscellaneous travel expense. Generally, there are no dollar caps placed on official business calls. However, it is the travel approving official's responsibility to ensure that all charges are necessary and reasonable. Excessive costs should be fully justified on the travel voucher.

Business calls whenever possible should be made from

1. the TDY location, or
2. the employee's government-issued mobile device (cell phone, blackberry, smart phone, etc.), or
3. from his/her hotel room

If a call on an employee owned personal communication device e.g. cell phone must be made, it will only be reimbursed if:

1. The call was made outside of the employee's regular plan minutes (including text and data); and
2. The bill must show the date, time, telephone number, and cost per minute of the business call. (**Note:** If the call is within the employee's plan minutes and shows as a cost of \$0.00, the employee will not be reimbursed for the cost of the call.)

### Personal Telephone Calls

It is HHS policy that commercial charges for brief telephone calls placed for personal reasons while in travel status are reimbursable as a miscellaneous travel expense to civilian employees, subject to the following restrictions:

1. Employees are expected to incur telephone call expenses in the same manner as a prudent person would.
2. Calls should be made on the FTS network when possible
3. If not possible, calls should be made using your government-issued calling card or government-issued mobile device (cell phone, blackberry, smart phone, etc.). Telephone calls made with government-issued calling cards are automatically billed to the FDA.
4. An average of one call per day is authorized for domestic travel to the extent that the cost falls under the \$5 ceiling and \$10 for international travel explained below.
5. The employee must incur a minimum of one night's lodging on official travel, domestic, non-foreign, or foreign.

Calls made using a personal credit card or similar billing arrangements should be claimed on your travel voucher. Receipts required regardless of amount.

You are reimbursed through the voucher system when a surcharge is imposed for credit card calls from the traveler's motel/hotel room. Refer to [Staff Manual Guide 2343.2](#) to determine the maximum allowable reimbursement for telephone calls home.

## 1.2.9 - ITINERARIES

Since situations arise which necessitate contacting you while in travel status, provide your supervisor with a travel itinerary listing where and how you can be reached.

## SUBCHAPTER 1.3 - LEAVE

Annual, compensatory, and sick leave is charged in one-quarter hour increments. Prior approval must be obtained from your supervisor for all leave, whenever possible. If this is not possible, advise your supervisor within the first hour of your workday when you will not be on duty. Questions relating to leave should be directed to your immediate supervisor.

According to Article 42, Section 13 of the Collective Bargaining Agreement dated October 1, 2010; leave in conjunction with travel must be approved in advance and reflected on the travel authorization.

More leave information is also available at <https://www.opm.gov/policy-data-oversight/pay-leave/leave-administration/> compensatory time at <https://www.opm.gov/policy-data-oversight/pay-leave/pay-administration/fact-sheets/compensatory-time-off/> and credit time at <https://www.opm.gov/policy-data-oversight/pay-leave/work-schedules/fact-sheets/credit-hours-under-a-flexible-work-schedule/>. Information for Commissioned Corps is located in the officers' handbook under Leave and Work Schedules.

## SUBCHAPTER 1.4 - DISCLOSURE OF OFFICIAL INFORMATION

You are not to release or divulge any information obtained during FDA investigative or inspectional operations, unless you are authorized to do so and the sharing (regardless of the manner) complies with FDA's information disclosure laws and procedures. This includes information contained in regulatory notes, except for official issuance of forms or documents to addressees. Do not release any originals or copies of reports, memos, regulatory notes, forms (e.g., FDA-483, 484, 464, etc.), or similar investigational documents to anyone outside the Agency without express concurrence of Division or Headquarters management, the Office of Chief Counsel, or disclosure personnel and without following FDA's laws, the Code of Federal Regulations (CFR) (21 CFR [20.85](#) - federal, 21 CFR [20.88](#) -state/local, 21 CFR [20.89](#) - foreign, [21 CFR Part 20 -Freedom of Information Act \(FOIA\)](#), [21 CFR Part 21 -Privacy Act](#)), and other disclosure procedures, as noted below. If information is inadvertently disclosed, follow [ORA's Inadvertent Disclosure SOP](#).

## 1.4.1 - SUBPOENA

If you are served a subpoena (commanding your appearance in court) or a subpoena duces tecum, (commanding the production of any record or testimony, or the giving of information relating to official FDA matters), immediately advise your supervisor and ORA's Division of Information Disclosure (DIDP) "[ORA OSPOP Testimony – Info Sharing Team](#)" <ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov> in ORA Headquarters. You will be instructed by a Testimony Specialist as to the

proper procedures and actions on your part in complying with the subpoena. See 21 CFR [§ 20.1](#), [§ 20.2](#) and the [Regulatory Procedures Manual \(RPM\) chapter 10-11, "Testimony; Production of Records; Certification of Records."](#)

## 1.4.2 - REQUESTS BY THE PUBLIC, INCLUDING TRADE

Be guided by IOM 1.4.4 on requests for information desired by the public under the Freedom of Information Act (FOIA). For procedures for sharing non-public information with federal, state, local, or foreign government officials, see IOM 1.4.3.

In the case where a complainant requests sample results, see IOM [8.1.3](#). For procedures on the release of Establishment Inspection Reports to the establishment inspected see Field Management Directive [\(FMD\)-145](#) and for the disclosure of analytical results to establishments pursuant to Section 704(d) of the FD&C Act [\[21 U.S.C. 374 \(d\)\]](#), see IOM 4.1.1.4 and [FMD 147](#).

## 1.4.3 - SHARING NON-PUBLIC INFORMATION WITH OTHER GOVERNMENT OFFICIALS

If you receive requests for non-public information from officials of other federal agencies or from state, local or foreign government officials, contact your designated state liaison. Follow the current guidance: 1. [SMG 2830.3](#) Sharing Non-Public Information with Foreign Government Officials, and 2. [RPM Chapter 3](#) (specifically 3-6-4 Sharing Non-Public Information with Federal Government Officials and RPM 3-6-3 Sharing Non-Public Information with State and Local Government Officials.).

FDA's practice regarding requests for non-public information from state government officials and agencies is governed by 21 C.F.R. § 20.88 "Communications with state and local government officials". All exchanges of confidential commercial information with all state government officials must be authorized through DIDP and made pursuant to a written confidentiality agreement with the government official or officials seeking to access the non-public information.

Requests for non-public information that the FDA receives from other federal government departments and agencies are governed by 21 C.F.R. § 20.85. All exchanges of non-public information with federal government officials outside of DHHS must be must be authorized through DIDP pursuant to a written confidentiality arrangement with the government official.

For any questions you might have regarding the sharing of non-public information with a state or local or federal entity, please contact DIDP at [ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov](mailto:ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov).

## 1.4.4 - FREEDOM OF INFORMATION ACT

The Public Information section of the Administrative Procedures Act, [5 U.S.C 552](#), more commonly known as the FOIA, adopts a general rule that, except where specifically exempt, all documents in government files shall be made available to the public. There are various exemptions in certain areas, and it is these that mostly affect your operations in FDA. The regulations exempt certain information, such as personal privacy, deliberative process, open investigatory, as well as a company's trade secrets or confidential commercial information.

You can find information about disclosure and confidentiality of information in 21 CFR Parts 20 and 21, 21 CFR 71.15, 170.102, 312.130, 314.430, 514.11, 514.12, 601.50, 814.9, and others, related to FDA records and documents. In addition to the FOIA, various other Acts such as the Federal Food, Drug, and Cosmetic (FD&C) Act, the Public Health Services (PHS) Act, and 18 U.S.C. 1905 each contain information relating to the confidentiality of information in government files. Special care should be taken to protect the identity of confidential sources. See IOM 5.2.9.3.

All ORA staff are responsible for adherence to FDA's laws and procedures regarding the maintenance of confidentiality of non-public information.

Division and Headquarters office. All ORA staff are responsible for adherence to FDA's laws and procedures

### 1.4.4.1 - Requests for Documents

If you receive requests for information you can direct the requester to the FDA Electronic Reading Room (<https://www.fda.gov/regulatory-information/freedom-information/electronic-reading-room>). If answers cannot be found individuals can be directed to submit a FOIA request at <https://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARrequest/ucm2007229.htm>. If your office receives a request, forward an electronic copy of the request to the Director of the [Division of Freedom Information](#) (DFOI).

## 1.4.5 - INTERNAL FDA DOCUMENTS

FDA records that are intended for internal use only, may contain information protected from disclosure to the public by a FOIA exemption. An example would be "work plans",



internal decision memos, or attorney-client communication. Do not divulge such records without consultation from an information disclosure expert in ORA Headquarters. If you receive requests for internal documents or for parts of them, refer to IOM 1.4.4 and IOM 1.10.2.5.

## SUBCHAPTER 1.5 - SAFETY

Safety is a responsibility of FDA employees, their supervisors, and the Agency's management. These responsibilities include:

1. The reporting of any hazards or suspected hazards;
2. Taking the necessary safeguards to minimize the opportunity for safety problems.

The Agency cannot permit employees or supervisors to disregard established or otherwise reasonable safety precautions and thereby place themselves and/or their fellow employees and/or the Agency's facilities at risk. Refer to IOM 5.2.1.2 - Personal Safety for additional inspectional safety concerns.

Be alert for problems associated with defective or misused equipment or supplies and their possible impact on patients and/or users. Contact your supervisor and/or the headquarters contacts listed in the applicable compliance program as necessary for assessment. The home district of the manufacturer should be notified of product misuse, so it may be brought to the manufacturer's attention for consideration of precautionary labeling or redesign of the product. Fully document these problems, to include the hazard and/or defect observed and whether user actions could be a contributing factor. Documentation should present sufficient data, such as photos and diagrams, to supplement a narrative describing the situation as well as the collection of samples.

When conducting an inspection or collecting a sample in a facility which requires donning personal protective equipment, guidance should be provided by the firm's management as follows:

1. Information about the specific hazards that may be encountered
2. The potential concentrations of these hazards
3. The personnel protective equipment determined to protect against these hazards

The firm's management should be able to provide you with documentation showing how these hazards were determined, what the expected exposures are and how they relate to the Occupational Safety and Health Administration's (OSHA) Permissible Exposure Limit (PEL). It should also offer information about the personal protective equipment that will protect you against a hazardous exposure. If you have any doubts about the hazards or the equipment recommended or provided to protect against them, do not enter these areas. The Safety Liaison for your Program or District or the ORA Safety Office will be able to help you evaluate the information provided to you, or furnish information regarding the hazard and the recommended personal protective equipment.

If you do not have the specific personal protective equipment recommended by the firm's management, have your District furnish what you need. In some cases, the firm may be willing to provide the necessary personal protective equipment, however if respiratory protection is required, you should comply with ORA's Respiratory Protection Program. You should only use respirators provided by FDA, unless your District's IH or the National Safety Office has approved the use of other devices. See IOM 1.5.1. It is ultimately your responsibility to ensure that you do not expose yourself to any hazard.

Disaster conditions present inherently dangerous situations. See IOM 8.5.

Operations in the radiological area also pose special dangers. See IOM 1.5.4.2.4. Obtain advice on protective measures from the ORA Radiation Safety Officer whose contact information is listed in the FAQs (#12) on the ORA Safety webpage.

## 1.5.1 - PROTECTIVE EQUIPMENT

### 1.5.1.1 - Eye Protection

Wear safety glasses during all inspectional activities in which there is a potential for physical or chemical injury to the eye. These glasses should at a minimum meet the American National Standards Institute standard z87.1 for impact resistance. Guidance should be provided by the management of the facility being inspected as to additional eye protection required. Indirectly vented or unvented goggles should be worn whenever there is the potential for a chemical splash or irritating mists. Additional eye protection may be required in facilities that use exposed high intensity UV lights for bacteriostatic purposes, tanning booth establishment inspections (EIs), etc. Follow the manufacturer's recommendation regarding eye protection for any instrumentation generating light in the UV or higher energy wavelength range. You may contact the ORA Safety for assistance in selecting eye protection against physical or chemical injury. You may contact the ORA Laser Safety Officer or ORA Radiation Safety Officer for guidance on protective eye wear when working near radiation-emitting devices.

### 1.5.1.2 - Hearing Protection

You should wear hearing protection in noisy areas. The OSHA PEL for employees exposed to noise ranges from 90 decibels for an 8-hour time-weighted average to 115 decibels for 15 or fewer minutes per day. However, risk factors for hearing loss include personal susceptibility, noise intensity, noise frequency, distance from the noise source, etc. The noise reduction rating is provided by the manufacturer of various earplugs and muffs, but also depends on the appropriate fit. The efficiency of muff type protectors is reduced when they are worn over the frames for eye-protective devices.

### 1.5.1.3 - Protective Clothing

1. Wear safety shoes on inspections, as required.
2. Wear hard hats in hard hat designated areas.
3. Use appropriate gloves to avoid slivers and/or splinters when handling rough wooden cases or similar items. Use protective gloves when handling hot items or working around steam pipes, and when handling frozen products or working in freezers. Use protective gloves when handling lead pigs containing radioactive materials to avoid hand contamination. If you are handling solvents, wear gloves that are impermeable to the solvent. Your regional Industrial Hygienist or the ORA National Safety Officer can provide guidance in the type of gloves to use for a particular solvent.
4. Plan ahead for the clothing that may be required for a particular location or situation. Such clothing includes coveralls, lab coats, freezer coats, rubber or vinyl aprons, and disposable paper-like coveralls.

### 1.5.1.4 - Respiratory Protection

If it is possible to perform an inspection without entering areas in which respiratory protection is mandated or recommended, do not enter these areas. If you determine it is necessary to enter an area in which you must wear a respirator, you must have documented evidence showing the requirements of the District Respiratory Protection Program have been met prior to wearing your respirator. Your District shall have a written Respiratory Protection Program, as delineated in IOM 1.5.1.4.1.

#### 1.5.1.4.1 - PROGRAM PROVISIONS

In any workplace where respirators are necessary to protect the health of the employee, or whenever respirators are required by the employer, OSHA requires the employer to establish and implement a written respiratory protection program with worksite specific procedures according to the requirements in [29 CFR 1910.134](#). The program must include the following provisions:

1. Procedures for selecting respirators for use in the workplace, and annual fit testing of each employee wearing the selected respirator(s).
2. Medical evaluation of employees required to use a respirator prior to the employee's use of a respirator, and repeated as specified in the Respiratory Protection Program. A medical evaluation can be obtained by contacting your local Industrial Hygienist.
3. Procedures for using respirators in routine and reasonably foreseeable emergency situations.
4. Procedures for maintaining respirators.
5. Training of employees in the hazards to which they are potentially exposed during routine and emergency situations, and in the proper use of respirators including limitations of their use and fit checking procedures each time the respirator is donned.
6. Procedures for regularly evaluating the effectiveness of the program. OSHA requires each employer perform an evaluation of any workplace which may contain

respiratory hazards. If these respiratory hazards cannot be removed through engineering controls, the employer must provide respirator protection. Do not enter any area you suspect may contain an unevaluated respiratory hazard. Your training should include a determination of the minimum respiratory protection for each type of inspection you may perform. Your regional Industrial Hygienist or the ORA Safety and Occupational Health Manager may be consulted for guidance in the type of respirator, type of cartridge or filter, and the useful life of the cartridge or filter.

#### 1.5.1.4.2 - FIRMS WITH POTENTIAL RESPIRATORY HAZARDS

The following list includes situations, which have been identified as having the potential for respiratory hazards:

1. Feed, drug or tobacco plants where there is a possible inhalation hazard due to airborne particulates.
2. Fumigation or storage facilities where treated grain or produce is encountered, including trucks, vessels, railroad cars, fumigation chambers.
  - a. Do not enter any structure or conveyance or sample any product that is being treated with the fumigants Methyl Bromide, Phosphine or Sulfuryl Fluoride. If a sampling area is suspected of having been fumigated with methyl bromide, phosphine, or Sulfuryl Fluoride and has not been cleared according to the EPA requirements, contact your local industrial hygienist for guidance as to how to ensure that the area is safe to enter. Do not enter the area until it is appropriately aerated and tested. If entry is required using personal protective equipment, your local industrial hygienist can provide guidance to ensure you are using the appropriate respirator and cartridge, and any other protective equipment necessary based upon the fumigant concentration. See IOM 1.5.3.4, Asphyxiation Hazards, and IOM 1.5.4 Inspections, for additional cautions related to fumigants.
  - b. Areas and/or products being treated with fumigants are required by Environmental Protection Agency (EPA) to be placarded, and the placards not removed until the treatment is complete (usually 12 hours to 4 or more days) and the areas and/or products are clear of fumigant gases (phosphine <0.3 ppm and methyl bromide <1 ppm).
  - c. Self-contained breathing apparatus (SCBA) is generally the only respiratory protection gear approved for use in areas being fumigated. It is necessary to follow many other precautions when working around fumigants. See Note on Methyl Bromide and Phosphine at the end of this section for additional information.
3. Facilities using ozone, or where ozone is produced as a by-product of the manufacturing operation.
4. Facilities where sterilizers utilize ethylene oxide gas (EO) - See IOM 1.5.4.2 Factory Inspection.
5. Grain elevators or other grain storage facilities, which may present asphyxiation hazards, toxic decomposition gases, or biological toxins such as aflatoxin. See IOM 1.5.3.3.2.

6. Grain elevators or other grain storage facilities that potentially contain aflatoxin in the dust.
7. Spice grinders and repackers that potentially produce airborne respiratory irritants such as pepper.
8. Any rodent-infested area. - See IOM 1.5.5.4 Hantavirus Associated Diseases.
9. Poultry Houses – exposure to particulates, chemicals and possible infectious agents.

**1.5.1.5 - Health and Hygiene**

Inoculations - FDA provides operating field personnel with various inoculations for protection from infection or injury on the job.

The following schedules of shots are recommended:

1. Domestic Work:
  - a. Tetanus: Permanent immunity through the Tetanus Toxoid series followed by a booster dose every ten years;
  - b. Typhoid: No longer required even if working in a contaminated environment. Booster dose may be given every three years if desired and requested by employee;
  - c. Smallpox: No longer required in the U.S.;
  - d. Other: As required by your specific job.
  - e. Hepatitis B Vaccine: a synthetic vaccine has been developed and is available to those employees that may be exposed to the virus during the normal course of official duties. Contact your AO to arrange for this vaccination. Keep in mind a vaccination is not to be considered a substitute for good laboratory/field safety practices. This vaccine is specific for Hepatitis B virus (HBV) only, and not for other blood pathogens.
2. Foreign Travel - Check with your supervisor well in advance of planned foreign travel as to specific requirements of the countries to be visited.
  - a. Typhoid: recommended for travel to areas where typhoid fever is endemic.
  - b. Cholera: a primary vaccination or a booster within six months is required for traveling to India and Korea. May also be required occasionally for other nations.
  - c. Other: as required for specific country.

Physical Examinations - There is no requirement for periodic physical examinations. Even so, it is your responsibility to adhere to good personal hygiene and health practices.

If any firm management demands evidence of recent physical examination before permitting inspection, consult your supervisor. A mere request to examine your hands for sores, etc., is not unreasonable. However, do not accede to a physical examination.

**1.5.2 - AUTOMOBILE SAFETY**

Prior to operating a motor vehicle that is owned, leased, or rented by HHS/FDA, any federal employee or contractor

authorized to do so must self-certify that their driver's license is valid, recertify that their license is valid every two years, complete the training titled **Driver's Overview and Fleet Card Use** (accessible via the HHS Learning Portal <http://inside.fda.gov:9003/EmployeeResources/FacilityServices/FleetServices/ucm503525.htm>) and ensure that the use of any government vehicle is for official business only. Individuals authorized to use a vehicle for official business must:

1. Operate the motor vehicle with due regard for public safety.
2. Operate, park, store and lock as appropriate to prevent theft or damage.
3. Obey all applicable Federal Executive Orders, state and local traffic laws.
4. Use all safety devices (including seat belts).
5. Pay any parking fees and fines.

Prior to driving, check the following:

1. Tires, check for tread wear, etc.
2. Mirrors, for proper adjustment
3. Brakes
4. Windshield
5. Lights, headlight, turn signals and brake
6. Gasoline and oil gauges
7. Spare, jack, lug wrench, first aid kit, flares, etc.
8. Fire extinguishers are no longer required in vehicles
9. Seat belts must be used

When transporting materials of trade or items that when shipped commercially would be regulated as hazardous materials/dangerous goods, adherence to US DOT Regulations may not always be required, but is always highly recommended.

For example:

Ensure all volatile solvents, either in the sample collection kit or contained in a sampled material, are properly packaged and sealed to prevent spills or leakage. Be especially aware of the hazards associate with transporting dry ice. The concentration of carbon dioxide gas can cause a dangerous over-pressurization if sealed improperly or displace oxygen which can cause drowsiness, or even an asphyxiation hazard, if the dry ice is carried in an unventilated vehicle. See IOM 1.5.3.4

**1.5.3 - SAMPLING**

When you are collecting samples, always be alert for possible dangerous conditions (e.g., poisonous materials or fumes, flammable or caustic chemicals, high places, etc.)

**Opioid Sampling**

Opioids are substances derived from the opioid poppy or manufactured synthetic analogues. When conducting opioid sampling adequate safety precautions must be observed during the sampling process. Do not handle opioids including fentanyl and fentanyl analogues without

appropriate Personal Protective Equipment (PPE) which may include nitrile gloves, coveralls, goggles and a respirator depending on the situation and exposure risk. Possible routes of opioid exposure may include inhalation, ingestion and dermal contact. Opioids have the potential to be inhaled in situations where drug samples are disturbed, and particles become airborne. Avoid tasks that may aerosolize fentanyl or other opioids. Change gloves if they become contaminated. Avoid contact with eyes, mouth, nose or unprotected skin with contaminated gloves. Wash hands with soap and water immediately after sampling or as soon as feasible. Do not use alcohol-based hand sanitizers to clean contaminated skin as this could increase the drug absorption.

Opioid overdose symptoms include respiratory distress with slow shallow breathing, small constricted "pinpoint" pupils, confusion, drowsiness, nausea and vomiting and loss of consciousness. The opioid antidote medication Naloxone (Narcan) nasal spray can reverse the effects of opioid overdose and restore normal breathing. Naloxone (Narcan) training is available for individuals at risk for exposure to opioids. Contact a supervisor or industrial hygienist for training information.

Sources:

<https://www.cdc.gov/niosh/topics/fentanyl/healthcareprevention.html>

[https://www.cdc.gov/niosh/ersbdb/emergencyresponsecard\\_29750022.html](https://www.cdc.gov/niosh/ersbdb/emergencyresponsecard_29750022.html)

### 1.5.3.1 - Sample Fumigation and Preservation

Follow safety precautions when fumigating and/or preserving samples. Guidance is as follows:

1. Whenever possible, freeze the sample. If freezing is not practical, contact your servicing laboratory for alternative fumigants and preservatives.
2. When fumigants or preservatives are used, exercise care to limit your exposure to these chemicals. Contact your ORA Safety for the appropriate precautions necessary with these chemicals.
3. Safety Data Sheets (SDS) for each of these chemicals must be available at each duty site (e.g., District office, resident posts), and can be obtained from the chemical manufacturer. These sheets list the hazards involved with these chemicals and precautions to take for use. You must read and follow the instructions in the SDS prior to using the chemical. If a measured amount of chemical fumigant or preservative is present at the time of shipping, follow the guidance and properly ship the item as indicated if the substance is a regulated hazardous material. Again, if you have any questions regarding safety or shipping concerns contact ORA Safety.

### 1.5.3.2 - Electrical Hazards

Many samples are collected in poorly lighted areas, or in older poorly wired buildings. Be alert for low hanging wires,

bare, exposed, or worn wires, and broken or cracked electrical outlets.

When you are using portable power tools, etc., be extra cautious of the shock hazard. See Inspectors Technical Guide # 22 regarding Ground Fault Circuit Interrupters, and use one if feasible.

### 1.5.3.3 - Physical Hazards

Be alert for dangerous conditions on all sampling operations. If it is necessary to use a flame to sterilize sampling equipment, use extreme care. All flammable liquids in your sampling kits must be in metal safety cans. See IOM 4.3.6.1.2

Care must be taken when handling sharp objects, e.g., knives, syringes with needles, glass, etc. If it is necessary to sample such objects, take care in packing the sample to avoid injuring anyone who handles the sample later. Place them in a rigid container, e.g. glass jar, plastic box, etc. In addition, state in the Remarks or Flag Section of the Collection Report (C/R) (FDA-464) that a syringe and needle were collected as part of your sample.

#### 1.5.3.3.1 - RAIL SAFETY

Railyards:

Railyards are dangerous areas. If there is a Safety Office at the yard, inquire about specific information concerning current hazards.

Maintain a safe distance from equipment in motion and cross tracks at right angles whenever possible without stepping on rails. Be aware of the pressure-wave created as a train (or any moving vehicle) passes. The force can knock people down and into the path of subsequent cars.

Railcars:

1. When sampling, make sure doors are propped open to avoid accidental closing if the car is bumped while you are in it.
2. Display a warning flag or similar device to alert others you are in the car. Always have a railroad yardman or another FDA investigator present.
3. When entering the car, make sure the ladder is secure.
4. On hot days, or after a car has been fumigated, it should be aired out prior to entering, preferably by opening both doors.
5. Observe "No Smoking" in rail cars.
6. Don't crawl under railcars - go around them.
7. Avoid any cables between the railroad tracks. These are often used to move cars on sidings. A cable snapping taut can kill or maim.

#### 1.5.3.3.2 - GRAIN HANDLING FACILITIES

Grain storage structures, such as grain elevators and feed mills, can present life-threatening hazards. It is always preferable to inspect them or collect samples from the

outside. If it is not possible to collect the samples from the outside, consult your supervisor prior to collection. Before entering a grain storage structure:

- Meet with the facility's operator to discuss hazards that may be present in the storage structure, including entrapment or engulfment in grain, asphyxiation, or the presence of toxic or flammable atmospheres, as well as procedures to be followed in the event of an emergency.
  - Confirm that the operator will lock out any moving equipment within the storage structure such as conveyors and augers, and will conduct atmospheric tests for oxygen, combustible gases and toxic gases. Contact your Supervisor for any questions.
1. Refer to IOM 1.5.4.1 Man Lifts and Ladders for guidance. Do not use Man Lift without supervisor approval.
  2. Make sure cross-rungs on ladders are safe.
  3. When stepping off ladders or man lifts, be sure the floor is actually a floor and not a bin covered with canvas, cardboard, or other temporary non-supportive cover.
  4. Never stand or walk across the surface of the material stored in a silo. The surface may only be a "thin crust" over a hollow space in the silo. Breakthrough the crust often causes death by engulfment of the material and subsequent asphyxiation.
  5. Make sure walkways between bins are sturdy.
  6. Use caution when sampling from high bins or tanks. Wet or icy conditions may prevail, so check these conditions.
  7. When brass grain bombs are used to collect bin samples, do not drop the bomb to the surface of the grain. This could cause sparks if it hits the bottom or side of a bin. Lower the bomb gently to the grain surface, then raise it four to five feet and let it fall to the grain surface to collect the sample. Do not use steel grain bombs; use only brass bombs for sampling.
  8. Do not use flash units in dusty areas because of the possibility of explosion hazard. Any electrical devices (flashlights, cell phones, communication radios, etc.) used should be explosion-proof. See IOM 5.3.4 for additional information.
  9. Do not enter a grain storage structure without appropriate personal protective equipment or if any grain is frozen or caked to the walls. Wear PPE during inspection and sampling including bump caps.

### 1.5.3.3.3 - CLOTHING

Clothing:

1. Do not wear loose fitting clothes when collecting samples or conducting inspections, the clothes could catch on equipment or conveyor belts and lead to injuries.
2. Do not carry notebooks, credentials, etc., in the outer pockets of your inspectional uniform because they could fall into the equipment.
3. Steel mesh gloves should be worn when cutting portions from frozen products such as fish, etc.

### 1.5.3.3.4 - TRUCKS

Make sure any truck you enter during sampling and/or inspection will remain stationary while you are in it.

### 1.5.3.4 - Asphyxiation Hazards and Confined Spaces

This hazard is not exclusive to any program or inspection/sampling site. Many firms can have areas or operations that may present hazards associated with confined spaces, permitted confined spaces, or oxygen deficient atmospheres. OSHA's permit-required confined spaces standard defines "confined space" and "permit-required confined space (permit space)" at 1910.146(b). OSHA defines a confined space as meeting the following criteria: **Is large enough for an employee to bodily enter and work; Has limited or restricted means of entry and exit.** There are specific OSHA requirements for training that may be required when conducting inspection/sampling activities. If there are no additional instructions provided by SOP's, safety requirements listed in the sampling assignment or local work instructions that provide this additional guidance, contact ORA Safety.

In addition to items 1-6 listed below, the following is a partial list of examples work areas that could require additional OSHA required training:

Ship cargo holds  
Walk in freezers  
Walk in refrigerators  
Walk in autoclaves

1. Prior to entering closed areas, ascertain if they have been fumigated and, if so, air them out prior to entering.
2. When sampling or inspecting at rendering plants or fishmeal plants, be alert to possible hydrogen sulfide accumulations in dump pits and other areas. These fumes can be deadly.
3. Be alert and take proper safety precautions in plants, silos, bins, pits, and any closed areas where semi-solid buttermilk or other liquid dairy products, silage, or other bulk products are stored. If not properly stored, improperly handled, or decomposing, certain products can produce dangerous amounts of carbon dioxide, or other gases, or may deplete the oxygen supply in these areas.
4. When transporting dry ice or packages containing dry ice in your car, have some external ventilation (See IOM 1.5.4.2.2 and 4.5.3.5 for additional dry ice cautions).
5. When sampling from the top of a grain elevator, do not jump down, stand on, or walk across the top of grain. There may be a cavity caused by crusted grain which could break and result in you being buried in grain, or being in an atmosphere of fumigating gas.
6. Be alert when entering storage areas having controlled atmospheres, e.g., where oxygen has been replaced by carbon dioxide to prolong fruit storage, added sulfur dioxide for preservation purposes, etc. These areas

must be aerated and deemed safe by the firm prior to entering.

Contact ORA Safety if you require guidance to determine what hazards or DOT regulations may be applicable to a substance when being transported.

### 1.5.3.5 - Radioactive Product Sampling

Sampling of potentially contaminated FDA-regulated products from all FDA programs could result in potential internal and external exposures to ionizing radiation. Safety equipment required include a radiation dosimeter and radiation pager. Sampling of volatile or powdery material containing radioactive particles requires special training. Air monitor or use of a respirator may also be required. DOT and IATA regulations pertain to shipping these samples. Contact ORA RSO for details.

### 1.5.3.6 – Incident Command System

How to safely conduct work activities in an ICS structure:

You may be assigned to collect samples of FDA regulated products at the scene of an incident, where an ICS structure has been implemented. These scenes may involve chemicals that pose a threat to human health or the environment. Examples incidents that can be expected have an active ICS structure include chemical spills or hazardous waste sites. In such instances, unprotected personnel are not permitted into hazardous zones. You shall follow the Incident Command System (ICS) at the field level. The Incident Management Team (IMT) will be responsible for tactical operations (i.e., perform investigations/inspections, collect samples, and or/or detain or destroy contaminated product) in accordance with the Incident Action Plan (IAP) it develops.

### 1.5.3.7 - Carbadox Sampling

If there is no labeling and /or a dealer refuses to identify any yellow powder, inform the dealer of the hazards of Carbadox. Contact your supervisor and consult with ORA Safety Officer before collecting any samples of suspected Carbadox. If instructed to collect a sample, follow the directions provided by ORA Safety Officer and notify the laboratory about the suspect product before shipping. Copy the ORA Safety Officer on any message to the laboratory.

## 1.5.4 - INSPECTIONS

Many firms pose safety hazards or problems. Some include:

1. Flying glass in bottling plants
2. Explosion hazards from dust
3. Man-lifts which do not operate properly

4. Asphyxiation problems in rendering plants, fish meal plants, fumigated bins in elevators, fumigation chambers and any closed bins or areas
5. Forklifts and other power equipment operated in the plant. Be alert for their presence and avoid being hit.

### 1.5.4.1 - Man Lifts, Aerial Work Platforms, Scaffolding and Ladders

#### Man Lifts

Do not ride on a rotating belt man lift style elevator at any time.

#### Aerial Work Platforms

Many firms have aerial work platforms, mobile aerial devices or bucket trucks to provide temporary access to elevated areas at a facility. Do not operate or ride in firm aerial work platforms. Specific operational and safety training is required to utilize the equipment.

#### Non-Permanent Scaffolding

Do not stand on non-permanent scaffolding at any time.

#### Ladder Safety

Read and follow any labels or markings on the ladder including maximum load rating. Prior to using ladders always inspect them. Do not use ladders that are damaged or in disrepair. Do not use makeshift ladders or ladders that are positioned on top of boxes or unstable bases. Always maintain a 3-point contact with the ladder when climbing. Do not carry supplies or materials in your hand while climbing the ladder. Do not stand on the top rung unless it is designed for that purpose. If using a portable extension ladder, follow a 4:1 ratio for maintaining the proper angle of a ladder (for every 4 feet of ladder height up to where the ladder rests on a surface, position the ladder base 1 foot away from the wall with 3 feet extending beyond the upper landing surface). Do not overextend the ladder. If possible, have the ladder held by someone while you are using it. When collecting samples from a ladder extreme care should be taken to not overreach or lean too far beyond the center of the ladder and increase the risk of falling.

### 1.5.4.2 - Factory Inspection

#### 1.5.4.2.1 - RETORTS

Inspections of retorts require extra safety precautions. Be alert for live steam and other potentially dangerous heat sources. Do not enter a retort if your safety cannot be assured. When it is necessary to enter a retort, inform plant management. The firm must have a confined space policy in place. If the firm is not aware of the OSHA confined space requirements or does not have a confined space program, DO NOT ENTER THE RETORT.

Contact your Program Liaison Industrial Hygienist for additional information/training about confined space, which includes lock-out/tag-out procedures.

### 1.5.4.2.2 - THERMAL

The Occupational Safety and Health Act (OSH Act) requires employers to comply with hazard-specific safety and health standards. In addition, pursuant to Section 5(a)(1) of the OSH Act, employers must provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm. In some circumstances heat or cold stress could be considered conditions that require training and other mitigation actions be implemented. ORA Safety can be contacted if you have concerns regarding heat or cold stress.

### 1.5.4.2.3 - CHEMICAL

When conducting inspections of firm's using chemicals, pesticides, etc., ask to review the MSDS for the products involved to determine what, if any, safety precautions you must take. This could include the use of respirators or other safety equipment.

Ethylene Oxide (EO) - EO is a colorless gas or volatile liquid with a characteristic ether-like odor above 500 ppm. Unmonitored and inadequate ventilation will allow EO buildup of extremely high concentrations, especially in facilities utilizing malfunctioning or leaking equipment. Door gaskets, valves, and threaded fittings are typical areas where leaks have been observed. Additionally, exhaust vents from the sterilizer and the sterilizer room should not be located near air conditioning intake vents, or vented directly into work areas. If the odor of EO is detected, ventilation and containment are inadequate. Leave the area and report the situation to your supervisor for further inspectional guidance. Special EO monitoring equipment is available upon request from the Office of Regulatory Science's National Safety Officer for investigators' safety monitoring of inspectional site.

OSHA standard regulating employee exposure to EO is presently 1 ppm over an 8-hour day. You should avoid all unnecessary and preventable exposure to it. This gas has toxic (including possible cancer and reproductive hazards), flammable and explosive properties, and must be used and handled with caution. Adhere to any procedures the firm has established for protection of personnel from over-exposure to EO. Where improper venting procedures or defective equipment are observed, take adequate precautions, i.e., do not enter potentially hazardous areas, and/or wear protective clothing and a respirator. Refer to IOM 1.5.1. [29 CFR 1910.134](#) contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

### 1.5.4.2.4 - IONIZING RADIATION

Each investigator who visits a manufacturer of radioactive products or tests ionizing radiation emitting products (e.g., diagnostic x-ray tests) must wear a Thermoluminescent Dosimeter (TLD) to estimate external exposure. These are available in each district; personal alarm dosimeters are

also available. These can alert the investigator to high exposure areas during visits to manufacturing firms. Make an estimate of the time spent in areas where radiation is present, and estimate exposure during this time from your personal dosimeter. The estimate can be compared to the results from the TLD badges, which would be processed by Winchester Engineering and Analytical Center (WEAC). Contact WEAC for additional information concerning TLD badges.

Experience has shown there is a potential for internal exposure from inhalation of radioactive material, especially in the case of iodine isotopes. Ingestion of radioactive material from contaminated notebooks, workpads, etc. is also possible.

When you are inspecting radiation-emitting devices and substances, take every precaution to avoid undue exposure or contamination. Time, distance, and shielding are important when working around radioactive materials. Adhere to the firm's established safety procedures and precautions. Where employees are required to wear protective apparel, eyeglasses, or monitoring equipment, follow those procedures. Use protective gloves to avoid hand contamination when handling the lead pigs containing radioactive materials.

Monitoring devices must be used whenever exposure is possible. Monitoring equipment must be calibrated periodically in order to be accurate. There are a variety of meters that can be utilized for radiation protection. Film badges are usually used to determine accumulated amounts of radiation, and unless these are analyzed the exposure dosage is unknown. This will be done by WEAC. Dosimeters will provide a reading at the time of exposure.

Investigators conducting inspections of facilities operating positron emission tomography (PET) scanners must receive radiation safety training from the ORA Radiation Safety Officer or complete RH 102 Radiation Safety course to the inspection. Investigators are also required to wear a personal alarm pager and a dosimeter when performing inspection in a PET facility. Intrinsically safe batteries should be installed in Powered Air Purifying Respirators (PAPR) when being worn where there is a potentially explosive condition.

## 1.5.5 - MICROBIOLOGICAL HAZARDS

When processes involve potential for microbiological contamination, normal controls and procedures should contain or protect against any possible hazards. The procedures may include routine use of protective clothing and equipment. Precautions mentioned below concerning gowning, masks, gloves, etc., in this section, are also important in the event that accidents, spills or unexpected, uncontrolled contamination occurs while you are in work areas. If contamination is known in advance to be uncontrolled or you must handle contaminated materials, do not enter an area or handle these materials without first consulting with your supervisor or ORA safety before

entering known contaminated areas. ORA safety is available for consultant on specific topics.

### 1.5.5.1 - Animal Origin Products

Caution: It may be necessary to wear gowns, masks, rubber gloves, etc., when inspecting some of these work areas. Be guided by how the firm's employees dress for their work areas, and dress accordingly. Consult with the firm's management and your supervisor regarding dress and precautions to follow.

When inspecting manufacturers, or collecting samples of animal origin products, be alert for possible routes of contamination that could lead to your injury or illness. Some possible vectors of disease exist in firms that process products which use animal origin products as raw materials. They include:

1. Anthrax - Care must be taken during inspections of processors of bone meal, dicalcium phosphate and gelatin.
2. Tularemia - Use caution when inspecting rabbit processors. Be careful of scratches from bone splinters. Use gloves for protection.

### 1.5.5.2 - Viral and Other Biological Products

Take proper precautions to protect yourself. If necessary, consult your supervisor and/or Division microbiological personnel. NOTE: Inspection of vaccine manufacturers may require inoculation in advance of the inspection to adequately protect the investigator. Contact ORA Safety for guidance

Methods of transmission include aerosols, which may be created by manufacturing operations (e.g., centrifugation, filling, etc.) or spills. Transmission may occur through inhalation; contact with contaminated objects, including equipment, animals, waste materials, reagents, file cabinets and doorknobs. Transmission can occur through ingestion, inhalation, or through broken skin.

#### 1.5.5.2.1 - PROTECTIVE AND PREVENTIVE MEASURES

Protective and preventive measures include:

1. Precautions listed in IOM 1.5.5.1 and 1.5.5.3
2. Do not touch. This means equipment, materials, reagents, animals, etc.
3. Wear protective clothing. Evaluate the needs for gowns, caps, masks, gloves, and shoe coverings, and wear them where necessary. Protective clothing worn in a work area where a virus or spore bearing microorganism is handled must not be worn into a work area for another product. Leave all used protective clothing at the firm for proper disposal.
4. Wash hands thoroughly after leaving each work area.

5. Determine if the firm has established safety precautions and procedures, and follow them if adequate.
6. If the firm is processing viruses or other potentially infectious biological agents during the inspection, determine if it is advisable to enter the work areas. Chances of infection through aerosols are reduced when there is no active processing.
7. Females of childbearing age are advised not to inspect areas where the Rubella virus is actively processed unless immunity has been established. Infection during pregnancy may result in congenital abnormalities.
8. Vaccines are available for your protection against some organisms (e.g., Rubella). For information on inoculations and physical examinations, refer to IOM 1.5.1.5.

#### 1.5.5.2.2 - VIRAL HEPATITIS AND HUMAN IMMUNODEFICIENCY VIRUS

Precaution - Blood and Plasma Inspections - Viral Hepatitis and Human Immunodeficiency Virus (HIV) - the virus that causes Acquired Immune Deficiency Syndrome (AIDS). Be alert around blood banks or blood processing operations to the possible dangers of these and other infectious agents.

Keep in mind the following warnings:

1. Do not touch. This means do not handle lab instruments, blood samples, containers or reagents in blood bank labs unless absolutely necessary. Wear lab coats with long sleeves. Disposable lab coats that are impervious to blood are best. These should be left in the laboratory area.
2. Do not smoke, drink, eat or have meetings in the blood banks or in the testing areas for Hepatitis B Surface Antigen (HBsAg), HIV, or any other infectious agents.
3. Consider blood samples, the antigen and antigen testing kits and other associated HIV, HBsAg, and other test reagents as potentially infectious.
4. Consider the possibility of aerosol contamination if there is spilling or splashing of test reagents or blood samples.
5. Use care when placing inspectional or personal equipment in lab areas. Wash hands thoroughly after these inspections. Hepatitis can be transmitted by hand to mouth.
6. Use disposable gloves. Spills may be wiped with a 5% sodium hypochlorite solution and/or solutions such as Wescodyne or Betadine. Autoclaving is the preferred method (121 degrees C for 60 minutes) for sterilizing reagents, samples and equipment.  
Note: When accidental spills, etc. occur in your presence, you are not required to participate in cleaning or disposing of materials. This is the firm's responsibility.
7. Use scrupulous Adhere to Standard/universal personal hygiene at all times in the blood bank and in the testing areas for HBsAg, HIV, and other infectious agents.



### 1.5.5.2.3 - PRECAUTIONS FOR NON-CLINICAL LABORATORY INSPECTIONS

Precaution - Non-Clinical Laboratory Inspections - During inspections/investigations of sub-human primate facilities (e.g., Good Laboratory Practices (GLPs), non-clinical laboratory testing facilities, animal holding facilities, etc.) do not enter rooms housing sub-human primates. Monkeys normally housed in these facilities can carry "Herpes-B Virus", "Simian B Virus", or "monkey-virus". During inspections of this type, use the following guidance:

1. Investigators shall not enter any rooms which hold or house subhuman primates. Bioresearch monitoring (BIMO) inspectional information should be derived from personnel interviews and record examinations conducted outside of the primate areas.
2. All study records usually found in the monkey rooms (Standard Operating Procedures (SOPs); protocols; animal housing, feeding, handling, and care records; animal isolation and health records, room environmental records; dosing and animal I.D. records; animal daily observation records; equipment and room cleaning records, et al.) should be reviewed outside of the rooms.
3. Although contact with subhuman primates in the course of an inspection is prohibited, information on animal room activities may be obtained through personnel interviews.

### 1.5.5.3 - Bacteriological Problems

Take proper precautions to protect yourself. If necessary consult with your supervisor and/or ORA Safety for referral to the ORA National Bio-Safety officer. Possible routes of salmonellosis include dust inhalation in dried milk and dried yeast plants. Thyroid processing plants may also be a source of this problem.

In no case should you taste any item implicated or suspect of causing injuries or illnesses (e.g., consumer complaint samples, etc.). Handle these with extra care since even minute portions of certain items may cause serious illness or even death.

### 1.5.5.4 - Hantavirus Associated Diseases

Rodents and other small mammals have been identified as the primary hosts for recognized Hantaviruses. Infected rodents shed the virus in saliva, urine and feces. The time of this virus' survival in the environment is unknown.

Human infection may occur when contact is made with infected saliva or excreta, through inhalation of aerosol produced when the animals sneeze, or contaminated dust particles are stirred up. In addition, infection can also occur when dried contaminated materials are disturbed and directly introduced into broken skin or onto the conjunctivae.

Hantaviruses can present some or all of the following symptoms: fever, headache, muscle aches, nausea and vomiting, chills, dry cough, and shortness of breath.

Investigators/Inspectors may be subject to an increased risk of infection because of unpredictable or incidental contact with rodents or their habitations, i.e., entering various buildings, crawl spaces and other sites that may be rodent infested.

When encountering or suspecting rodent infested areas, the following protective and preventive measures are recommended:

1. First and foremost, DO NOT HANDLE RODENTS - DEAD OR ALIVE.
2. Be careful when moving items around, excessive dust may increase the risk.
3. To prevent eye contamination, wear goggles or a full-face respirator.
4. High-Efficiency Particulate Air (HEPA) filter masks or respirator cartridges are recommended to avoid inhalation of aerosols.
5. Wear coveralls, and handle and dispose of as infected material.
6. Wear disposable latex or rubber gloves. Be careful to avoid hand contamination when removing gloves. Wash hands thoroughly after removal.
7. In addition to these measures, follow any guidance issued by state health departments.

### 1.5.6 - WIRELESS DEVICES

The following information is provided regarding the use of wireless devices:

1. If you carry a blackberry, cell phone, or other wireless device, always enquire about a firm's policy with regard to their operation within the establishment as they may pose a safety hazard.
2. An Executive Order, signed by President Barack Obama and issued by the White House on October 1, 2009 prohibits federal employees from engaging in text messaging while driving GOVs, or POVs while on official business, or using government provided electronic equipment, e.g. blackberry, while driving.
3. FDA policy prohibits the use of hand held wireless phones or other wireless devices while operating government, commercially leased/rented vehicles. Drivers who use cell phones within their scope of work are required to use hands-free cell phones and other hands-free devices.

### 1.5.7 - REPORTING

Automobile Accidents - See IOM 1.2.2.2 - Accidents, for procedures.

Injuries - If you are injured during the performance of official duties, report immediately to your supervisor. If medical aid is required, obtain it as soon as possible. Check with your

supervisor on what accident report forms are required and procedures to be followed.

## SUBCHAPTER 1.6 - PUBLIC RELATIONS, ETHICS & CONDUCT

FDA's ethics program is administered to help ensure that decisions made by Agency employees are not, nor appear to be, tainted by any question of conflict of interest. The "ethics" laws and regulations were established to promote and strengthen the public's confidence in the integrity of the Federal Government. The ethics program is available on the FDA intranet and standards of conduct are available at <https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm>.

### 1.6.1 - PUBLIC RELATIONS (PRESS, RADIO, TV AND NON-GOVERNMENT MEETINGS)

Over the past few years, the inspectional and investigational activities of the FDA have received extensive coverage in the electronic and print media. District Directors are the spokespersons for FDA in their respective areas. However, investigators and inspectors are occasionally requested by the media to comment or provide information on their individual inspectional activities. Such requests include being interviewed and filmed during inspections, investigations and sample collections. If media representatives contact you, be courteous and helpful, but refer all requests for information, interviews and personal appearances to your supervisor. Those requests must be approved in advance and should be referred to [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov) for handling working with FDA's Office of Media Affairs.

Do not solicit media interviews or on-camera appearances. There may be occasions when management of a firm you are inspecting invites representatives from the news media to observe the inspectional process. Please see IOM 5.1.4.3 for instructions on how to appropriately handle such events.

**Refer all media inquiries to the ORA Press Office at [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov).**

#### 1.6.1.1 - Non-Government Meetings

Speakers and representation at meetings will be provided when such attendance is for official purposes, and consistent with the policies and best interest of FDA. As a public agency FDA must be responsive to public inquiries of all kinds.

Authorization - Attendance must be authorized in advance. Form HHS 99 is required, unless the primary purpose of attendance is to officially explain, interpret or acquaint the public with FDA programs or activities.

Selectivity - Selection will not arbitrarily favor one sponsoring organization over another.

Fees - Acceptance of payment in cash or kind must be approved in advance. No such payment may be accepted when inspectional or administrative and/or a supervisory relationship exists between the employee and the non-federal organization offering to pay his/her expenses.

### 1.6.2 - EQUIPMENT CARE, CUSTODY, AND LOSS

You are responsible for the proper care and custody of all government property entrusted to you. This includes:

1. Storing government vehicles in protected off-street parking facilities, when possible.
2. Keeping inspectional and investigational equipment securely locked in the trunk of the car while the car is under your direct control. Do not leave valuable equipment in the car's trunk while the car is in for servicing, unless you stay with the car. Do not leave electronic equipment, such as computers, in the trunk of the car for extended periods in extreme hot or cold weather conditions.
3. Storing all property in safe, secure areas.

Your responsibility for government property in your custody is specified in the Staff Manual Guide 2280.5.

#### 1.6.2.1 - Maintenance of Equipment

First-line maintenance rests with you as the custodian of the items entrusted to you. You are expected to perform, or have performed, the normal maintenance such as checking oil, tires, battery, windshield wipers, etc. on the GOV you are using. Other equipment requires little or no maintenance as such, other than dusting, replacing batteries and bulbs, making minor adjustments, properly packing in carrying cases, and proper protection as necessary. Common sense, and handling the equipment as if it belonged to you, should suffice.

##### 1.6.2.1.1 - REPAIRS

Any repairs needed, defects, or inoperative equipment observed, should be immediately reported to your supervisor.

When in travel status, necessary minor repairs to equipment may be obtained locally, if possible, and reimbursement claimed on your travel voucher. Major repairs should be cleared through your supervisor.

##### 1.6.2.1.2 - EQUIPMENT CALIBRATION

You are responsible to assure equipment assigned to you is calibrated for accuracy. This includes thermometers, pyrometers, balances, scales, stopwatches, etc. Keep a record of the calibration with each item requiring calibration.

Calibration of certain inspectional equipment can be done by your District laboratory.

Stopwatches may be calibrated using the atomic clock at the U.S. Naval Observatory in Washington D.C., using the commercial number at (202) 762-1401 or (202) 762-1069. Calibrate stopwatches at several different time intervals within the expected parameters of use. At least three runs should be made at each interval, then averaged for each interval and the correction factor, if any, entered on the record of calibration maintained with the watch. Calibration of your computer's internal clock can be obtained from the same source. Information and software is available on the U.S. Naval Observatory's Website.

### 1.6.2.2 - Lost or Stolen Equipment

As soon as you discover any government property assigned to you or in your custody is missing, report it verbally to your supervisor. A memorandum should be prepared detailing the circumstances surrounding the loss, including the comprehensive steps you took to recover the items.

Follow your District procedures for any additional requirements.

### 1.6.3 - OFFICIAL CREDENTIALS, BADGE

Show your credentials to appropriate firm personnel during all non-undercover investigations, inspections, sample collections, recall effectiveness checks, etc.

To apply for official credentials, you must complete FDA 2115 and submit it to ORA [FDA-ORACredentials@fda.hhs.gov](mailto:FDA-ORACredentials@fda.hhs.gov) for processing. Please see your Administrative Officer for additional information.

#### 1.6.3.1 - Delegated Authority

When you are issued the FDA official forms, certain parts of the Commissioner's enforcement authority, as specified in Staff Manual Guide 1410.32, are re-delegated to you. You are expected to use this authority wisely and judiciously. See IOM 5.1.1.2 on cautions against photocopying your credentials.

Your investigator badge, if you are issued one, is for use in certain situations to reinforce the official credentials when needed. Check your Division Staff Manual Guide, FDA 2280.3, 5b, for situations in which use of the badge may be appropriate.

#### 1.6.3.2 – Care of Credentials, Badge

FDA employees engaged in general inspectional and investigational operations are issued FDA credentials. By

virtue of their position, these employees are recognized as authorized to perform the duties assigned.

FDA Official Credentials confer extensive inspectional authority on you. Exercise the utmost care of your badge and credentials. Carry them in a manner that will assure positive protection against loss. For example, do not carry them in the upper pockets of your clothing where they may fall out if you bend over. You may not only lose your credentials and badge, but they may, during inspections, fall into vats or machinery resulting in embarrassment and possible financial loss to you as well. Also, carrying your credentials and badge in the glove compartment of your car or leaving them in the pocket of an unattended coat or jacket are invitations to loss or theft. If no longer performing the duties that required credentials or if there is a change in job position, the badge/credentials need to be returned to the District or headquarters. Maintaining badge/credential is dependent on the job description not the job series.

#### 1.6.3.3 - Lost or Stolen Credentials, Badge

The procedure for reporting loss or theft of credentials and/or badge is in the Staff Manual Guide (SMG) 2280.3. Notify your supervisor immediately. Report the loss or theft to local law enforcement authorities (police department) and request a copy of the report including the police report identification number. Also report the loss or theft to the local (state) FBI field office so that the number of the credentials/badge can be entered into the National Crime Information Center (NCIC) system.

A written report containing the police report number and a statement that the local FBI field office was notified must be submitted to your supervisor. Copies of the written report must be sent to Office of Security and Office of Operations prior to new credentials and/or badge being reissued.

#### 1.6.4 - BUSINESS CARDS

Business Cards are defined as cards of introduction bearing the name, address, phone number, fax number and e-mail address of active agency representatives. The distribution of business cards facilitates prompt and efficient communications by the persons and organizations with whom the Agency transacts business. The purpose of the business card is to further the Agency's statutory mission and; therefore, the purchase constitutes a proper expenditure from the Salaries and Expense Appropriation. Due to certain restrictions pertaining to the purchase of business cards, employees should consult with local management prior to purchasing such items, to ensure adherence to agency policy and procedures.

#### 1.6.5 - EMPLOYEE CONDUCT

As a government employee of the FDA, as few limits as possible are placed on your interests and activities. Nonetheless, certain limitations are necessary to protect

the interest of the government. These constraints are covered the Standards of Ethical Conduct for Employees of the Executive Branch. Consult with your supervisor if you have any questions or concerns in this regard. The Standards of Ethical Conduct for Employees of the Executive Branch can be found on FDA's intranet under the Division of Ethics and Integrity.

As you work to advance the health and welfare of the public, seek to maintain the highest standards of ethical conduct. The essence of good government is the personal responsibility that each public servant feels for the public trust he/she holds. You are responsible for complying with the regulations, obtaining advice from your supervisor, personnel or local administrative staff, and when required, obtaining advanced approval for certain outside activities.

FDA employees must be persons of unrivalled integrity, and observe the highest standards of conduct. Because of FDA's special regulatory responsibility, its personnel must carry on the agency's business effectively, objectively, and without even the appearance of impropriety. Their actions must be unquestionable, and free of suspicion.

The Standards of Ethical Conduct for Employees of the Executive Branch ([5 CFR Part 2635](#)) gives concise details on what is expected, insofar as conduct is concerned. In addition, certain subparts, and Appendix A to Part 73 of the HHS Standards of Conduct, remain in effect. Additional information is also available on FDA's internet at <https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm>.

### 1.6.5.1 - Professional Stature

You are the eyes and ears of FDA, and to most of the public you are their only contact with FDA. Your actions may be the basis upon which they judge the entire FDA. The public expects exemplary behavior and conduct from the government employee. This responsibility applies to both on the job and off the job activities. As you inspect or appraise individuals, you are, in turn, being evaluated. Both the industries FDA regulates and the public-at-large are keenly aware of, and are quick to report, what they consider improper actions by government employees.

When you issue an FDA 483, the firm is provided with information as to how to contact the District Office with such reports and information on the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), which provides regulated industry a means for addressing industry concerns about government agency enforcement activities. See IOM 5.2.3.1.1. You may receive complaints or other questions from the regulated industry during routine field operations, such as sample collections, investigations, import entry reviews and establishment inspections where an FDA 483 was not issued. In these circumstances, provide the firm the "Information for FDA - Regulated Industry" Website "[www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)". Explain there are Small Business links on the webpage and the FDA Ombudsman link is located under the Contact FDA

heading and they may also call the Districtvision Office. Document this discussion in your regulatory notes and include it in your Establishment Inspection Report (EIR) in the Discussion with Management section, your Memorandum of Investigation, or the remarks section of your collection report.

If the firm does not have internet access, provide the firm the main District phone number.

### 1.6.5.1.1 - INTEGRITY

This is steadfast adherence to a strict moral or ethical code. It characterizes a person of deep-seated honesty and dependability, with a devotion to accuracy, objectivity and fairness.

Employees may not use or permit others to use official information not available to the general public for gain or to advance a private interest.

You are expected to conduct yourself in a prudent manner, so that the work of the Agency is effectively accomplished. Your job is to gather and present the facts. Accuracy and objective observation are absolutely essential.

The Office of Internal Affairs (OIA), Office of Criminal Investigations (OCI), is responsible for obtaining factual information for the FDA on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by Agency personnel. If you uncover or suspect any such problems, report them to your supervisor. The Division/Region will contact OIA. [21 CFR 19.21\(b\)](#) requires the facts be forwarded to OIA in writing. OIA will maintain the anonymity of your complaint, if you so desire.

Under the Federal Managers' Financial Integrity Act, it is your duty to report any serious problems of waste, mismanagement, fraud or misuse of Government funds by any personnel from other agencies or government contractors. These problems should be reported to your supervisor, who will in-turn, notify the Division of Management Operations.

### 1.6.5.1.2 - ATTITUDE

Be dignified, tactful, courteous and diplomatic. Make your approach firm but not unresponsive. Do not display strong-arm tactics, an air of superiority, an attitude of special authority, or an over-bearing posture. Do not apologize or justify your request for necessary and authorized information.

### 1.6.5.1.3 - ATTIRE

Good public relations and practical common sense requires you dress appropriately for the activity in which you are engaged. Consult your supervisor for District policy on normal office attire.

Protective clothing is required for many inspectional tasks. The District provides coveralls or other clothing for this purpose. Failure to wear suitable attire, including head coverings, while the firm's employees are so attired, is indefensible. Plastic foot guards over street shoes are required, if walking on raw materials such as bulk grains, bagged material, etc. Prophylactic measures - to guard against the spread of disease may be required during certain investigations. See IOM 1.5.1 and IOM 5.2.10.

### 1.6.5.1.4 - EMPLOYEE PROHIBITIONS - GIFTS, LUNCHEONS, AND SNACKS

The Standards of Ethical Conduct for Employees of the Executive Branch, [5 CFR Part 2635](#), Subpart B, specifically provide that an employee shall not, directly or indirectly, solicit or accept a gift:

1. From a prohibited source
2. Given because of the employee's official position.

Notwithstanding any of the exceptions provided in Subpart B, an employee shall not:

1. Accept a gift in return for being influenced;
2. Solicit or coerce the offering of a gift;
3. Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using his/her public office for private gain.

The Standards of Ethical Conduct for Employees of the Executive Branch cover many aspects governing employee conduct and provide that an employee shall avoid any action, whether or not specifically prohibited by the regulation which might result in or create the appearance of:

1. Holding a conflicting financial interest
2. Loss of impartiality in performing official duties
3. Using public office for private gain.

An area of concern for inspectional personnel is a setting where, during an establishment inspection, you have lunch with plant officials and/or personnel and find your lunch paid for by them, or there is no way you can pay for your portion of the luncheon.

It is always best for an employee to decline any gift, including meals, offered by a regulated company's staff. However, when circumstances arise where refusal is imprudent or impractical, such as finding your lunch paid for by the firm, be gracious, but make it clear the situation cannot be repeated. Always use your best judgment. Modest items of food and refreshment, such as soft drinks, coffee, and donuts offered as other than part of a meal, are excluded from consideration as gifts.

### 1.6.5.1.5 - ORA POLICY

ORA's policy requires you do not use or consume a firm's products at any of the firm's facilities. This can be

interpreted as acceptance a product is satisfactory and could embarrass the Agency, particularly in the event of a subsequent regulatory action against the firm.

### 1.6.5.1.6 - PROFESSIONAL PERSONNEL CONTACTS

During inspections and investigations, your activities often involve discussions, conferences, and interviews with professional people.

When dealing with top management officials and other professional persons, your presence may often be disruptive to their activities. Many times you may be squeezed into already crowded schedules and your interviews or investigations may, of necessity, be conducted in offices, waiting rooms, or other areas where customers, patients, or employees are present. If you find yourself in this type of situation, be aware your conversations or activities may be overheard by others.

If it is necessary to review records or conduct interviews, conduct your activities in a quiet and dignified manner. Always try to arrange with management for a private area for this work.

If the person becomes unreasonable, and it is impossible to continue the assignment, terminate the interview and consult your supervisor.

### 1.6.5.2 - Attempted Bribery

Bribery is the practice of offering something, such as money or a favor, to a person in a position of trust to influence that person's views or conduct. Occasionally, FDA employees experience bribery attempts.

Bribery or attempted bribery of a Federal Officer is a crime ([18 U.S.C. 201](#)). If you are offered money or anything else of value, pursue the following course of action:

1. Attempt to obtain a clarification of the offer (e.g., Ask questions like, "What is this for?").
2. Do not accept or refuse the offer. Appear to vacillate, and keep the door open for future contact.
3. Calmly terminate the exchange.
4. As soon as possible, prepare detailed notes concerning what transpired.
5. Contact your supervisor as soon as possible. The Division should notify the OCI office immediately. You may be asked to assist the OCI and other investigative bodies by accepting proffered money as evidence, under controlled conditions. Do not participate in any such activity, or accept anything of value outside the controlled conditions of an undercover activity conducted by OCI and/or other involved Federal law enforcement agencies.

## SUBCHAPTER 1.7 - INTERDIVISION ASSIGNMENTS

See IOM 1.1 English language requirement. This subchapter defines the procedures for issuing assignments between Divisions and referring information between Divisions and ORA headquarters. FDA has put a data system in place, Field Accomplishments and Compliance Tracking System (FACTS), which includes the ability to generate assignments. This system should be used whenever possible to issue and manage all assignments. You received training on that process during your basic FACTS training. If you have any questions, contact your FACTS Lead User.

### 1.7.1 - ISSUANCE AUTHORITY

FACTS is the preferred method to generate, issue, and manage assignments for all activities. Memorandums must be used when hard copy attachments accompany the assignment. If mail delay for memorandums is objectionable, overnight delivery is authorized. Use the telephone when urgency requires instant communication; however, all assignments must be entered into FACTS as soon as possible. The receiving Division can use the "ad hoc" process in FACTS to generate the assignment in urgent situations. The EIR endorsement shall not be used to make assignments, although it may be an attachment to a written assignment. E-mail the receiving Division of an assignment if there is any urgency.

Assignments, excluding recall audit checks, must be approved and signed or issued by a first line manager/ team leader, compliance officer, those acting in these positions, or a higher level of management. Recall audit checks may be signed by the Recall and Emergency (R&E) Coordinator.

Assignments involving three or more districts, or requiring more than three working days to complete, shall be approved by the branch director or appropriate manager of the issuing Division. Multiple Division assignments need to be closely monitored by the issuing Division to avoid unnecessary duplication of work.

### 1.7.2 - PROCEDURES

Each assignment shall contain the following details:

1. Description of the problem and nature of the assignment, i.e., sample collection, records collection, inspection, etc.
2. Full name, address and the FDA Establishment Identifier (FEI) number of the responsible firm. You may also provide the central file number (CFN) if known or available.
3. Program Assignment Code (PAC).
4. Product code and full description of product including lot number(s) and code(s).
5. Home District code.
6. Full name and address of the firm (or firms) and individual(s) to contact to accomplish the assignment.
7. Priority and requested completion date.

8. Name, telephone number and mailing symbol of the contact person who can answer questions concerning the assignment and the person who should be notified of results.
9. Where to send samples, records, reports, etc.

### 1.7.3 - ASSIGNMENTS AND REPORTING

If all the data is contained in the FACTS fields, there may be no need for a separate memorandum.

Assignments for fieldwork are to be sent to the accomplishing division(s). Assignment memorandums, attachments, or other documents needed to complete the assignment should be sent to the appropriate branch director in the accomplishing Division.

When you observe objectionable conditions which may be of public health significance and are the result of general corporate policies and/or procedures at establishments outside your Division, notify your supervisor as soon as possible. Your Division management and/or Emergency Response Coordinator (ERC) should assess your findings and notify other Division(s) and State counterparts as appropriate.

Copies of assignments which involve emergencies, danger to health situations or highly publicized investigations shall be sent via e-mail or overnight courier to the Emergency Operations Center, HFA-615 (301-796-8240 or 1-866-300-4374). Completion and referrals - A copy of the Establishment Inspection Report (EIR), C/R, memorandum, etc., showing results should be sent to the person specified in the assignment, along with a copy of the assignment. When an assignment is completed, make sure the appropriate FACTS fields are updated/entered as necessary. Copies of responses to assignments that involve emergencies, danger to health situations, or highly publicized investigations shall also be sent to the Emergency Operations Center, HFA-615.

In the case of samples going to a non-FDA laboratory or a Headquarters' laboratory, a copy of the assignment should be printed and attached to a copy of the C/R which is included in the FDA-525.

All documents relating to an assignment shall include the FACTS assignment and/or operation number.

## SUBCHAPTER 1.8 - ORGANIZATION OVERVIEW

A complete description of the FDA's organizational structure and its functional statement is found in various chapters of the Staff Manual Guides (SMG) which are available on FDA's Intranet Website.

The following is a list of internet websites that contain FDA's organizational structure:

1. Office of the Commissioner: [About the Office of the Commissioner](https://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/default.htm) with organizational charts at: <https://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/default.htm>
2. Center for Biologics Evaluation and Research: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/default.htm> with organizational charts at: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122875.htm>
3. Center for Drug Evaluation and Research: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm> with organizational charts at: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm>
4. Center for Devices and Radiological Health: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/default.htm>
5. Center for Veterinary Medicine: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm> with organizational charts at: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/WhatWeDo/default.htm>
6. Center for Food Safety and Applied Nutrition: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/default.htm> with organizational charts at: <https://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm385057.htm>.
7. Center for Tobacco Products: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/default.htm>
8. Office of Regulatory Affairs: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/default.htm> with organizational charts at: <https://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm347891.htm>

The FDA is a part of the Department of Health and Human Services (HHS). An appointed Commissioner who serves at the discretion of the President heads the agency.

There are approximately 13,700 FDA employees.

The FDA is a team of dedicated professionals working to protect and promote the health of the American people.

FDA is responsible for ensuring:

Foods are safe, wholesome, and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; electronic products that emit radiation are safe; and human cells, tissues, and Cellular and Tissue-Based Products (HCT/PTs) are free from communicable diseases.

Regulated products are honestly, accurately, and informatively represented.

These products are in compliance with the law and FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the marketplace.

## 1.8.1 - FDA PRINCIPLES

We strive to:

Enforce FDA laws and regulations, using all appropriate legal means.

Base regulatory decisions on a strong scientific and analytical base and the law; and understand, conduct, and apply excellent science and research.

Be a positive force in making safe and effective products available to the consumer, and focus special attention on rare and life-threatening diseases.

Provide clear standards of compliance to regulated industry, and advise industry on how to meet those standards.

Identify and effectively address critical public health problems arising from use of FDA-regulated products.

Increase FDA's effectiveness through collaboration and cooperation with state and local governments; domestic, foreign, and international agencies; industry; and academia.

Assist the media, consumer groups, and health professionals in providing accurate, current information about regulated products to the public.

Work consistently toward effective and efficient application of resources to our responsibilities,

Provide superior public service by developing, maintaining, and supporting a high-quality, diverse workforce.

Be honest, fair, and accountable in all our actions and decisions.

## SUBCHAPTER 1.9 - OFFICE OF REGULATORY AFFAIRS

### 1.9.1 – OFFICE OF REGULATORY AFFAIRS

The Office of Regulatory Affairs (ORA) is responsible for the operational activities of FDA through the work of its headquarters and field staff. As of December 2012, there were over 4,400 ORA employees. For ORA field contact information, see the ORA Contacts Directory at the end of this manual. ORA is under the leadership of an Associate Commissioner known as the ACRA.

ORA employees are dispersed throughout the United States. Over 85 percent of ORA's staff works in 20 District Offices, 13 Laboratories, and more than 150 Resident Posts and Border Stations.

ORA Headquarters is comprised of the Office of the Associate Commissioner for Regulatory Affairs; Office of Management; Office of Communications and Project Management; Office of Training, Education, and Development; Office of Partnerships and Operational Policy; Office of Human and Animal Food Operations; Office of Medical Products and Tobacco Operations; Office of Enforcement and Import Operations; Office of Regulatory Science; and the Office of Criminal Investigations located throughout the U.S. FDA maintains Offices and staff in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and in all States except Wyoming.

## **1.9.2 - ORA HEADQUARTERS ORGANIZATION**

### **1.9.2.1 OFFICE OF THE ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS (OACRA)**

The Office of the ACRA (OACRA) executes direct line authority over all Agency field operations; serves as the central point within the Agency through which Headquarters' offices obtain field support services. The OACRA advises Agency officials on regulations and compliance-oriented matters that have an impact on policy development and execution and long-range program goals.

### **1.9.2.2 - Office of Management (OM)**

The Office of Resource Management (ORM) is now called the Office of Management (OM). OM provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA), other ORA senior managers and staff on all areas of management, including budget formulation and execution, domestic and foreign travel, financial management, human capital management and analysis, ethics, labor relations, safety, and ORA wide administrative operations and facilities management.

OM has four Divisions: the Division of Management Operations (DMO); the Division of Financial Operations (DFO); the Division of Travel Operations (DTO), and the Division of Field Administration (DFA).

#### **1.9.2.2.1- Division of Management Operations (DMO)**

The Division of Management Operations (DMO) provides overall strategic leadership and guidance to ORA on aspects of human capital management, commissioned

corps management, management analysis, administrative management operations, safety management, and property management activities in accordance with established guidelines. DMO works to advance the strategic goals and objectives related to workforce management and development in ORA.

DMO contains three branches – the Facilities Management Branch (FMB), Human Capital Management Branch (HCMB), and Management Operations and Analysis Branch (MOAB). DMO also houses a commissioned corps management group that advises and supports senior leadership, management and Commissioned Officers on all personnel actions, performance management, honor and service awards, discipline, adverse actions, standards of conduct, training, travel, details, and reduction-in-strength.

#### **1.9.2.2.2 - Division of Financial Operations (DFO)**

The Division of Financial Operations (DFO), formerly known as the Division of Budget Formulation and Execution (DBFE), provides overall guidance and planning for all aspects of financial management for ORA senior leaders, including budget execution, budget formulation, and acquisitions. DFO prepares ORA's annual budget estimates at all phases of budget analysis, formulation, execution, and presentation and assists staff in justifying anticipated needs. DFO serves as liaison with the ORA Office of Strategic Planning and Operational Policy (OSPOP), Division of Planning and Evaluation on work-planning and resource utilization allocation and with the ORA Strategic Planning Staff in OSPOP for information about ORA and agency priorities. DFO provides guidance related to financial inquiries from outside government organizations and provides guidance related to the federal government budget and financial-related legislation, regulations, and applicable laws. DFO serves as the ORA Liaison with the agency's User Fee Council, Office of Budget, and Office of Financial Management and serves as the ORA financial representative for all User Fee renegotiations.

DFO has three branches – the Contracts and Grants Branch, Budget Execution Branch, and Budget Formulation Branch.

#### **1.9.2.2.3 - Division of Travel Operations (DTO)**

The Division of Travel Operations (DTO) provides overall strategic leadership and guidance to ORA on all aspects of travel in accordance with established guidelines. DTO works to advance the strategic goals and objectives related to travel policies and guidance in ORA and assures compliance with statutes, executive orders, and administrative directives.



DTO has three branches – Domestic Travel Branch, Human and Animal Food Foreign Travel Branch, Medical Products Foreign Travel Branch.

#### 1.9.2.2.4 - Division of Field Administration (DFA)

The Division of Field Administration (DFA) provides administrative support to the Programs and labs in a wide range of functional areas including budget/finance, building/facilities, fleet management, HR/personnel, mail services, property, purchasing, records management, safety/security, timekeeping, training, and travel. DFA also provides advice and counsel to the Associate Director for Management, Office of Management (OM), and the OM Divisions in the development of resource policy.

DFA contains three branches – the Field Administrative Program and Policy Branch (FAPPB), Field Office Administration Branch (FOAB), and the Laboratory Administration Branch (LAB).

#### 1.9.2.3 –Office of Human and Animal Food Operations

The Office of Human and Animal Food Operations (OHAFO) is responsible for the following activities as they relate to the safety of the nation's domestically produced and imported human and animal foods, and cosmetics:

- ORA's oversight of inspectional operations and compliance actions to protect and advance public health.
- Leading ORA's collaboration with the FDA's Office of Veterinary Medicine's Centers for Food Safety and Applied Nutrition (CFSAN) and Veterinary Medicine (CVM).
- Working with external partners such as states, locals, tribals, territorials and foreign counterparts in conjunction with the Office of Partnerships.
- Implementing new authorities granted by legislation.
- Developing regulatory program standards for quality improvements.
- Enforcement of FDA regulations related to Human and Animal Food.
- Investigations of consumer complaints, recalls and emergencies.

OHAFO has three Offices as well as the Audit Staff – the OHAFO East, OHAFO West, the Office of the State Cooperation Programs.

##### 1.9.2.3.1 – Office of Human and Animal Food Operations East

OHAFO East oversees all field inspection and compliance operations related to human and animal food and other

products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) through six Divisions of Human and Animal Food Operations.

OHAFO East also has the Division of Foreign and Human Animal Food Operations (DFHAFO) and includes two Foreign HAF Inspection Branches and two Foreign HAF Inspection Planning Branches.

##### 1.9.2.3.2 – Office of Human and Animal Food Operations West

The Office of Human and Animal Food Operations (OHAFO) – West oversees all field inspection and compliance operations related to human and animal food and other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) in the Divisions of Human and Animal Food Operations

West also includes the Division of Domestic Human and Animal Food Operations (DDHAFO)

##### 1.9.2.3.3 – Office of State Cooperation Programs

State Cooperative Programs provides technical support, guidance, training, and standardization to assist regulatory partners with reducing foodborne illness associated with these commodities. In support of these programs, Memoranda of Understanding (MOUs) have been signed between FDA and the Interstate Milk Shippers Conference, the Interstate Shellfish Sanitation Conference, and the Conference for Food Protection.

The Office of the State Cooperative Programs includes three divisions – the Division of Shellfish Sanitation (DSS), the Division of Milk Safety (DMS) and the Division of Retail Food Protection (DRFP).

##### 1.9.2.3.4 – Audit Staff

The Audit Staff conducts audits of domestic and international regulatory partners to measure their performance against program standards. Audits include reviews of regulatory systems and more specifically the inspection, investigation, sample collection and analysis, enforcement, response, recovery, and/or outreach components of these regulatory systems. The Audit Staff develops and maintains the program standards framework and corresponding audit and assessment methodology and makes determinations on implementation and conformance status for domestic and international regulatory partners. They coordinate with other ORA units on the development of training and certification programs for regulatory partners. They also coordinate with the Office of Strategic Planning and Operational Policy (OSPOP) and support the development of program

standards and associated audit programs that may apply to international and/or State regulatory partners and ORA. The Audit Staff represents ORA and may coordinate ORA participation on Agency workgroups responsible for comparability assessments and equivalence determinations of foreign regulatory partners, and supports the development and execution of third party auditing programs.

### **1.9.2.4 – OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS (OMPTO)**

The Office of Medical Products and Tobacco Operations (OMPTO) oversees four program directors (PDs) in the coordination, interpretation, and evaluation of the Agency's overall field inspections and compliance efforts in the areas of medical products and tobacco. OMPTO provides advice and counsel to the ACRA and other senior Agency leaders on medical product and tobacco inspection, compliance and other field activities. OMPTO coordinates medical product and tobacco operations with the Office of Enforcement and Import Operations (OEIO) and the Office of Regulatory Science (ORS); and supports medical products and tobacco partnerships and policy through collaboration with the Office of Partnership and Operational and Policy (OPOP). OMPTO also oversees and coordinates across programs medical product and tobacco related recalls, consumer complaints, and quality system activities and directs and coordinates ORA's emergency preparedness and response activities relative to medical products and tobacco.

OMPTO is led by an Assistant Commissioner (AC) for Operations who reports directly to the ACRA. OMPTO has four Offices – Office of Bioresearch Monitoring Operations (OBIMO), Office of Pharmaceutical Quality Operations (OPQO), Office of Biological Products Operations (OBPO), and Office of Medical Device and Radiological Health Operations (OMDRHO). The OMPTO Office of the Director also includes the Tobacco Operations staff.

#### **1.9.2.4.1 – Office of Bioresearch Monitoring Operations (OBIMO)**

The Office of Bioresearch Monitoring Operations (OBIMO) oversees all domestic and foreign Agency field inspectional operations related to the Bioresearch Monitoring (BIMO) Program, including all clinical and nonclinical research conducted in support of preapproval, licensing, premarket and marketing clearance applications submitted to the agency for products regulated by all FDA product centers. OBIMO provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Agency leaders relative to BIMO field operations including emergency response activities. OBIMO coordinates, directs and assists with BIMO investigative activities and directs and coordinates ORA's investigational response to reports of adverse events relative to clinical and nonclinical research

in collaboration with the Centers and the Office of Strategic Planning and Operational Policy (OSPOP). OBIMO supports the development of instructions for investigations for BIMO field operations and serves as an operational liaison for BIMO inspection programs to FDA's foreign offices. OBIMO coordinates international BIMO regulatory activities, including the planning of all BIMO foreign inspections and investigations and coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency.

OBIMO is led by the Bioresearch Monitoring program director (PD) and has two Divisions – the Division of Bioresearch Monitoring Operations I and II. OBIMO also includes the Bioresearch Monitoring Operations Staff

#### **1.9.2.4.2 – Office of Pharmaceutical Quality Operations (OPQO)**

The Office of Pharmaceutical Quality Operations (OPQO) provides advice and counsel to the ACMPTO and other FDA leaders relative to pharmaceutical products field operations and emergency response activities, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM). OPQO coordinates, directs and assists with pharmaceutical product investigative activities, including conducting investigations and inspections of pharmaceutical products, and other CDER and CVM-regulated commodities, as well as providing technical assistance regarding pharmaceutical investigational operations. OPQO supports the development of policy and guidance for investigations and compliance for pharmaceutical products. OPQO creates, reviews, and/or facilitates the issuance of field assignments with the Centers for pharmaceutical programs and monitors and serves as technical point of contact for these assignments. OPQO participates as subject matter expert in the design, implementation and presentation of pharmaceutical training programs, and serves as a subject matter expert on field operations relative to external and internal cross-Agency pharmaceutical product committees, workgroups, and task forces. OPQO develops and maintains cooperative relationships with State, local and other Federal agencies; serves on interagency councils; and encourages improved State and local consumer protection programs pertinent to Agency-enforced laws and regulations. OPQO coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency.

OPQO includes the Division of Pharmaceutical Quality Operations I, II, III, and IV which carry out similar operational responsibilities across the division boundaries, Division of Pharmaceutical Quality Programs, Division of Foreign Pharmaceutical Quality Programs.

### 1.9.2.4.3 – Office of Biological Products Operations (OBPO)

The Office of Biological Products Operations (OBPO) provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Agency leaders on field operations and emergency response activities related to Center for Biologics Evaluation and Research (CBER)-regulated products. OBPO coordinates, directs and assists with CBER-regulated product investigative activities and supports the development of policy and guidance for investigations and compliance for biological products. OBPO divisions conduct investigations and inspections of biological products, and other CBER-regulated commodities and provides technical assistance regarding biological product investigational operations. OBPO participates as subject matter experts in the design, implementation and presentation of biologics training programs. OBPO creates, reviews, and/or facilitates issuance of field assignments with Centers for biologics programs. OBPO coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency. This Office also develops and maintains cooperative relationships with State, local and other Federal agencies, serves on interagency councils, and serves as subject matter expert on field operations relative to external and internal cross-Agency biologics program committees, workgroups, and task forces.

OBPO has two Divisions – Division of Biological Products Operations I and II. Each Division includes an Investigations Branch, a Compliance Branch, and a Biological Products Inspection Staff (Team Biologics). OBPO also includes the Biological Products Operations Staff within the Office of the Director.

### 1.9.2.4.4 – Office of Medical Device and Radiological Health Operations (OMDRHO)

OMDRHO provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Agency leaders relative to medical device and radiological health program operations including emergency response activities. It coordinates, directs and assists with medical device and radiological health investigative activities. OMDRHO supports the development of policy and guidance for investigations and compliance for medical device and radiological health. OMDRHO contributes to system recognition efforts with other FDA components and national and international governments. OMDRHO participates as subject matter experts in the design, implementation and presentation of medical device and radiological health training programs. The Office monitors emerging issues and advancements in technology and recommends program improvements as necessary. OMDRHO serves as subject matter expert on program

operations relative to medical device and radiological health on external and internal cross-Agency committees, workgroups, and task forces. OMDRHO creates, reviews, and/or facilitates issuance of inspectional assignments with Centers for medical device and radiological health programs. OMDRHO monitors and serves as technical point of contact for these assignments. OMDRHO develops and maintains cooperative relationships with State, local, and other Federal agencies; serves on interagency councils; and encourages improved State and local consumer protection programs pertinent to Agency-enforced laws and regulations.

OMDRHO is led by the Medical Device and Radiological Health program director (PD) and has three Divisions – Division of Medical Device and Radiological Health Operations I, II, and III. OMDRHO also includes the Foreign Medical Device and Radiological Health Inspection Staff and Medical Device and Radiological Health Operations Staff.

### 1.9.2.4.5 – Tobacco Operations Staff

The Tobacco Operations is responsible for the following activities as they relate to supporting the Center for Tobacco Products (CTP) and activities under the Tobacco Control Act including:

- Rigorous compliance and enforcement program aims to ensure that the tobacco industry follows the law and regulations designed to reduce the health burden of tobacco use.
- Supporting CTP contracts with states and territories to inspect places where tobacco is sold.
- Conducting domestic and foreign inspections of manufacturing and clinical trial facilities in all states and territories.
- Conducting investigations at events where tobacco product manufacturers distribute free samples.
- Provide assistance to take action against tobacco product retailers and businesses for violations of the Tobacco Control Act.

### 1.9.2.5 – OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS (OEIO)

The Office of Enforcement and Import Operations (OEIO) is responsible for the following cross-Center activities:

- Providing direction, assistance, management and oversight of field import operations, including conducting field investigations and compliance activities.
- Serving as the agency focal point for headquarters/field relationships on all import programs, operations, and problems. Establishes field uniformity for import activities through adherence to procedural policy and operation's automated systems. Establishes and oversees a field import quality control program.

- Coordinating agency import activities with the U.S. Customs and Border Protection, including the development and institution of joint regulations, procedures, policies, and operations, as well as coordinating activities with other Federal agencies and foreign governments with border responsibilities through interagency agreements, memoranda of understanding, and informal working relationships.
- Providing subject matter expertise and direction for the development of import policies and new import procedures and regulations.
- Providing support and direction for designated compliance and recall operations that cut across programs.

OEIO includes the Division of Food Defense Targeting (DFDT), the Division of Import Operations Management (DIOM), and the Division of Import Program Development (DIPD).

The Import Program includes the Division of the Northeast Imports, the Division of the Southwest Imports, and the Division of the West Coast Imports each with one investigations branch and one compliance branch. The Division of the Northern Border Imports and the Division of the Southeast Imports each have two investigations branches and one compliance branch.

### **1.9.2.5.1 Division of Food Defense Targeting**

The Division of Food Defense Targeting (DFDT) serves as the liaison between law enforcement agencies and FDA officials regarding intelligence involving food products, including animal feed, which will be imported or offered for import into the United States. For the purposes of enforcing the prior notice regulation, DFDT receives and reviews prior notice and intelligence data on food products, including animal feed, which will be imported or offered for import into the U.S. and directs the field and/or the U.S. Customs and Border Protection (CBP) on the appropriate action to take. The division serves as the liaison with CBP in the field, providing technical expertise in the inspection, examination and sampling of imported food products including animal feed that are held at the ports. DFDT develops and reviews staff instructions and recommends procedures regarding the receipt, review, and response to prior notice submissions. The division recommends compliance actions based on violations of the prior notice regulation and serves as a liaison, in conjunction with other components in the program, to manage and coordinate the acquisition of equipment needed by CBP to inspect, examine, and sample imported food and animal feed products.

### **1.9.2.5.2 - Division of Import Operations Management (DIOM)**

The Division of Import Operations Management (DIOM) serves as the focal point for the Office of Regulatory Affairs (ORA) on all import programs and operations. It is the liaison to other federal agencies and foreign governments related to FDA import operations. The DIOM coordinates FDA import surveillance and compliance activities.

DIOM has two branches – Import Operations Branch and Import Compliance Branch.

### **1.9.2.5.3 - Division of Import Program Development (DIPD)**

The Division of Import Program Development (DIPD) provides support for import program development and information sharing. DIPD serves as the liaison to other federal agencies and foreign governments related to import operations.

DIPD has two branches – the Program Development Branch and the Import Technical Assistance Branch.

### **1.9.2.6 - OFFICE OF REGULATORY SCIENCE (ORS)**

The Office leads the planning, development, and implementation of ORA's scientific programs including the development, modification, and validation of test methods and measurement techniques, risk assessments and hazard analyses, and generic techniques to enhance public health protection and respond to emergencies. ORS is responsible for budget formulation, execution, and oversight for ORA's Field Laboratories; manages human and capital resources for the ORA science enterprise; and oversees lab accreditation activities, including proficiency testing for ORA's laboratories.

ORS will consist of the Office of Business and Safety Operations – Immediate Office (OBSSO-IO), the Office of Research Coordination and Evaluation, the Office of Medical Products, Tobacco, Specialty Laboratory Operations, and the Office of Food and Feed Laboratory Operations.

#### **1.9.2.6.1 – Office of Business Safety Operations – Immediate Office (OBSSO-IO)**

The Office of Business and Safety Operations-Immediate Office (OBSSO-IO) is part of the Office of the Assistant Commissioner for Regulatory Science. This Office provides quantitative and qualitative studies to improve processes, planning systems, and decision models in ORS programs, including productivity, cost estimation, and workload measurement analyses. It also leads in the creation of outcome-based measures that facilitate the development of various ORS strategic plans. The Office is responsible for developing and implementing national

safety policies and programs in ORA Laboratories, ensuring conformance with federal safety standards. With the assistance of the Division of Field Administration Program and Policy Group, the office oversees budgets for all laboratories and Field Management Directive equipment purchases. In addition, OBSO-IO stands in as proxy for the ORS Office Director.

### **1.9.2.6.2 – Office of Research Coordination and Evaluation**

This Office provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness. Works with Centers to define research priorities for ORA labs that align with agency's risk-informed analytical needs. Recommends priorities for ORA applied research to joint Center/ORA Steering Committees for consideration based on product risk and potential or emerging public health issues. The Office includes laboratory quality management oversight in coordination with the new Office of Quality Management.

### **1.9.2.6.3 – Office of Medical Products, Tobacco, Specialty Laboratory Operations**

Office of Medical Products, Tobacco, and Specialty Laboratory Operations with eight laboratories and associated programmatic staff. This Office provides oversight on scientific issues and laboratory analysis related to pharmaceuticals, tobacco, medical devices, radiochemistry, and forensic chemistry. Works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources.

### **1.9.2.6.4 – Office of Food and Feed Laboratory Operations**

Office of Food and Feed Laboratory Operations also with eight labs and associated programmatic staff. This Office provides oversight on scientific issues and laboratory analysis related to the chemical and microbiological analysis of human and animal food. Works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources.

## **1.9.2.7 - OFFICE OF COMMUNICATIONS AND PROJECT MANAGEMENT (OCPM)**

The Office of Communications and Project Management (OCPM) provides, maintains and applies expertise in strategic communications and project management in support of ORA and FDA programs, and provides executive secretariat services across ORA. OCPM also oversees the media, public outreach, web and social media programs across ORA

OCPM includes the Executive Secretariat Staff and has two divisions: the Division of Communications (DC) and the Division of Project Management (DPM).

### **1.9.2.7.1 - Executive Secretariat (Exec Sec) Staff**

The Executive Secretariat (Exec Sec) Staff develops, tracks, and coordinates ORA responses to executive and Congressional requests. Exec Sec serves as the ORA clearance liaison to the Office of Legislation, the FDA Office of Executive Secretariat, and Center counterparts. Exec Sec responds to a broad range of inquiries on behalf of ORA, including written and telephone inquiries. Exec Sec coordinates and obtains supporting documentation from other Agency components to prepare a response. Exec Sec provides direct support to the Associate Commissioner for Regulatory Affairs (ACRA), and senior ORA staff by preparing, clearing, and reviewing briefing materials, position papers, or other documents to assure timeliness and consistency with Agency and Office policy. Exec Sec coordinates the development and clearance of background information for meetings that may include external organizations either in the public or private sector. Exec Sec maintains records of all correspondence and provides to senior leadership as historical records when incoming inquiries reference similar subjects.

### **1.9.2.7.2 - Division of Communications (DC)**

The Division leads the organization's communications activities and provides strategic counsel and advice to the Office of Regulatory Affairs and agency leadership. This includes preparing, coordinating and developing relevant material in collaboration with other FDA technical, regulatory, and policy units. DC creates and coordinates communications approaches and tools that reach key ORA, cross-agency and external stakeholders. DC develops consistent organizational messaging on key issues, tracks senior leader and employee appearances to outside organizations, provides consultative services for various ORA initiatives, and manages the organizations' Web and digital media presence.

DC has three branches – Public Affairs Branch (PAB), Web and Digital Media Branch (WDMB), and Strategic Communications Branch (SCB).

### 1.9.2.7.3 - Division of Project Management (DPM)

The Division of Project Management (DPM) serves as ORA's principal resource for managing high priority and cross-cutting projects. DPM provides information to senior leadership on how various ORA projects contribute to ORA strategic priorities. DPM analyzes the ORA project portfolio based on strategic alignment, risk, and investment and provides senior leadership information about the distribution of projects.

### 1.9.2.8 – OFFICE OF PARTNERSHIPS AND OPERATIONAL POLICY

The Office of Partnerships and Operational Policy (OPOP) collaborates with Center program offices on the development of new or modified Agency compliance policies and regulatory procedures for all domestic and imported products regulated by the Agency, and leads the development of strategic plans and priorities for the Office of Regulatory Affairs (ORA). OPOP also provides overall leadership and guidance for ORA's information disclosure and Freedom of Information Act program.

OPOP advances the Agency's cooperative relationships and partnerships with international, federal, state, local, tribal, and territorial regulatory and public health agencies and partners, and provides oversight to the development of programs and policies that enhance the Integrated National Food Safety System.

OPOP leads the development of ORA's quality management system and its implementation and integration into core program areas and business processes.

The Office provides oversight to all ORA activities related to information technology needs, systems development and maintenance, and coordinates IT with the operational/business components of ORA and the Centers.

OPOP collaborates with domestic and international partners, focusing on public health, while striving to continuously improve the organization by providing support to ORA with its quality management system and information technology systems.

OPOP is a new office which has four offices reporting to it – the Office of Strategic Planning and Operational Policy (OSPOP), Office of Partnerships (OP), Office of Information Systems Management (OISM), and the Office of Quality Management System (OQMS).

#### 1.9.2.8.1 – Office of Strategic Planning and Operational Policy (OSPOP)

The former Office of Policy and Risk Management (OPRM) is now OSPOP. The Office of Strategic Planning and Operational Policy (OSPOP) provides advice and

counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and officials concerning information that may affect current or proposed FDA policies, legislation, or other regulatory matters. The Office supports and coordinates development of new or modified Agency compliance and regulatory policies for all products regulated by the Agency. OSPOP also directs and coordinates the preparation and maintenance of operational policy publications, including the Compliance Policy Guides Manual, guidance for industry, Federal Register notices, and specific policy aspects contained within procedural documents such as the Regulatory Procedures Manual. In collaboration with Centers, the Office of Policy, Planning, Legislation, and Analysis (in the Office of the Commissioner), and the Office of Chief Counsel, OSPOP establishes compliance and enforcement strategies for inclusion in Compliance Programs and policy documents as noted above. OSPOP develops ORA policy and coordinates sharing public and non-public information with foreign governments, Federal agencies, state and local government agencies, the public, and other stakeholders. In addition to developing the ORA workplan, OSPOP analyzes and evaluates operational performance outcomes, their impact, and overall accomplishments. OSPOP facilitates the development of ORA's strategic priorities and goals.

OSPOP has four Divisions – the Division of Operational Policy (DOP), the Division of Information Disclosure Policy (DIDP), the Division of Planning and Evaluation (DPE), and Division of Enforcement (DE). OSPOP also includes the Strategic Planning Staff (SPS)

#### 1.9.2.8.1.1 - Division of Enforcement (DE)

The Division performs final administrative review of proposed legal actions for sufficiency of evidence and resolves disputes or other problems encountered during case review to assure that Agency decisions are consistent. DE provides guidance for and participates in the development of new, novel, or precedent-setting cases. DE serves as the Agency clearance point and coordinator for all warrants, both administrative and search and seizure. DE serves as the Agency focal point for guidance on recall plans and procedures. DE Directs and coordinates ORA's activities related to the investigation of health fraud; serves as the health fraud liaison to the Centers; and provides management and oversight of the Agency's debarment program. DE consists of the following teams:

Recall Team

Health Fraud Team

#### 1.9.2.8.2 – Office of Partnerships (OP)

The Office of Partnerships (OP) provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other ORA leaders on programs

related to the development, coordination, and evaluation of Agency partnerships with other federal, state, local, tribal, and territorial regulatory and public health agencies and international partners. OP develops, implements, coordinates, and evaluates the Agency's federal-state programs. OP serves as the ORA focal point for the coordination of cooperative relationships with federal, state, local, tribal, territorial, and international regulatory and public health agencies and associations. This office also serves as ORA's focal point for issuing and tracking credentials and information sharing agreements to state representatives.

OP coordinates with ORA, Office of International Programs, FDA's Intergovernmental Affairs staff, and Centers on collaborations with federal, state, local, tribal, territorial, and international regulatory and public health partners to ensure cohesive and uniform application of Agency policy. OP supports the commissioning and credentialing of state, local, and territorial officials. OP liaises with the Office of Food and Veterinary Medicine, the Center for Tobacco, the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine; and provides support to an Integrated National Food Safety System (IFSS) through the Partnership for Food Protection (PFP), national associations, and alliances. OP supports travel and other administrative functions for state officials related to ORA funded activities. OP coordinates training for State regulatory officials in collaboration with the ORA Office of Training, Education, and Development (OTED).

OP has three Divisions – the Division of Integration (DI), the Division of Partnership Investments and Agreements (DIPA), and the Division of Standards Implementation (DSI).

### **1.9.2.8.3 – Office of Information Systems Management (OISM)**

The Office of Information Systems Management (OISM) provides advice and counsel to the ACRA and other senior management officials on all matters related to ORA's information technology needs, systems development, and related budgetary issues. The IT Staff is now called OISM. OISM leads and coordinates information system and technology management activities across ORA. OISM develops, evaluates, and prioritizes business needs in relation to current and planned information technology systems, data standards, reporting and visualization functions in partnership with internal clients in ORA offices, field offices, and laboratories as well as partners external to ORA. OISM facilitates ORA IT-related hardware and software requests and interactions with the FDA Office of Information Management and Technology (OIMT). OISM translates business priorities into a single, organization-wide portfolio of information systems and technology initiatives that are delivered through strategic partnerships with OIMT. OISM develops long-range strategic plans for ORA's information technology infrastructure and systems. OISM solicits

feedback from end-users throughout ORA to achieve efficiencies within IT systems and to ensure customer needs are met. OISM evaluates new policies and regulations for impacts to ORA IT systems. OISM coordinates and manages ORA's IT Investment Review Board (ITIRB), and Change Control Boards (CCBs). OISM manages ORA's IT Portfolio and provides Capital Planning and Investment Control (CPIC) functions to ensure that all IT initiatives are managed with sound life cycle management principles and practices consistent with the agency policies and procedures.

OISM has two Divisions – the Division of Special Initiatives and Coordination and Division of Systems Solutions. OISM also includes the Data Quality, Governance, and Reporting Staff.

### **1.9.2.8.4 – Office of Quality Management System (OQMS)**

The Office of Quality Management System (OQMS) provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and ORA managers in the development of strategies and application of quality management to core program areas and business processes. The Quality Management System Staff is now OQMS. OQMS has responsibility to plan, develop, and implement processes and procedures and programs to identify, prevent, and correct process deficiencies.

OQMS consists of two groups – the Audit and Document Control Group and the Process Improvement and Training Group.

### **1.9.2.9 – OFFICE OF TRAINING, EDUCATION, AND DEVELOPMENT (OTED)**

The Office of Training, Education and Development (OTED) develops the strategic training, education and development plan for ORA personnel and where appropriate, state and local regulatory partners, in line with ORA's mission, program priorities and core values. OTED provides advice and counsel to the ACRA and other ORA senior leaders on ORA national training, education and development policies, programs, and procedures. OTED provides and coordinates training and development programs for ORA employees in support of the FDA and ORA mission. OTED maintains ORA and related State and local training data, approves ORA certification programs and associated standards for regulatory staff, and provides oversight of OTED's accreditation commitments.

OTED's Office of the Director includes the Administrative, Logistics, and Finance Staff responsible for managing human resource functions, budget, acquisition, travel

facility and property management activities, and printing and logistical services for the office, as well as maintaining online training resources and retaining records in support of training accreditation standards and personnel certification. The OTED Office of the Director also includes the Registrar Staff responsible for managing systems for ORA's education, training, and certification records, and providing student and course completion data reports.

OTED has four Divisions – the Division of Programmatic Training (DPT), the Division of Multi-Program Leadership and Management Training (DMPLMT), the Division of Instructional Systems and Technology (DIST), and the Division of Testing, Measurement and Certification (DTMC).

### 1.9.2.9.1 – Division of Programmatic Training (DPT)

The Division of Programmatic Training (DPT) designs, develops, and delivers training and educational programs to ORA staff and regulatory partners across all ORA program areas. DPT collaborates with Center and ORA subject matter experts to develop course content for training, education, and development programs. DPT leads the establishment of national curriculum standards to provide consistency and uniformity in training development and delivery and maintains compliance with accreditation standards.

DPT has three Branches – Cooperative Food Training Programs Branch, Manufactured Food Training Branch, and Medical Products and Tobacco Training Branch.

### 1.9.2.9.2 – Division of Multi-Program Leadership and Management Training (DMPLMT)

The Division of Multi-Program, Leadership and Management Training (DMPLMT) designs, develops, and delivers training and educational programs to ORA staff and other regulatory partners in the program areas of compliance, imports, laboratory, ORA IT systems, administration, leadership, management and basic investigator programs. DMPLMT collaborates with Center and ORA subject matter experts to develop course content for training, education, and development programs. This Branch leads the establishment of national curriculum standards to provide consistency and uniformity in training development and delivery, as well as maintains compliance with accreditation standards.

DMPLMT has two Branches – the Multi-Program Training Branch and the Leadership, Management and Administrative Training Branch.

### 1.9.2.9.3 – Division of Instructional Systems and Technology (DIST)

The Division of Instructional Systems and Technology (DIST) directs analyses, assessments, design plans, and summative and formative assessments. DIST evaluates intention and use of training products to determine efficiency and effectiveness. This Branch collaborates with internal and external experts to develop qualified assessment instruments, as well as with other OTED Training Divisions to coordinate design and development training activities. DIST creates media products in support of design and development of training products, and maintains compliance with accreditation standards.

DIST has two Branches – the Instructional Systems and Multi-Media Branch I and the Instructional Systems and Multi-Media Branch II. Both Branches perform similar functions.

### 1.9.2.9.4 – Division of Testing, Measurement and Certification (DTMC)

The Division of Testing, Measurement and Certification (DTMC) directs planning, design, development, implementation and evaluation of assessment strategies and surveys. DTMC establishes ORA certification programs which determine competency standards that qualify regulatory staff through fair and reliable assessment practices. This Branch maintains separation between test and measurement functions and certification functions to prevent conflicts of interest with respect to certification.

DTMC has two Branches – the Test and Measurement Branch and Certification Branch.

### 1.9.2.10 - Office of Criminal Investigations (OCI)

This office advises and assists the ACRA and other key officials on regulations and criminal violations involving regulated activities and products. OCI directs and conducts criminal investigative activities in coordination with FDA headquarters units and with other Federal, state and local law enforcement agencies. OCI is instrumental in implementing FDA criminal investigation policy, training, and coordination. OCI interfaces directly with Federal and local prosecutorial offices and participates in grand jury proceedings and judicial actions as required. OCI has over 270 employees in headquarters and the field.

## 1.9.3 - ORA FIELD ORGANIZATION

The ORA field organization is now divided into program-based operation- Bioresearch Monitoring, Biological Products, Human and Animal Food, Medical Device and Radiological Health, Pharmaceutical Quality, Tobacco, and Imports.

- Bioresearch Monitoring- has two Divisions: the Division of Bioresearch Monitoring Operations I and II



- Biological Products - has two Divisions: Division of Biological Products Operations I and II and a Biological Products Inspection Staff (Team Biologics). OBPO also includes the Biological Products Operations Staff within the Office of the Director.
- 
- Human and Animal Food - divided into two regions East and West Divisions. East consists of East Division I-VI and West consists of West Divisions I-VI.
- Medical Device and Radiological Health- has three Divisions: Division of Medical Device and Radiological Health Operations I, II, and III.
- Pharmaceutical Quality- has four divisions: the Division of Pharmaceutical Quality Operations I, II, III, and IV
- Tobacco - does not have any program divisions and compliance functions are supported by the Center for Tobacco Products.  
Imports - has the following divisions: Northeast Imports, Southeast Imports, Southwest Imports, West Coast Imports, and Northern Border Imports.

## SUBCHAPTER 1.10 - REFERENCES

This subchapter will help you to locate regulatory references and FDA staff.

### 1.10.1 - LAW, REGULATION AND GUIDANCE

[The Food Safety Modernization Act](#) (FSMA) of 2011, [Family Smoking and Tobacco Control Act](#) (Tobacco Control Act) of 2009, [Food and Drug Administration Amendments Act of 2007](#) (FDAAA), the [Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#) (the Bioterrorism Act), the [Medical Device User Fee and Modernization Act of 2002](#) (MDUFMA), the [FDA Modernization Act of 1997](#), (FDAMA), the International Conference on Harmonization (ICH), Mutual Recognition Agreement (MRA), national emergencies and initiatives, and other forces continue to impact FDA inspectional operations as changes in law, regulation, guidance and internal procedures issue. As ICH members (Japan, U.S. and European Union) reach consensus agreements, ICH guidelines are adopted by all three governments. In the United States, they may replace outstanding FDA guidance in the medical device, human and animal drug areas. FSMA amended the FD&C Act to ensure the US food supply is safe by shifting the focus from response to prevention. The Tobacco Control Act amended the FD&C Act giving the agency the authority to regulate the manufacture, distribution, and marketing of tobacco products. Amendments under FDAAA include the addition of Section 417 to the FD&C Act authorizing the establishment of a Reportable Food Registry (RFR) – an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. Unless exempted, the Bioterrorism Act and

implementing regulations require most domestic food facilities and foreign food facilities who export to the U.S. to register as of December 12, 2003; FDA began accepting registrations on October 16, 2003. The Bioterrorism Act requires that FDA receive prior notice of food imported into the United States, beginning on December 12, 2003. The 2002 MDUFMA authorizes FDA to charge user fees for medical device premarket review; it allows third party medical device inspections, sets out new regulatory requirements for single-use devices, and directs FDA to establish the Office of Combination Products. FDA drug GMP initiative and Process Analytical Technology (PAT) efforts are underway.

In conducting inspections and investigations according to changing policies, in order to be effective, FDA regulators must understand the difference between regulatory requirements and guidance.

Laws or statutes, enacted by Congress, and regulations or rules, promulgated by Federal agencies, contain regulatory requirements.

FDA's guidance documents, on the other hand, have a different legal status and serve purposes different from laws and regulations. The purposes of guidance documents are to:

1. Provide assistance to the regulated industry by clarifying requirements that have been imposed by Congress or issued in regulations by FDA, and by explaining how industry may comply with those statutory and regulatory requirements, and
2. Provide specific review and enforcement approaches to help ensure that FDA's employees implement the agency's mandate in an effective, fair, and consistent manner.

The term "guidance documents" includes documents prepared for FDA staff, applicants/sponsors, and the public that:

1. Relate to the processing, content, and evaluation/approval of submissions;
2. Relate to the design, production, manufacturing, and testing of regulated products;
3. Describe the agency's policy and regulatory approach to an issue; or
4. Establish inspection and enforcement policies and procedures.

Guidance documents do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms. FDA procedures issued for staff to follow, such as the IOM, are internal procedures intended to direct your activities and you are to follow them.

Guidance documents for industry do not establish legally enforceable rights or responsibilities and are not legally

binding on the public or the agency. Rather, they explain how the agency believes the statutes and regulations apply to certain regulated activities. For a more detailed explanation of the background to the development, issuance and use of guidance documents see the preamble to the February 27, 1997 Federal Register Volume 62 Number 39. To access 21 CFR 10.115 Good Guidance Practices, see <https://www.govinfo.gov/content/pkg/CFR-2018-title21-vol1/pdf/CFR-2018-title21-vol1-sec10-115.pdf>.

Also see <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm> to access the CDRH Manual for the Good Guidance Practices (GGP) Regulation - Final Guidance for FDA Staff (2/01). For a comprehensive list of FDA current guidance documents, see <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/Guidanceforindustry/default.htm>.

The Federal Register is the official daily publication for rules, proposed rules, and Notices of federal agencies and organizations as well as Executive Orders and other Presidential documents. The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive Departments and agencies of the Federal Government. Most regulations enforced by FDA are located in Title 21 of the CFR. For a listing of all titles in the U.S Code, see <https://www.govinfo.gov/app/collection/USCODE>.

## 1.10.2 - SOURCES OF INFORMATION

### 1.10.2.1 - Contacting FDA Employees

Easily finding colleagues you need to contact can make your work life more productive. See IOM 1.8 and 1.9 for the organization of FDA offices, including a directory of ORA field offices and program managers. The Office of Regulatory Affairs organizational directory (blue pages) is available in electronic format. See ORA Directory. At the end of the blue pages, find a listing of Division program monitors. For FDA Center staff directories:

CFSAN - See <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoodandDrugs/CFSAN/default.htm>

CDER - See <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm>

CDRH - See <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/default.htm>. For a list of resource staff by topic of specialization in the Division of Industry and Consumer Education (DICE) (formerly the Division of Small Manufacturers, International and Consumer Assistance) see <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactDivisionofIndustryandConsumerEducation/default.htm>.

CVM - See <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoodandDrugs/CVM/default.htm>

CDER - See <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm>. For a list of resource staff, by topic of specialization, in the CDER Office of Manufacturing and Product Quality, (HFD-320) see <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm>.

CTP - See <https://www.fda.gov/TobaccoProducts/AboutCTP/ucm383225.htm>

To obtain contact information for an FDA employee in your e-mail directory, find the name, and then click on "properties" for telephone number and office designation. If the telephone number listed is inaccurate for an FDA employee you wish to contact, call the FDA Personnel Locator at telephone number 301-443-1544 for an update.

You may also search the Department of Health and Human Services electronic employee directory, which includes FDA and all other HHS staff. See <http://directory.psc.gov/employee.htm>. See IOM Chapter 3 for other Federal agency and State contact information, or to check the Directory of State and Local Officials on the FDA web site, see <http://dslo.afdo.org/>.

### 1.10.2.2 - Internet and Intranet

The FDA Internet Web site at <http://www.fda.gov> provides access to FDA references in electronic format: laws, regulations, policy, guidance, correspondence, reports and other publications. From the FDA home page link to laws enforced by FDA and related statutes at [www.fda.gov/opacom/laws](http://www.fda.gov/opacom/laws). From there you can access the Code of Federal Regulations, the Federal Register, and FDA Manuals and Publications. Under the heading "FDA Manuals and Publications" is a link to a comprehensive list of current FDA guidance documents at <http://www.fda.gov/opacom/morechoices/industry/guidedc.htm>.

Two features will facilitate your navigation of the FDA website, For the FDA "Website Index", see [www.fda.gov/opacom/hpchoice.html](http://www.fda.gov/opacom/hpchoice.html). To access the FDA "Website Map", see site map link at the bottom of the index.

Subscribe to various FDA e-mail lists for updates on web postings. See [www.fda.gov/emallist.html](http://www.fda.gov/emallist.html).

FDA libraries are accessible on the FDA intranet site.

### 1.10.2.3 - FDA/ORA Manuals and Reports

ORA headquarters and the OC Office of Information Resources Management support a change to electronic manuals, not paper manuals, because electronic manuals are easier to issue, revise and distribute. As part of the ORA Quality Management System, ORA HQ supports electronic manual dissemination through developing Intranet master lists or indices for directives used by ORA. See the FDA Intranet for more information. During transition from paper to electronic manuals, a limited selection and number of paper manuals will be available as follows:

1. Compliance Policy Guides (CPGs): A limited number of paper manuals are available by contacting the Office of Policy and Risk Management (OPRM)
2. Compliance Program Guidance Manual (CPGM): No paper manuals;
3. Data Codes Manual: No paper manuals; for electronic lists of program assignment codes and establishment type codes contact OPRM/Division of Planning Evaluation and Management
4. Enforcement Reports: No paper reports;
5. Field Management Directives (FMDs) - No paper manual;
6. Guide to International Inspections and Travel - No paper manual
7. Inspection Technical Guides - No paper manuals;
8. International Cooperative Agreements Manual - No paper manuals;
9. Investigations Operations Manual (IOM) - Current edition paper manuals available by contacting ORA/OO/OMPTO/Division of Medical Products and Tobacco Program Operations
10. Laboratory Manual (LM) - No paper manuals;
11. Laboratory Information Bulletins (LIB) - Available on Intranet and eLexnet; Hard Copies available to Labs through ORS
12. Regulatory Procedures Manual (RPM) - No paper copies;
13. Recalls and Safety Alerts - No paper copies;
14. Staff Manual Guide: No paper manuals;
15. State and Federal Cooperative Agreements: No paper copies.

### 1.10.2.4 - Forms and other Publications

The FDA on line Public Forms Catalog contains a list of FDA forms and the information necessary to order them.

Paper copies of the forms may be ordered electronically from the Program Support Center. To submit a forms request, or for other questions concerning FDA forms, see <https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ucm236184.htm>.

The Department of Health and Human Services (DHHS) Program Support Center, 16071 Industrial Drive, Gaithersburg, MD 20877 maintains a limited selection of

FDA forms and publications. To inquire about printing, please contact [pscpublishing@psc.hhs.gov](mailto:pscpublishing@psc.hhs.gov).

The INTRANET FDA's [Electronic Forms](#) Catalog is another resource. Internal forms related to field operations are located at that site. For example, you can find seals, affidavits, Form FDA 482 Notice of Inspection, and many other forms on which FDA documents its activities related to investigations, inspections and sample collection and analysis. Forms are organized alphabetically as well as by form number.

### 1.10.2.5 - Regulatory References and the General Public

The general public must make a request under the Freedom of Information Act (FOIA) in order to obtain certain FDA documents requiring redaction. See IOM 1.4.4 (Freedom of Information Act) and IOM 1.4.5 (internal FDA documents) for additional information on FOIA. For instructions to the public on how to file an FOIA request, see

<https://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeFOIARequest/default.htm>.

Many FDA documents are available to the public without an FOIA request. To obtain forms, direct the public to the FDA Public Use Forms web page. The public can purchase paper editions of various agency manuals, such as the Food Code and Compliance Program Manuals if ordered by NTIS item number from the National Technical Information Service (NTIS). Instruct the person seeking a publication to first locate the NTIS item number by calling the NTIS sales department at 888-584-8332. The next step is to enter the NTIS item number in the search box at the NTIS website at [www.ntis.gov](http://www.ntis.gov), and follow directions on ordering the publication. For additional information on NTIS publications, direct the public to contact:

National Technical Information Service  
Technology Administration  
U.S. Department of Commerce  
Alexandria, VA 22312  
Order Desk: 703-605-6050  
[customerservice@ntis.gov](mailto:customerservice@ntis.gov)

The public may also obtain federal publications from the U.S. Government Bookstore on-line.

FDA references are available to the public in electronic format from the FDA website. From the FDA homepage, link to special information for consumers, industry, health professionals, patients, state and local officials. For example, direct industry to the FDA industry web page.

Those regulated by FDA may contact their ORA Regional Small Business Representative (SBR) for an explanation of how FDA requirements apply to specific circumstances. SBRs also locate relevant references, make referrals,

conduct or participate in workshops and conferences, or make non-regulatory audits on request.

Direct industry inquiries in accordance with Division policy, either to appropriate Division personnel, to the ORA Small Business Representative for your region, to an FDA industry assistance office or the Center Ombudsman, or to the Office of the Commissioner. In CDRH, the Division of Industry and Consumer Education (DICE) staff specializes in industry assistance. For FDA drug manufacturing queries, a list of resource staff in the CDER Office of Manufacturing and Product Quality, (HFD-320) identifies each staff member by area of knowledge. Refer questions about good clinical practice requirements to the FDA's GCP staff.

Refer consumer inquiries to the appropriate District Public Affairs Specialist.

Try to refer appropriately to make your government work more effectively for all concerned.

### **1.10.2.6 - Acronyms**

To access explanations for some of the hundreds of acronyms in FDA references, try the following:

1. FDA Acronyms and Abbreviations database
2. CFSAN Abbreviations and Acronyms from the CFSAN Risk Analysis Working Group Report "Initiation and Conduct of All Major Risk Assessments within a Risk Analysis Framework" (3/02)
3. Listeria monocytogenes Risk Assessment report: Abbreviations and Acronyms
4. ORA Glossary of Computerized System and Software Development Terminology
5. Fiscal Year 2001 Performance Plan, FY 2000 Final Performance Plan, and FY 1999 Performance Report Glossary of Acronyms
6. Fiscal Year 2004 Annual Performance Plan, FY2003 Revised Performance Plan, FY 2002 Annual Performance Plan see [Appendix F Glossary of Acronyms](#).

### **1.10.3 - SPECIAL REGULATORY INFORMATION BY PRODUCT CATEGORY**

Information including product databases, inspection guides, industry guidance, and regulatory references are available by product category on-line at DMPTO's intranet site.

EXHIBIT 1-1

ALLOWABLE EXPENSES CHART

This Table lists allowable expense items and the requirements that must be met to assure reimbursement. Unless "xx" appears in one or more of the columns at the right, there are no special requirements for reimbursement. Please see your administrative staff or supervisor for additional information.

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount
<b>BAGGAGE</b>	xx	xx	
1. All fees pertaining to the first checked bag			
2. Additional charges relating to the second and subsequent bags may be reimbursed when the Agency determines those expenses are necessary and in the interest of the Government (See <a href="#">FTR 301-70.300</a> )	xx	xx	xx
3. Excess Baggage Charges for government property	xx	xx	xx <sup>1</sup>
4. Service Charge for checking baggage by checking agent where such charges for checking baggage in baggage rooms, or station or air terminal	xx	xx	xx
5. Storage Charges (e.g., when traveler stores baggage or equipment when such charges are result of official business.)	xx	xx	xx <sup>2</sup>
6. Transfer Charges - when necessary for official travel (e.g., when changing between stations where free transportation is not issued by common carrier.) CAUTION: Where the traveler's plans are changed he/she shall make sure that baggage has been checked beyond the point where he/she leaves the train is stopped or transferred. If baggage cannot be intercepted or transferred and is carried to original destination on unused portion of ticket, the traveler shall give full explanation of facts when submitting unused portion of ticket. Failure to do so will result in any excess cost being charged to traveler.	xx	xx	xx
<b>FEES OR TIPS</b>	xx	xx	
1. Tips – Allowable tips are 15 percent of the reimbursable fare.		(over \$75)	
2. Parking Fees - charges for parking automobiles	xx	(over \$75)	
3. Porter - allowable only at transportation terminals for handling Government property carried by travelers. NOTE: Porter fees for personal property, brief cases, etc. are not allowed.			xx <sup>3</sup>
4. Traveler Checks Money Orders Certified Checks Transaction Fees for use of Automated Teller Machines (ATMs) – Government contractor issued charge card	xx xx xx xx	xx xx xx xx	
5. Registration Fees – Attendance at local non-government sponsored meetings			
a. Payment of registration fee should be made via the J.P. Morgan Chase Visa government credit card if the organization(s) will accept credit card.	xx	xx	xx
b. J.P. Morgan Convenience Checks	xx	xx	xx
c. If the credit card cannot be used, and the organization accepts the purchase order, HHS-99 or SF-182 the organization may bill FDA directly	xx	xx	xx
Please see your Administrative Officer for additional information and guidance when requesting payment of registration fees.			
6. Exchange of Currency			
a. Allowed	xx	xx	

<p>i. Fees for cashing U.S. Government checks or drafts reimbursing traveler for travel expenses only incurred in foreign countries</p> <p>ii. Commissions for conversion of currency in foreign countries</p> <p>iii. Costs of traveler's checks, money orders, certified checks purchased in connection with official travel. Costs may not exceed amount needed to cover reimbursable expenses.</p> <p>b. Not allowed: exchange fees for cashing checks or drafts issued in payment of salary.</p>	XX XX	XX <sup>4</sup> XX	
7. Special Expenses for Foreign Travel - Passports, visa fees, costs of photographs for passports and visas, costs of certificates of birth, health, identity, and of affidavits, and charges for inoculations not obtainable through a Federal dispensary	XX	XX	
<b>HIRE OF ROOM</b> 1. Allowed when necessary to engage a room in a hotel or other place to transact official business	XX	XX	XX <sup>6</sup>
2. Not allowed for personal use (cost included in subsistence allowance).			
<b>PERSONAL SERVICES</b> 1. Stenographic and typing services, guides, interpreters, drivers of vehicles, etc.	XX	XX	XX <sup>5</sup>
<b>POSTAGE</b> Postage necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	XX	XX	XX <sup>7</sup>
<b>POST OFFICE BOX RENTAL</b> Where necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	XX	XX	XX
<b>PUBLIC TRANSPORTATION WHILE IN TRAVEL STATUS</b> Public transportation fares are allowed from (or to) common carrier, or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business.	XX	XX (over \$75)	XX <sup>8</sup>
Public transportation fares between places where meals are taken, and places of business or places of lodging <b>are not</b> allowed, except where nature and location of work at temporary duty station is such that suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.			
<b>TAXICABS WHEN USED LOCALLY WHILE IN TRAVEL STATUS</b> Taxicabs are allowed from (or to) common carrier or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business where cheaper mode of transportation is not available or is impracticable to use.	XX	XX (over \$75)	XX <sup>8</sup>
Taxicabs are not allowed between places where meals are taken and places of business, except where nature and location of suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.	XX	XX (over \$75)	XX <sup>8</sup>
Limousine service plus taxicab tip rates between airport and limousine pick-up or discharge point	XX	XX (over \$75)	
<b>TELEPHONE CALLS / INTERNET CHARGES</b> 1. Official Business – Charges for local and long distance calls are allowed when made on official business		XX <sup>9, 10</sup>	
2. Personal Calls – Employee traveling overnight within CONUS may be reimbursed for one brief telephone call per day to her/his residence in accordance with government-wide rules and regulations. Reimbursement is limited to actual expenses, not to exceed \$5.00 times the number of consecutive nights of travel on official business; applicable only when the employee is authorized to be on travel for one or more consecutive nights; and conditioned upon the unavailability of government-provided long distance telephone systems and services (including government-issued telephone calling cards) during each day of travel on which expenses are incurred.		XX	

a. OCONUS Travel may be reimbursed only for telephone call(s) home from a foreign country which have been authorized prior to the beginning of travel and are shown on the travel authorization. Permitted frequency and cost must be stated on the travel authorization and adhered to by the employee.			
3. Internet Charges – (Federal and Departmental policy requires specific written or electronic authorization when the use of internet services are required for official business.)	xx	xx (over \$75)	
<b>RECORDS</b> Charges for copies of records furnished by State officials, such as Clerks of Courts, etc., when necessary for performance of official business		xx	xx <sup>5</sup>
<b>SHIPMENTS (FREIGHT OR EXPRESS) - see IOM 4.5.5</b>		xx	xx <sup>12</sup>
<b>MISCELLANEOUS EXPENSES</b> 1. Cash used in lieu of transportation request for passenger transportation and accommodations. 2. Purchase of emergency supplies. 3. Any other miscellaneous expenditure incurred by traveler in performance of official business, such as samples of drugs, cosmetics, etc., purchased by FDA inspectors and investigators.	xx  xx xx	xx  xx xx	xx <sup>5</sup>
<b>LAUNDRY EXPENSES</b> 1. Employees will be reimbursed for laundry, cleaning, and pressing expenses equal to the number of travel days multiplied by \$5. a. For CONUS travel, employees must be on travel for four or more nights. b. Employees on OCONUS travel are not permitted to claim separate laundry expenses		xx	

FOOTNOTES:

- <sup>1</sup> Voucher must show weight of baggage and points between which moved.
- <sup>2</sup> State that storage is solely on account of official business.
- <sup>3</sup> State that porter fee was for handling Government property carried by traveler.
- <sup>4</sup> Voucher shall show rate of conversion and commission charges.
- <sup>5</sup> Voucher shall show date of service, quantity, unit, and unit price.
- <sup>6</sup> In addition to information required in footnote #5, state necessity for hire of room.
- <sup>7</sup> State that postage was used for official mail.
- <sup>8</sup> State necessity for daily travel.
- <sup>9</sup> For telegrams, faxes, cablegrams, and long distance telephone calls, show points between which service was rendered, date, amount paid on each and "official business".
- <sup>10</sup> For local telephone, calls show number of calls, rate per call, total amount expended each day, and "official business".
- <sup>11</sup> When government Bill of Lading is not used, explain circumstances.
- <sup>12</sup> Continental United States (CONUS) is defined as the 48 contiguous states and the District of Columbia.

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## SUBCHAPTER 2.1 - REGULATORY NOTES

Regulatory notes are the contemporaneous, sequential record of your daily investigatory efforts. They record your observations relevant to violations and active cases. They are the vital link between your findings and your subsequent testimony in court. Because of the data, which regulatory notes contain, such as information pertaining to open investigatory files, trade secrets, and personal information protected under the Privacy Act, they are confidential. Regulatory notes are government property. The notes cannot be released to anyone outside the Agency, except with the express permission of your management and after following FDA's procedures. (See IOM Subchapter 1.4)

See IOM 1.2.4 for guidance on administrative notes.

### 2.1.1 - USES OF REGULATORY NOTES

Accurate regulatory notes are to refresh your memory when reporting certain important details of a sample collection, inspection, and investigation. Notes also support the principle of "presumption of regularity", i.e., in the absence of clear evidence to the contrary, courts presume public officers properly discharge their official duties. Regulatory notes are useful as a means to refute assertions by defendants, witnesses or others. Regulatory notes also aid in defending lawsuits against FDA agents. This has been an issue of significance in a number of regulatory cases in the Federal Sector.

## 2.1.2 - REGULATORY NOTES CHARACTERISTICS

See IOM 1.1 for English language requirement. Regulatory notes should be accurate, objective, factual, and free of personal feelings or conclusions. Regulatory notes should be made at the time of the event they represent. Regulatory notes are original contemporaneous, sequential recordings of an activity, and may be handwritten (in ink) or electronic. Do not erase, edit or rewrite original notes. Do not leave excessive space between diary entries. Whether handwritten or electronic, any additions, deletions, or corrections to regulatory notes should be identified by strike through (~~strike through~~ font for electronic notes) for deletions, brackets [ ] for additions and by initialing and dating your changes.

Electronic Regulatory notes: you should be able to identify and attest the electronic notes were taken by you to ensure document integrity. You should exercise good judgment when deciding if a change is contemporaneous or if change should be initialed and dated. For example, changes or backspacing to correct information ordinarily would not need initialing and dating as long as the changes were made contemporaneously with the activity being documented. Otherwise, you should initial and date the change. Adhere to agency directives and procedures to safeguard and file electronic notes. Regulatory notes can be printed, and each page initialed (handwritten initials) and dated by the investigator. If this procedure is used, the original disk or Compact Disk-Recordable (CD-R) can be identified with the firm name, dates, and investigator's initials; placed in a FDA-525 envelope or equivalent; and then sealed with an Official Seal, FDA-415a. NOTE: See IOM 5.3.3 - Exhibits, for guidance on the identification and storage of electronic data obtained from inspected firms, and used as exhibits for the EIR.

## 2.1.3 - REGULATORY ENTRIES

Regulatory notes should contain sufficient detail to refresh an investigator's memory regarding inspections, investigations and sample collections. They should include objectionable conditions, pertinent information about your activities during an operation, details of a sample collection, etc. If a checklist is used during an inspection, don't repeat that information in your regulatory notes and attach it to your EIR. The checklist should be handled as part of the notes. See also 5.11.1. Likewise, when relevant information is contained on an FDA form, or in an exhibit collected during an inspection, that information need not be repeated in your notes.

Regulatory notes should contain the substance of all significant discussions with people contacted during the activity; e.g., discussions of individual responsibility and refusals. When entering a direct quote in your regulatory notes, such as a statement against self-interest, it is important the exact words be used to preserve the original intent of the individual and subject. Every quote of

significance appearing in the final report should be in your regulatory notes since they are part of the source documents, which will support any regulatory or administrative action.

Regulatory notes should not contain purely administrative information. See IOM 1.2.4 for guidance on administrative notes.

## 2.1.4 - FORMAT FOR REGULATORY NOTES

Keep your handwritten regulatory notes in a bound notebook. Bound notebooks provide continuity and integrity and also prevent lost or misplaced pages. Loose-leaf and spiral bindings allow easy removal of pages, an invitation to vigorous and heated cross-examination on the witness stand.

Regulatory notes in electronic format are a valuable tool to expediting the conduct of an inspection. They may be stored on computer disk or CD-R, but should be preserved in a manner that ensures data integrity.

Regulatory notes whether written or electronic are subject to audit at any time; must be available for review; and must, on demand, be surrendered to your supervisors or other authorized personnel. The bound notebook in which your regulatory notes are kept should be identified with your name, telephone number, and address to facilitate their return if lost. To assist in the return of lost regulatory notes, include the following information in the bound notebook's inside cover or as a placard affixed to the back cover:

This book is the property of the U.S. Government.

If found, drop in mail box.

POSTMASTER: Postage guaranteed

Please return to: [Enter the appropriate District (or resident post's) mailing address here, including the zip code]

Advancing technology may increase the preservation options available. District policy should be followed regarding the preservation of all regulatory notes.

### 2.1.4.1 - Regulatory Notes In Restricted Environments

In rare circumstances, you may be unable to take regulatory notes using your notebook or electronic note-taking device because doing so might introduce contamination from your notebook into the environment (e.g. pharmaceutical clean rooms) or from the environment into your notebook (e.g. environmental sampling of manure pits during egg inspections, drug manufacturing areas where high-potency, cytotoxic, or  $\beta$ -lactam drugs are exposed). Additionally, if you use an electronic notetaking device, you may be unable to use it in environments that present an explosion hazard.

You should attempt to take contemporaneous notes in the most reasonable manner possible. Make a note in your official regulatory notes that you will be taking notes using

another method and the reason (e.g. "Entering cleanroom to observe sterile operations – notes to be taken on sterile cleanroom paper provided by firm to prevent contamination"). If taking notes on unbound sheets of paper, please refer to supervisory guidance.

If you are unable to take notes in any manner, you should record your recollection of the events and/or observations in your regulatory notebook as soon as you are able to. Include the reason you could not contemporaneously take notes in your regulatory notebook and the time between the event and/or observations and the notes.

After the inspection, preserve the notes according to your Division policy and in consultation with supervisor guidance.

### 2.1.5 - RETENTION OF REGULATORY NOTES

Identify your regulatory notes with your name and the inclusive dates they cover before they are turned over for storage. Follow your Districts policy regarding the maintenance of regulatory notes.

Based on your Division's policy, regulatory notes (including computer disks or CD-Rs) may be kept by you, filed with the final report, or kept by the District in a separate, designated file. At a minimum, retain regulatory notes for the same period of time as the inspection report, collection report or other investigational report, or until all court actions, including appeals, have been adjudicated.

If you leave FDA, or are transferred from your District, identify any regulatory notes in your possession and turn them in to the District you are leaving. District are to retain regulatory notes as official records as outlined in the FDA Staff Manual Guide.

Regulatory notes prepared by headquarters' personnel during a field inspection/investigation are official records. Headquarters personnel are to follow their Center's policy regarding the retention of regulatory notes. In general, all regulatory notes should be maintained in the Division or Center where the original report is filed.

## SUBCHAPTER 2.2 - STATUTORY AUTHORITY

Various acts specify the authority conferred on the Secretary of DHHS. This authority is delegated by regulations to the Commissioner of Food and Drugs, and certain authorities are delegated further by him.

### 2.2.1 - FEDERAL FOOD, DRUG, AND COSMETIC ACT

This Act, as amended, and its regulations provide the basic authority for most operations.

Examinations, Investigations, and Samples - Collecting samples is an important and critical part of FDA's regulatory activities. While inspections and investigations may precede sample collection, a case under the law does not normally begin until a sample has been obtained. Proper sample collection is the keystone of effective enforcement action.

The basic authority for FDA to take samples falls under the statutory provisions of [section 702\(a\) of the FD&C Act](#) [21 USC 372(a)], which authorizes examinations and investigations for the purposes of this Act.

For tobacco products, [section 702\(a\)\(1\)\(B\)](#) of the FD&C Act directs FDA to contract with states to inspect retailers within that state in connection with the enforcement of the Act when feasible.

[Section 702\(b\) of the FD&C Act](#) [21 USC 372(b)] requires FDA to furnish, upon request, a portion of an official sample for examination or analysis to any person named on the label of an article, the owner thereof, or his attorney or agent. In a precedent case, "United States v. 75 Cases, More or Less, Each Containing 24 Jars of Peanut Butter, the U.S. Circuit Court of Appeals for the Fourth Circuit held the taking of samples is authorized under section 702(b) of the FD&C Act [21 U.S.C. 372(b)], since this section "clearly contemplates the taking of samples." See Kleinfeld and Dunn 1938-1949 at 126. The FD&C Act also refers to samples in [sections 704\(c\) and 704\(d\)](#) [21 USC 374(c) and 374(d)].

#### 2.2.1.1 - Authority to Enter and Inspect

Authority to Enter and Inspect - [Section 704 of the FD&C Act](#) [21 U.S.C. 374] provides the basic authority for establishment inspections. This authorizes you to enter, and to inspect at reasonable times, within reasonable limits, and in a reasonable manner, establishments or vehicles being used to process, hold or transport food, drugs, devices, tobacco products, or cosmetics. The statute does not define, in specific terms, the meaning of "reasonable". FDA's establishment inspection procedures maintain this authority extends to what is reasonably necessary to achieve the objective of the inspection.

#### 2.2.1.2 - Food Inspections

Authority to inspect food plants resides in the general inspectional authority of [Section 704 of the FD&C Act](#) [21 U.S.C. 374]. Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") (PL 107-188), signed into law on June 12, 2002, created a new [section 414, "Maintenance and Inspection of Records," in the FD&C Act](#). Under this new authority, the Secretary of Health and Human Services (the Secretary) may by regulation establish requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive,

hold, or import food to establish and maintain food records. These records identify the immediate previous sources and the immediate subsequent recipients of food. In addition, section 414(a), "Records Inspection," and section 704(a), "Factory Inspection" authorize the Secretary to access and copy all records related to an article of food if: (1) the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) the records are necessary to assist the Secretary in making such a determination. FDA plans to carry out its authority to inspect all records and other information described in section 414 in a similar manner as FDA's authority to perform inspections of facilities (i.e., upon presentation of appropriate credentials and a written notice at reasonable times, within reasonable limits, and a reasonable manner.) FDA employees will not invoke this authority during inspections unless the requirements for record access under the Bioterrorism Act are satisfied. Further guidance is available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/default.htm>.

The Infant Formula Act of 1980 added new authority to the FD&C Act. [Section 412 of the FD&C Act](#) [21 U.S.C. 350a] extends the definition of adulteration to include specific nutritional, quality and good manufacturing control requirements. It also mandates a firm make available batch records, quality control records, nutrient test data and methodology, and similar documents for examination and copying. [Section 704\(a\)\(3\) of the FD&C Act](#) [21 U.S.C. 374(a)(3)] gives investigators the right to examine and copy these records.

### 2.2.1.3 - Device Inspections

[Section 704\(a\) of the FD&C Act](#) [21 U.S.C. 374(a)] provides the general inspectional authority to inspect medical device manufacturers. The Medical Device Amendments of 1976 provided additional authority to inspect records, files, papers, processes, controls, and facilities to determine whether restricted devices are adulterated or misbranded. The Amendments also provide FDA authority, under [section 704\(e\)](#) [21 U.S.C. 374(e)], to inspect and copy records required under [Section 519](#) or [520\(g\)](#) of the FD&C Act [21 U.S.C. 360i or 360j(g)].

### 2.2.1.4 - Drug Inspections

In the case of drug inspections, FDA has explicit authority to address the delay, denial, limiting, or refusal of an inspection, under Section 707 of the Food and Drug Administration Safety and Innovation Act (FDASIA), which created new Section 501(j) of the FD&C Act [21 U.S.C. 351(j)]. Section 501(j) deems adulterated any drug that is manufactured in an establishment that delays, limits, denies or refuses to permit entry or inspection. FDA issued [draft guidance](#) with examples of the types of conduct that FDA considers to be in violation of Section 501(j) of the

FD&C Act. This guidance also specified that under certain circumstances delaying, denying, limiting or refusing a request for records in advance or in lieu of an inspection under Section 706 may also result in a manufacturer's drugs being adulterated under the FD&C Act.

### 2.2.1.5 - Limitations

[Section 704 of the FD&C Act](#) [21 U.S.C. 374] provides authority for FDA to conduct inspections of factories, warehouses, establishments, and vehicles, and all pertinent equipment, finished and unfinished materials, containers, and labeling therein where food, drugs, devices, tobacco products, or cosmetics are manufactured or held. This section does not include a provision to inspect records within those facilities, except for inspections of prescription drugs, nonprescription drugs intended for human use, and restricted devices, or tobacco products as stipulated in [Section 704\(a\)\(1\)\(B\)](#) [21 U.S.C. 374(a)(1)(B)], or inspections of infant formula described in [Section 704\(a\)\(3\)](#) of the FD&C Act [21 U.S.C. 374(a)(3)].

Keep in mind that several other sections of the Act or of regulations also include provision for inspection and copying of required records. For example, [505\(k\)](#) provides authority to access and copy records required for new drug applications and abbreviated new drug applications, [512\(k\)\(2\) and 512\(m\)\(5\) of the FD&C Act](#) [21 U.S.C. 360b(k)(2) and 360b(m)(5)] provide access and copying of records regarding new animal drug and medicated feed permits, HACCP regulations in [21 CFR 123](#) for fish and fishery products provide for access and copying of required records, and 920(c) provides access, with written notice, to records in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

Some firms will allow access to files and other materials for which the FD&C Act does not give mandatory access, but retain the right to later refuse. Management may propose the following alternatives:

1. That inspections to obtain data from these files be made without issuing an FDA-482, Notice of Inspection. You cannot agree to this because the act requires the notice be issued before the inspection.
2. That when data is provided, you are advised in writing it is being given voluntarily. In this instance accept the written or oral statement and include it as part of the EIR.

Management may insist answers to specific questions be provided by the firm's legal department or other administrative officers. In some instances, management may request questions be submitted in writing. In these cases, try to obtain answers necessary to complete the inspection. Do not submit lists of questions unless specifically instructed to do so by your supervisor.

### 2.2.1.6 - Electronic Radiation Product Examinations and Inspections

The authority for obtaining samples of radiation-emitting electronic products for testing is provided in [Section 532\(b\)\(4\) of the FD&C Act](#) [21 U.S.C. 360ii(b)(4)].

The authority to inspect factories, warehouses, and establishments where electronic products are manufactured or held is provided in [Section 537\(a\) of the FD&C Act](#) [21 U.S.C. 360nn(a)]. This authority is limited; FDA must find "good cause" that methods, tests, or programs related to radiation safety (such as noncompliance with a standard) may be inadequate or unreliable. If there is no finding of "good cause," inspections must be voluntary unless another authority, such as [Section 704\(a\) of the FD&C Act](#) [21 U.S.C. 374(a)] for medical devices, exists. The authority to inspect books, papers, records, and documents relevant to determining compliance with radiation standards is provided in [Section 537\(b\) of the FD&C Act](#) [21 U.S.C. 360nn(b)]. The Electronic Product Radiation Control prohibited acts and enforcement authorities are specified in [Sections 538 and 539 of the FD&C Act](#) [21 U.S.C. 360oo and 360pp].

### 2.2.2 - SELECTED AMENDMENTS TO THE FD&C ACT

The amendments to the FD&C Act are summarized in Regulatory Procedures Manual (RPM) chapter 2-2.

### 2.2.3 - OTHER ACTS

See IOM 2.2.10 and IOM 3.2.1.3 for special authorities involving detentions under the [Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection, Acts](#).

#### 2.2.3.1 - Anabolic Steroids Control Act of 1990

The Anabolic Steroids Control Act amends the Controlled Substances Act by adding Anabolic Steroids to Schedule III of section 202(c).

#### 2.2.3.2 - Fair Packaging and Labeling Act (FPLA)

[Fair Packaging and Labeling Act](#) (FPLA) is an Act to prevent the use of unfair or deceptive methods of packaging or labeling of certain consumer commodities.

#### 2.2.3.3 - Federal Anti-Tampering Act

[Federal Anti-Tampering Act](#) prohibits certain tampering with consumer products (18 USC 1365). See [IOM 8.1.5.9](#) for guidance on tampering investigations.

### 2.2.3.4 - Federal Import Milk Act

[Federal Import Milk Act](#) regulates the importation of raw and pasteurized bovine milk and cream from foreign producers.

### 2.2.3.5 - Federal Caustic Poison Act

Primarily a labeling Act specifying warnings and precautionary statements on labeling of certain household caustic preparations.

### 2.2.3.6 - Poison Prevention Packaging Act

Provides for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances.

### 2.2.3.7 - Public Health Service Act (PHS)

[Public Health Service Act](#) (PHS) - Sampling: For biological products, which are also drugs under the FD&C Act, the sampling authority of both Acts exists.

[Section 351\(c\) of Part F, Title III of the Public Health Service \(PHS\) Act](#) [42 USC 262(c)] authorizes inspections of establishments that manufacture biological products (virus, therapeutic serum, toxin, antitoxins, , vaccines, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound)). Authority to collect samples and records is found in [21 CFR 600.22](#). [Section 361\(a\) of Part G of the PHS Act](#) [42 USC 264] authorizes inspection and other activities for the enforcement of [21 CFR 1270](#), Human Tissue Intended for Transplantation, and [21 CFR 1240](#), Interstate Quarantine Regulations. Part 1240 covers the mandatory pasteurization for all milk in final package form intended for direct human consumption; the safety of molluscan shellfish; the sanitation of food service; and food, water, and sanitary facilities for interstate travelers on common carriers.

#### 2.2.3.8 - Mammography Quality Standards Act of 1992

[Mammography Quality Standards Act of 1992](#) amends the Public Health Service Act to establish the authority for the regulation of mammography services and radiological equipment.

#### 2.2.3.9 - Comprehensive Smokeless Tobacco Health Education Act

Section 204 of the Family Smoking Prevention and Tobacco Control Act (TCA) amended the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA). CSTHEA mandates a program to inform the public of any

dangers to human health resulting from the use of smokeless tobacco products and includes specific requirements for smokeless tobacco products' labeling and advertising.

### 2.2.3.10 - Federal Cigarette Labeling & Advertising Act

Section 201 of The Family Smoking Prevention and Tobacco Control Act (TCA) amended the Federal Cigarette Labeling & Advertising Act (FCLAA) FCLAA requires a comprehensive federal program to deal with cigarette labeling and advertising to adequately inform the public of health risks and create a uniform regulatory structure across the United States. The Act includes specific requirements for cigarette labeling and advertising.

## 2.2.4 - CODE OF FEDERAL REGULATIONS (CFR)

The [Code of Federal Regulations](#) is a codification of the general and permanent rules published in the [Federal Register](#) by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. For example, the specific regulation covering drug GMPs appears as "21 CFR 211", that is, Title 21, Part 211. Regulations enforced by FDA are found in volumes 1-8 of Title 21, parts 1-1299. They are updated as of April 1 of each year. The Federal Register and the CFR must be used together to determine the latest version of a given rule.

## 2.2.5 - DEFINITIONS

The following terms are used in assignments, correspondence, and various procedures described in this manual and used throughout FDA.

### 2.2.5.1 - Civil Number

A docket number used by US district courts to identify civil cases (seizure and injunction).

### 2.2.5.2 - Citation (Cite)

The [section 305 Notice](#) is a statutory requirement of the FD&C Act. It provides a respondent with an opportunity to show cause why he should not be prosecuted for an alleged violation. Response to the notice may be by letter, personal appearance, or an attorney(s).

### 2.2.5.3 - Criminal Number

A docket number used by the US district courts to identify criminal cases (prosecutions).

### 2.2.5.4 - FDC and INJ Numbers

The number used by the Chief Counsel's office to identify FDA cases.

### 2.2.5.5 - Complaint for Forfeiture

A document furnished to the U.S. attorney for filing with the clerk of the court to initiate a seizure.

### 2.2.5.6 - Home District

The Home District is the district in whose territory the alleged violation of the Act occurs, or in whose territory the firm or individual responsible for the alleged violation is physically located. The original point from which the article was shipped, or offered for shipment, as shown by the interstate records, is usually considered the point where the violation occurred; and the shipper of such article, as shown by such records, may be considered to be the alleged violator.

Where actions against a firm are based on goods which became violative after interstate shipment was made, or after reaching its destination (such as 301(k) violations), the dealer in whose possession the goods are sampled may be considered the violator and the location of this dealer determines the "Home Division".

### 2.2.5.7 - Nolle Prosequi (Nol-Pros)

The prosecutor or plaintiff in a legal matter will proceed no further in prosecuting the whole suit or specified counts.

### 2.2.5.8 - Nolo Contendere (Nolo)

A plea by a defendant in a criminal prosecution meaning "I will not contest it".

### 2.2.5.9 - Seizing District

The District where seizure is actually accomplished. The seizing District is not necessarily the collecting District, as in the case of in transit samples.

### 2.2.5.10 - Subpoena Duces Tecum

A writ commanding a person to appear in court bringing with him certain designated documents or things pertinent to the issues of a pending controversy.



### 2.2.5.11 - Supervising District

The District which exercises supervision over reconditioning lots in connection with seizure actions.

## 2.2.6 - SEIZURE

Seizure is a judicial civil action directed against specific offending goods, in which goods are "arrested." Originally designed to remove violative goods from consumer channels, it was intended primarily as a remedial step; however, the sanction often has a punitive and deterrent effect.

For more information on seizure actions consult [RPM Chapter 6-1](#) "Seizures."

### 2.2.6.1 - District Recommendation

The District considers all evidence, including any establishment inspection, sample collection, and analytical results. If indicated, seizure is recommended to headquarters.

### 2.2.6.2 - Headquarters

Except for certain direct seizure authority, District seizure recommendations are referred to the appropriate center for approval. If approved, the case is referred to the Office of Enforcement and Import Operations (HFC-200) which then requests the Chief Counsel to initiate seizure action.

### 2.2.6.3 - Department of Justice

The Food and Drug Division of the Department's Office of Chief Counsel reviews and forwards the seizure action to the U.S. attorney in whose judicial district the violative goods are located, through the seizing District. The U.S. attorney files a Complaint for Forfeiture addressed to the U.S. district court, setting forth the facts of the case and calling for the "arrest" of the goods. This Complaint is filed with the appropriate district court.

### 2.2.6.4 - U.S. District Court

The court orders the arrest of the goods by issuing a motion and warrant to the U.S. marshal, directing seizure of the goods.

The marshal seizes the goods, which then become the property of the court. You may be asked to assist the marshal in the seizure. If so, submit a memorandum to your District office covering this activity.

### 2.2.6.5 - Claimant and Options

Any person who has an interest in the goods may appear as claimant or to intervene and claim the goods.

### 2.2.6.6 - Abandonment

If no claimant appears within a specified time, (return date), then the U.S. attorney requests a Default Decree of Condemnation and Forfeiture, in which the court condemns the goods and directs the U.S. marshal to destroy or otherwise dispose of the goods. Usually, the District assists the marshal in determining the method of disposal, and you may be asked to help in the actual disposition. Any disposition must be in accordance with the [National Environmental Policy Act of 1969](#) (NEPA); 42 U.S.C. 4321-4347.

### 2.2.6.7 - Reconditioning for Compliance

A claimant may appear and propose the goods be reconditioned to bring them into compliance. After the FDA agrees to the method of reconditioning, the court issues a Decree of Condemnation permitting reconditioning under the supervision of the FDA, after a bond is posted. Salvage operations may include:

1. Cleaning, reworking, or other processing,
2. Relabeling, or
3. Denaturing.

### 2.2.6.8 - Contested Seizure

A claimant may file an answer to the complaint and deny the allegations. The issues then go to trial.

### 2.2.6.9 - District Follow-up

The District seizure recommendations are concurrently reviewed by the Center, OSPOP and the OCC.

## 2.2.7 - PROSECUTION

Prosecution is a criminal sanction directed against a firm and/or responsible individuals. They can be pursued at two levels: misdemeanor or felony. A prosecution is punitive, with the view of punishing past behavior and obtaining future compliance.

### 2.2.7.1 - Section 305 Notice

The [section 305 Notice](#) is a statutory requirement of the Act. It provides a respondent with an opportunity to explain why he should not be prosecuted for the alleged violation. Response to the notice may be by letter, personal appearance or attorney.

Under certain circumstances, the Agency will refer prosecution (or for further investigation) without first

providing the opportunity for presentation of views in accordance with section 305 [See [21 CFR 7.84\(a\)\(2\) and \(3\)](#)].

The facts developed at the hearing are reviewed, along with other evidence, and the District prepares a recommendation that the case be:

1. Placed in permanent abeyance, with no further action, or
2. Placed in temporary abeyance, in which case the decision is delayed pending additional evidence, or for other reasons, or
3. Considered, with RFDD concurrence, for an ad hoc meeting when there is an indication of potential felony charges or the case is especially unusual, or
4. Forwarded to the Justice Department for prosecution.

The District recommendation is reviewed by Headquarters units in the light of current policy and procedure. If prosecution is indicated, the case is forwarded to the Office of Chief Counsel (OCC) for review. If the Chief Counsel agrees, the matter is forwarded to the Department of Justice (DOJ) where it is reviewed again. If DOJ concurs, the case is forwarded to the appropriate U. S. Attorney. Non-concurrence results in return of the case to FDA.

### 2.2.7.2 - Information

An Information is a legal document filed in misdemeanor actions identifying the defendants and setting forth the charges. The Information is forwarded to the appropriate U.S. Attorney, who then files the legal instruments. A trial date is set by the court. Ideally, trial preparation is collaboration between representatives of the U. S. Attorney's office, OCC, the Division and the involved Center.

### 2.2.7.3 - Grand Jury Proceedings

The Justice Department must proceed by indictment in all felony cases. Evidence in possession of the government is presented to a grand jury which decides if it is sufficient to warrant prosecution. If the grand jury returns a "True Bill", and the defendant pleads not guilty at the arraignment, preparation for trial begins.

The deliberations of a federal grand jury are secret, and only those whom the court has placed under Rule 6(e) of the Federal Rules of Criminal Procedure may be privy to the grand juries activities. Consequently, if you have been designated under the Rule, you may not divulge your knowledge of grand jury affairs to anyone, including colleagues or supervisors, unless they, too, have been placed under the Rule. Strict adherence to the rule of grand jury secrecy protects not only the integrity of the government's investigation, and the validity of any indictment the grand jury might return, but the rights of the

person accused. See IOM 5.2.2.9 Working with a Grand Jury.

When you are assigned to work with, or for, a grand jury and are instructed as part of that assignment to conduct an inspection or an investigation, do not issue a Notice of Inspection (FDA-482) (See IOM 5.2.2.4 Conducting Regulatory Inspections When the Agency is Contemplating Taking, or is Taking, Criminal Action). Check with District management and the Assistant U.S. Attorney or Chief Counsel Attorney involved, prior to initiating this type of assignment. Also, refer to IOM 5.2.2.4, 5.2.2.5, 5.2.2.6, 5.2.2.7, 5.2.2.8 and 5.2.2.9.

### 2.2.7.4 - District Follow-up

Appropriate reports are made to the Administration when the case terminates. Follow-up may involve inspections either of a routine nature or as directed by the court.

## 2.2.8 - INJUNCTION

An injunction is a civil restraint issued by the court to prohibit violations of the Act. Injunction is designed to stem the flow of violative products in interstate commerce, and to correct the conditions in the establishment.

Injunction actions must be processed in strict time frames. Therefore, you may be requested to conduct an inspection to determine the current condition of a firm and to obtain specific information required for the injunction.

### 2.2.8.1 - Temporary Restraining Order (TRO)

Upon presentation of evidence, the U.S. district court may issue an order restraining defendant from certain acts, for a specific length of time. This period may be extended by order of the court.

### 2.2.8.2 - Hearing for Injunction

Prior to the expiration of the TRO, if one is involved, the U.S. Attorney, assisted by the district, presents evidence to support an injunction.

### 2.2.8.3 - Consent Decree of Injunction

The defendants may, following conferences with the U.S. Attorney, consent to a decree of preliminary or permanent injunction. If not, the issue goes to trial.

### 2.2.8.4 - Trial for Injunction

A preponderance of evidence is required to support an injunction. This differs from a prosecution, which requires evidence establishing guilt "beyond a reasonable doubt". Trial is before the district court. There is no trial by jury,

unless demanded by the defendant. In violations of injunction (contempt), the action is brought under the Rules of Criminal Procedure.

### 2.2.8.5 - Preliminary or Permanent Injunction

A preliminary or permanent injunction enjoins a firm or individuals from continuing a specific violation(s). The terms of the injunction specify the steps to be taken to correct the violations at issue.

### 2.2.8.6 - District Follow-up

Generally, the Division will police an injunction to assure the terms of the decree are met. This may include routine inspections or actual supervision of compliance activities dictated by the terms of the injunction.

## 2.2.9 - EMERGENCY PERMIT CONTROL

Section [404 of the FD&C Act \[21 U.S.C. 344\]](#) provides for the issuance of temporary permits prescribing the conditions governing the manufacture, processing or packing of certain classes of foods. It applies to foods subject to contamination by injurious microorganisms, where such contamination cannot be adequately determined after such articles have entered interstate commerce.

## 2.2.10 - DETENTION POWERS

FDA has administrative detention authority for food under section 304(h) of the FD&C Act [21 U.S.C. 334(h)], and for devices and drugs under section 304(g) of the FD&C Act [21 U.S.C. 334 (g)], when FDA has a reason to believe that the article is adulterated or misbranded.

FDA also has detention authority for certain products regulated by USDA under sections 402 and 409(b) of the [Federal Meat Inspection Act](#), sections 19 and 24(b) of the [Poultry Products Inspection Act](#), and sections 5(d), 19, and 23(d) of the [Egg Products Inspection Act](#). See IOM 2.7.1.2 for information on these authorities.

In essence, articles subject to the Federal Meat Inspection Act or the Poultry Products Inspection Act that are believed to be adulterated or misbranded under the FD&C Act may be detained. FDA representatives may detain articles subject to the Egg Products Inspection Act, which are suspected to be in violation of that statute.

Devices may be detained under the FD&C Act for a maximum of thirty days when there is reason to believe they are adulterated or misbranded under the FD&C Act.

See IOM 2.7.2 for inspectional procedures, which must be followed, in exercising the detention authority.

## 2.2.11 - COURTROOM TESTIMONY

Effective testimony, whether it be in court before a judge or jury, grand jury or opposing counsel at a deposition, is a result of quality investigative skills; the ability to prepare factual and informative investigative reports; and thorough preparation for being a fact witness.

As a witness, you are required to testify from memory, but you are allowed to refer to diary notes, reports and memoranda, when necessary to refresh your recollection. For this reason, and the fact they are available to opposing counsel, the Agency insists your notes, reports and the like always be accurate, organized and complete.

There is little difference in giving testimony in court, in a deposition or before a grand jury. In a deposition, testimony is given upon interrogation by opposing counsel, under oath, before a court reporter. Be guided by your (the Government's) attorney in preparing for a deposition. Once completed, the deposition is available to all persons interested in the case and is available for use at trial.

In a grand jury, testimony is given under oath to a group of jurors who determine whether sufficient evidence exists to charge someone with a felony (See IOM 2.2.7.3).

### 2.2.11.1 - Testimony Preparation

The following suggestions may be helpful in preparing to provide testimony in court, before a grand jury or at a deposition:

1. Carefully and thoroughly reviewing your diary notes, inspection reports and all samples collected.
2. Be neat in your personal appearance; dress conservatively in business attire and be well groomed.
3. When you take the witness stand, get comfortable, sit erectly and carefully look around to familiarize yourself with the court surroundings.
4. Tell the truth. If asked, do not hesitate to admit you have discussed your testimony in advance with the U.S. Attorney's office.
5. Be sure you understand the question before you answer. If you don't understand the question, request clarification. Take your time. Give each question such thought as required to understand and formulate your answer. Do not answer questions too quickly. Give your attorney time to raise an objection in case it is a question you should not answer. Answer questions clearly and loudly enough so everyone can hear you. Look at the jury and address your remarks to it so all jury members will be able to hear and understand you. Speak directly and authoritatively, and do not use ambiguous phrases such as, "I guess so", "I believe," etc. Do not be afraid to say, "I don't know".
6. Be polite and serious at all times. Give an audible answer to all questions. Do not nod your head yes or no.
7. Do not lose your temper, even if baited by an attorney. Do not spar with examining attorneys; answer questions frankly, factually and confidently, then stop. Do not answer questions, which have been objected to until the

- court rules on the objection. Do not volunteer information.
8. If you make a mistake answering a question, correct it immediately. If a question can't be truthfully answered with a yes or no, you have the right to explain your answer. If you are asked questions about distances, time or speed, and your answer is only an estimate, be sure you make that clear.
  9. If a recess is declared while you are on the stand, keep to yourself. Do not discuss your testimony with anyone except on special instructions from the U.S. Attorney or his/her assistant.
  10. Be natural, be yourself. Do not be intimidated by personalities.

### 2.2.11.2 - Interviewing Persons under Arrest

Miranda Warning - In the Agency's normal course of operation, it is not necessary to read a person their rights, (i.e.: Miranda warnings) because the Agency does not routinely interview individuals who are in custody (under arrest). Miranda warnings are not necessary, during discussions with management when conducting inspections, during investigational interviews, or during a [section 305 of the FD&C Act](#) [21 U.S.C. 335] meeting because the individuals being interviewed are not in custody, and are free to leave at any time.

In certain situations, however, FDA personnel may interview someone who is already in custody. In this case, the individual must be given their Miranda rights.

When this situation is encountered, copy page 1 of IOM Exhibit 2-1. If the subject cannot speak/read English, you must arrange for a form in the appropriate language. Read this material to the individual, preferably in the presence of another person, and then have them sign and date the waiver statement. Submit the signed statement with your report. If the individual refuses to sign the statement, indicate this on the unsigned statement, and identify the witness on the document. Submit the unsigned statement with your report.

## SUBCHAPTER 2.3 - RECONDITIONING AND DESTRUCTION

[Sections 304](#) and [801](#) of the FD&C Act [21 U.S.C. 334 and 381] provide the legal basis for reconditioning or destruction of goods under domestic seizure or import detention.

Reconditioning and destruction are the means whereby goods are brought into compliance with the law, or permanently disassociated from their intended use. Manpower may not be expended on supervision of reconditioning and destruction of goods except under administrative controls, detention, or emergency and disaster operations. See IOM 8.1.5.8 for operations in disasters.

FDA does not seek or condone the destruction of books or other publications. FDA policy and practice tries to be sensitive to the potential First Amendment issues associated with the regulation of books and other printed materials that function as labeling of a product. See [Compliance Policy Guide 140.100](#). In the context of judicial enforcement, disposition of any labeling subject to the court's jurisdiction is determined by the court. In a voluntary compliance situation, the disposition is the prerogative of the manufacturer, distributor, wholesaler, or retailer. Agency policy does not authorize field employees to direct or limit the options for disposition of violative labeling or other printed materials in such circumstances. Good judgment should always be exercised in such matters.

[Section 536\(b\) of the FD&C Act](#) [21 U.S.C. 360I (b)] provides authority for electronic products to be reworked if FDA determines they can be brought into compliance with radiation performance standards. Therefore, reconditioning of radiation-emitting products must be approved by CDRH, OHT7: Office of Invitro Diagnostics and Radiological Health, prior to implementation to assure compliance with performance standards. If a foreign manufacturer conducts the reconditioning, the Division should notify both the importer/consignee and the foreign manufacturer's agent of all FDA actions.

## 2.3.1 - DEFINITIONS

### 2.3.1.1 - Reconditioning

The reworking, relabeling, segregation, or other manipulation which brings a product into compliance with the law, whether or not for its original intended use.

### 2.3.1.2 - Destruction

The procedures involved in rendering a product unsalvageable. Destruction may be accomplished by burning, burial, etc.

### 2.3.1.3 - Denaturing

Decharacterization of a product, whereby it is made unusable for its originally intended purpose.

## 2.3.2 - DISASTERS

Reconditioning and destruction of contaminated merchandise in times of disasters can assume national proportions and is handled differently than normal operations.

Instructions for operations pertaining to reconditioning and destruction during non-attack type disasters is covered in [IOM 8.1.5.8](#).

**SUBCHAPTER 2.4 - CONSENT DECREE****2.4.1 - POLICY**

Seized goods may be released under bond, by court order to be destroyed or brought into compliance. The order normally provides for supervision of the operation by FDA. Release of the bond depends upon your certification the court order has been satisfactorily executed.

Do not undertake reconditioning until you are certain a court order has been entered, bond posted, and goods released by the marshal. Be certain the identity and amount of goods corresponds with that seized. Be sure you are familiar with the terms of the court order.

Reconditioning or destruction may, at times, be permitted without continuous supervision. However, the lot must be checked before operations start, rechecked intermittently and upon completion. Supervision must be sufficient to assure none of the lot was diverted. All of the goods involved in the action, including reconditioned goods as well as discarded material such as screenings, old labels, etc., must be accounted for. If organoleptic examination will not permit a judgment regarding the degree of compliance, collect suitable samples for laboratory examination. If the reconditioning process does not appear to comply with the order, immediately advise the claimant and your supervisor.

**2.4.2 - RELABELING**

Before permitting any relabeling operation, be sure FDA has approved the proposed new label. Provide an accounting of disposition of the old labels. Submit three (3) copies of the new label and three (3) copies of the old label with your report of the operation.

**2.4.3 - REWORKING**

Before permitting any manipulation, determine the proposed process has been approved by your Division. This includes ensuring the facilities and equipment to be used are sanitary and effective for the proposed process. Report the yield of the reworked product.

**2.4.4 - SEGREGATION**

Thoroughly examine goods set aside as legal, and submit samples for laboratory examination, if indicated. Follow up on disposition of reject material to prevent illegal diversion. Describe the method of destruction of unfit material resulting from the segregation process.

**2.4.5 - DESTRUCTION**

Supervise and describe the method of destruction of goods, labels, labeling, etc. and report the amount destroyed.

**2.4.6 - DISPOSITION OF REJECTS**

Arrange for reject materials to be destroyed in an approved manner, under your supervision. The method of disposition will have already been approved by the Division, and in some cases set out in the Consent Decree.

**2.4.7 - RELEASE OF GOODS**

Do not authorize release of reconditioned goods, unless specifically directed by your supervisor. Formal release is normally handled by Division headquarters.

**2.4.8 - REPORTING**

Promptly submit a detailed report upon conclusion of the operation. Where the operation is prolonged, submit interim progress reports. Include the following information in your report of the operation:

1. Identification of the case (sample number, court number, FDA number, product and claimant).
2. Description of the method of reconditioning or destruction.
3. Disposition of rejects; explanation for unaccounted goods.
4. Findings of field examinations.
5. Exhibits and samples collected. Do not pay for samples collected during reconditioning operations conducted under a Consent Decree.
6. Expenses, including time spent in supervision and travel, mileage, per diem, and incidental expenses.

**SUBCHAPTER 2.5 - DEFAULT DECREE****2.5.1 - POLICY**

When no claimant appears in a seizure case, the court issues a Default Decree of Condemnation condemning the goods. It may or may not specify the manner of disposal. Disposition, whether by destruction, distribution to charitable institutions or sale by salvage must be approved and monitored by the Government.

Primary responsibility for disposition of seized lots following a default decree lies with the U.S. Marshal's Office.

FDA inspectional personnel frequently accompany the marshal to witness the operation. Although you are there in an advisory capacity, assist the marshal in every way to assure compliance with the court order.

**2.5.2 - REPORTING**

Promptly submit a written report of your observations upon completion of the operation. See IOM 2.4.8.

## SUBCHAPTER 2.6 - COMPLIANCE ACHIEVEMENT

### 2.6.1 - POLICY

FDA uses a blend of industry voluntary correction and regulatory actions to help achieve industry compliance.

A voluntary corrective action is defined as the observed voluntary repair, modification, or adjustment of a violative condition, or product. For purposes of this definition, violative means the product or condition does not comply with the Acts or associated regulations enforced by the Agency.

Voluntary destruction in lieu of seizure of small lots of violative goods shall be encouraged, where the proposed method is adequate. Supervision of voluntary segregation and denaturing of violative goods shall not be provided, except where it can be accomplished with dispatch, minimal inspectional resources, and in a manner consistent with procedures outlined in this Subchapter.

The most extensive actions in this area usually occur in disaster situations. Follow instructions in [IOM 8.1.5.8 Disaster/Emergency Response](#).

Do not engage in actual destruction, reconditioning, repair, modification, etc. of goods. This is the responsibility of the owner or dealer. You are in the capacity of witness only. Samples of violative goods should be collected prior to voluntary destruction to support subsequent action against the responsible individuals. Take photographs where applicable. See IOM 5.11.2.1 and IOM 2.6.4, 2.6.4.1/2 or reporting requirements.

### 2.6.2 - DESTRUCTION

Before you supervise destruction, be sure management is aware the action is voluntary and that you are acting only as a witness. See IOM 2.6.4.

Witness all destructions personally, making certain destroyed goods are rendered totally unsalvageable for food, drug, device, etc. use. Keep in mind personal and public safety. Exercise proper precautions in dealing with potentially dangerous substances and situations. Comply with local ordinances regarding the disposition of garbage and trash.

Note certain products should not be disposed of in a conventional manner (e.g.: sanitary landfill, flushing down the drain, etc.). In particular, certain products which have been banned in the past (chloroform, methapyrilene, hexachlorophene, PCB, etc.), are classified by EPA as hazardous and toxic substances and may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of

without prior consultation by the firm with the [U.S. Environmental Protection Agency](#) and/or the regulating state authority. Refer to [21 CFR 25](#) and the [National Environmental Protection Act](#) for guidance regarding the environmental impact of voluntary destructions.

#### 2.6.2.1 - DEA Controlled Drugs

FDA and DEA have a written policy to permit FDA representatives, in certain situations, to witness the destruction of DEA controlled drugs. The procedures and instructions to follow when these drugs are destroyed are:

##### 2.6.2.1.1 - DEA APPROVAL

FDA and the [Drug Enforcement Administration](#) (DEA) have a mutual, written policy concerning witnessing the destruction of drugs under the distribution control of DEA. This provides for FDA, upon receiving a request to witness such destruction, to advise the DEA regional office and obtain approval for the action. If approval is requested by telephone and verbally approved, the approval should be reduced to writing for the record.

##### 2.6.2.1.2 - PROCEDURE

The necessity for FDA personnel to witness destruction of DEA controlled drugs will normally happen only when FDA is already present in the firm, encounters DEA controlled drugs, and is requested to witness destruction, or when DEA controlled drugs are to be destroyed at the same time FDA is witnessing destruction of drugs not under DEA control.

If you are in a firm either making an inspection or to witness destruction of drugs under FDA's distribution control, and the firm requests you also witness destruction of DEA controlled drugs, do not commit yourself. Telephone your supervisor for instructions. You will be advised whether or not to proceed after your Division communicates with DEA. In all other situations refer the requester to DEA.

If the request to witness the destruction is approved, observe the destruction, and prepare DEA Form DEA 41 as follows:

1. List each dosage form of each drug on a separate line. Calculate amounts for columns 6 and 7.
2. Line out the inappropriate sentences in the paragraph following line 32.
3. Date and sign the form.
4. Type or print your name, title, and Division under your signature.

Submit the form to your Division for transmittal to DEA.

## 2.6.3 - RECONDITIONING

The supervision of voluntary segregation of violative goods without the regulatory safeguards of seizure should be avoided. Voluntary segregation and destruction of violative lots should be encouraged; but under no circumstances should you supervise the voluntary segregation and salvage of unfit goods, regardless of the nature of the violation or the size of the lot. Be sure management is aware the segregation is its responsibility. Collect samples where indicated, and/or advise the dealer or owner of his responsibilities under the law. If the dealer decides to voluntarily destroy any lot, refer him to the [National Environmental Protection Act](#) (NEPA). See IOM 2.6.2.

## 2.6.4 - REPORTING

Report any voluntary correction of a problem unrelated to a Division recommendation for regulatory action.

### 2.6.4.1 - Documenting Voluntary Destruction

Prior to supervising voluntary destruction, prepare a statement on the firm's letterhead or on an FDA 463a, Affidavit, providing the following information.

1. Voluntary nature of the action, with you as a witness.
2. Name of the product, including applicable code marks.
3. Condition of the lot.
4. Amount.
5. Method of destruction.
6. Signature of responsible individual.

### 2.6.4.2 - Compliance Achievement Reporting

The following are examples of compliance actions to be described in the report, EI Record, and reported into the Compliance Achievement Reporting System in FACTS (Exhibit 5-15) per Division SOP's:

#### 2.6.4.2.1 - VIOLATIVE PRODUCTS

Voluntary destruction by the person in possession of any violative product.

#### 2.6.4.2.2 - DESTRUCTION BY COOPERATING OFFICIALS

Destruction of violative products by a cooperating food or health official, where such product was discovered by and reported to such official by FDA when those officials were doing work for FDA under contract. Do not report formal condemnation by cooperating officials in the usual course of their independent work.

## 2.6.4.2.3 - MANUFACTURER'S RAW MATERIALS

Voluntary destruction of manufacturer's raw materials during the course of an inspection. For example, decomposed cream or filthy milk.

### 2.6.4.2.4 - CAPITAL IMPROVEMENTS

Significant improvements correcting a violative condition such as new equipment, rodent-proofing, etc. These should be reported at follow-up inspections where actual improvement has been accomplished or committed, and the improvement is the result of a previous FDA observation or suggestion and not as a result of a seizure, injunction or prosecution.

### 2.6.4.2.5 - CORRECTION OF GMP DEVIATIONS

During an inspection the investigator observes GMP deficiencies have been corrected since the previous EI. These corrections are based on the previous FDA 483 and any communication following the previous inspection identifying significant deficiencies not listed in FDA 483.

### 2.6.4.2.6 - FORMULA/LABEL CORRECTION

Based on a sample analysis, consumer complaint, etc., a product formula or label is corrected.

### 2.6.4.2.7 - ADDITIONAL PERSONNEL

Employment of personnel for quality improvement or improved quality control.

### 2.6.4.2.8 - EDUCATIONAL AND/OR TRAINING

Initiation of an educational and/or training program among employees or producers, or other general industry movement to improve conditions.

### 2.6.4.2.9 - ITEMS NOT REPORTED IN FACTS

Do not report:

1. Recalls, although voluntary, because they are already recorded elsewhere (FACTS).
2. Corrections which are not directly attributable to the efforts of FDA, or states under contract to FDA.
3. Corrections as a result of a seizure, injunction or prosecution.

For products involving the field compliance testing of diagnostic X-Ray equipment, use form FDA 2473a to report these actions, as directed by the Compliance Program. Submit the completed form to your District. Your District will submit a copy to the CDRH, OHT7: Office of Invitro

Diagnostics and Radiological Health and maintain a copy for the District files.

## SUBCHAPTER 2.7 - DETENTION ACTIVITIES

### 2.7.1 - OVERVIEW AND AUTHORITY

Detention protects the public by preventing movement in interstate or intrastate commerce of a food, device, or drug that an authorized FDA representative has reason to believe is adulterated or misbranded, while FDA institutes appropriate action. Administrative detention is implemented to gain immediate control over products when there is reason to believe the products are adulterated or misbranded. Such actions are designed for swift and immediate action to ensure that adulterated or misbranded products do not enter commerce or, if they are already in commerce, to stop them from reaching consumers. FDA may initiate seizure against detained foods, devices, and drugs, and/or injunction under sections 304(a) and 302 of the FD&C Act, respectively. In addition, FDA may consider instituting other action against detained foods, such as mandatory recall under section 423 of the FD&C Act, suspension of a food facility's registration under section 415(b) of the FD&C Act, or emergency permit control under section 404 of the FD&C Act

The specific statutory authorities, as well as specific set of guidelines that apply to a food, device, or drug are outlined in this section of the [IOM](#)<sup>1</sup>. The detention of a food, device, or drug will depend on the product involved; the situation and evidence observed or collected; and the statutory authority for the detention.

#### 2.7.1.1 – Overview

Detention is an administrative action, as opposed to a civil judicial action, such as seizure or injunction, which is accomplished by a court order (See IOM 2.2.6<sup>2</sup> and 2.2.8<sup>3</sup>).

A food, device, or drug in "domestic import" as well as "import status" could be detained as described in this subchapter provided they meet the criteria listed below. Generally, however, we will use our import detention authority to detain foods, devices, and drugs in import status. Import detention is covered separately in IOM Chapter 6 - Imports.

#### 2.7.1.1.1 - ACCOMPLISHING A DETENTION

Accomplishing a Detention can take one or more paths depending on the product involved and the statute that applies. The applicable statutes and implementing regulations are explained in the "Authorities" section of this subchapter. The FD&C Act provides the authority for administrative detention of foods in section 304(h) and devices and drugs in section 304(g) of the FD&C Act.

Other statutes, such as the [Federal Meat Inspection Act](#)<sup>18</sup> (FMIA) ([21 U.S.C. 601 et seq.](#)), the [Poultry Products Inspection Act](#)<sup>19</sup> (PPIA) ([21 U.S.C. 451 et seq.](#)), and the [Egg Products Inspection Act](#)<sup>20</sup> (EPIA) ([21 U.S.C. 1031 et seq.](#)), provide the authority for detention of foods processed in a facility under dual jurisdiction of FDA and the U.S. Department of Agriculture (USDA).

#### 2.7.1.1.2 - DETENTION OF DEVICES

Detention of devices that an authorized FDA representative has reason to believe are adulterated or misbranded can only be accomplished under one statutory path: [FD&C 304\(g\)](#) of the FD&C Act with implementing regulations set forth in [21 CFR 800.55](#).

#### 2.7.1.1.3 - DETENTION OF FOODS

Detention of food (human or animal) except for food exclusively regulated by USDA, that FDA has reason to believe is adulterated or misbranded can be accomplished under one statutory path: section 304(h) of the FD&C Act with implementing regulations set forth in [21 CFR part 1, subpart K](#)<sup>17</sup>. FDA's administrative detention authority applies to both foods offered for import and food in domestic commerce. FDA's authority to administratively detain food under section 304(h) is separate and distinct from FDA's authority to refuse admission of imported food under section 801<sup>8</sup>(a). Import detention applies to food offered for import into the U.S. which may be subject to refusal of admission.

Detention of foods that USDA regulates (i.e., meat, poultry, or processed egg products) at a dual-jurisdiction facility that meets the jurisdictional requirements of section 304 of the FD&C Act and for which there is reason to believe that such food is adulterated or misbranded can be accomplished under one of the following three statutory paths: sections 402 and 409(b) of the FMIA [[21 U.S.C. 672](#)], section 19 of the PPIA [[21 U.S.C. 467](#)], or sections 19 and 23(d) of the EPIA [[21 U.S.C. 1048](#)], respectively. Alternatively to detaining food that USDA regulates within a dual-jurisdiction facility, detention of foods that USDA regulates (meat, poultry, and processed egg products) CANNOT be accomplished when those products are inside a USDA-inspected facility. FDA does not have authority to administratively detain food that is within the exclusive jurisdiction of the USDA

#### 2.7.1.1.4 - DETENTION OF DRUGS

Detention of drugs that an authorized FDA representative has reason to believe are adulterated or misbranded can only be accomplished under one statutory path: [FD&C 304\(g\)](#) of the FD&C Act with implementing regulations set forth in [21CFR 1.980](#).



**2.7.1.1.5 - DETENTION PROCEDURAL STEPS**

The procedures to be followed in both ordering and terminating a detention differ depending on the applicable authority. You must consult with your supervisor before detaining any food from a dual jurisdiction facility under section 304 of the FD&C Act or under the detention authorities in FMIA, PPIA, and EPIA. Furthermore, you must have the approval of the District Director in whose District the article of food is located or an official senior to the District Director prior to detaining any food under section 304(h) of the FD&C Act. You must have the approval of the FDA District Director before detaining any device or drug under section 304(g).

**2.7.1.2 - Authorities**

This subsection provides information on FDA's detention authorities. Pertinent sections of the FMIA, PPIA, EPIA, and FD&C Act, and FDA regulations pertaining to detention of devices, drugs, and foods, are printed on the reverse of page 1 of Form FDA 2289, Detention Order ([IOM Exhibit 2-2<sup>14</sup>](#)).

**2.7.1.2.1 - FOOD DRUG AND COSMETIC ACT**

Section 304(g) of the FD&C Act provides FDA with authority to detain a device or drug believed to be adulterated or misbranded. You should become familiar with this section and the regulations implementing this authority. See 21 CFR 800.55 and 21 CFR 1.980. At the present time, the device regulations apply only to devices intended for human use. See FD&C Act section 304(g) [21 U.S.C. 334 (g)].

Section 304(h) of the FD&C Act provides FDA with the authority to order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act, if FDA has reason to believe that such article is adulterated or misbranded. You should become familiar with this section of the FD&C Act and the implementing regulations in 21 CFR Part 1, Subpart K.

**2.7.1.2.2 - FEDERAL MEAT INSPECTION ACT**

[Federal Meat Inspection Act](#) (FMIA) - Sections 402 and 409(b) provide the FDA with the authority to detain meat products subject to the FMIA, found outside an USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. The detention may not exceed twenty (20) days and the items detained shall not be moved by any person from the place of detention until released by the FDA representative.

**2.7.1.2.3 - POULTRY PRODUCTS INSPECTION ACT**

[Poultry Products Inspection Act](#) (PPIA) - Sections 19 and 24(b) provide the FDA with the authority to detain poultry products subject to the PPIA found outside an USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. Detention may not exceed twenty (20) days and the items detained shall not be moved from the place of detention until released by the FDA representative.

**2.7.1.2.4 - EGG PRODUCTS INSPECTION ACT**

[Egg Products Inspection Act](#) (EPIA) - Sections 19 and 23(d) provide the FDA with the authority to detain egg products subject to the EPIA, found outside an USDA inspected plant, if the FDA has reason to believe the products are in violation of the EPIA Act. Detention may not exceed twenty (20) days and the items detained shall not be moved from the place of detention until released by the FDA representative.

**2.7.1.3 - Definitions****2.7.1.3.1 - DEVICE**

[Section 201\(h\) of the FD&C Act](#) [21 U.S.C. 321 (h)] defines a device as follows: "The term "device" \*\*\* means an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any primary intended purposes."

**2.7.1.3.2 – FOOD**

The term food as used in section 304(h) of the FD&C Act, is defined in section 201(f) of the FD&C Act<sup>22</sup>, as follows: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." In addition, a dietary supplement, as defined in section 201(ff) of the FD&C Act, is deemed a food within the meaning of the FD&C Act.

Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal

feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

### 2.7.1.3.3 - PERISHABLE FOOD

For the purpose of detention of food under [section 304\(h\)\(2\) of the FD&C Act](#), the term “perishable food” means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions. See [21 CFR 1.377](#)<sup>24</sup>.

### 2.7.1.3.4 - MEAT PRODUCTS AND POULTRY PRODUCTS (DUAL JURISDICTION)

For FDA purposes, meat products and poultry products are defined as the carcasses of cattle, sheep, swine, goats, horses, mules, other equines, or domesticated birds, parts of such carcasses, and products made wholly or in part from such carcasses, except products exempted by U.S.D.A. because they contain a relatively small amount of meat or poultry products (e.g.; meat flavored sauces, pork and beans, etc.). Examine labels for USDA Shield or coding information to help determine if it is a USDA product.

### 2.7.1.3.5 - EGG AND EGG PRODUCTS (DUAL JURISDICTION)

The term “egg” means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

The term “egg product” means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure the egg ingredients are not adulterated and such products are not represented as egg products. This would be done on a case by case basis by USDA.

### 2.7.1.3.6 - DRUG

Section 201(g)(1) of the FD&C Act [21 U.S.C. 321(g)(1)] defines a drug as follows: The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use

in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such statement.

### 2.7.1.3.7 – COMBINATION PRODUCT

A “combination product” is a product comprised of two or more different types of medical products (i.e., drug and device, drug and biological product, device and biological product, or all three together) (see 21 CFR 3.2(e)). A “constituent part” of a combination product is a drug, device, or biological product that is part of a combination product. Types of combination products:

- Single-entity combination product: The constituent parts are physically or chemically combined (e.g., a prefilled syringe or drug-eluting stent). See 21 CFR 3.2(e)(1).
- Co-packaged combination product: The constituent parts are packaged together (e.g., a surgical or first-aid kit containing devices and drugs, a delivery device packaged with a container of drug product). See 21 CFR 3.2(e)(2).
- Cross-labeled combination product: The constituent parts are distributed separately (classification applies to certain separately distributed products labeled for combined use) (21 CFR 3.2(e)(3), (4)).

## 2.7.2 - INSPECTIONAL PROCEDURE

Direct attention to meat, poultry, or egg products only when found during your regular operations; instructed to do so in a Compliance Program Guidance Manual; following up on complaints; or, on other assignments as directed by your supervisor.

Administrative detention of food under section 304(h) of the FD&C Act should be considered only when FDA has reason to believe that the article of food is adulterated or misbranded. The detention order must be approved by the FDA District Director of the District in which the food is

detained or an FDA official senior to such Director (21 CFR 1.391).

In evaluating whether FDA has reason to believe that the article of food is adulterated or misbranded for purposes of detention of food, consider a number of factors, including, but not limited to, the reliability and reasonableness of the evidence or information and the totality of the specific facts and circumstances involved..

### 2.7.2.1 - Criteria for Detention

The criteria listed below are for your guidance in judging whether or not the product or products should be detained. Detention should be considered when all of the requirements listed for the particular detention authority are met.

#### 2.7.2.1.1 - DEVICES

For detention of devices under [section 304\(g\) of the FD&C Act](#)<sup>25</sup>, the primary criteria are:

1. You have reason to believe the device is adulterated or misbranded.
2. There is no reasonable assurance the device will not be used, moved, altered, or tampered with in any manner before the FDA can take appropriate legal action.
3. The device is intended for human use.

#### 2.7.2.1.2 - FOOD

For detention of food under section 304(h) of the FD&C Act, the primary criteria are:

1. The article meets the definition of food in section 201(f) of the FD&C Act.
2. You have reason to believe that the article of food is adulterated or misbranded (if you believe that the food may also present a threat of serious adverse health consequences, immediately advise your supervisor of the situation so that the District can promptly notify CFSAN, CVM, and/or FDA's Emergency Operations Center, as appropriate, for assessment of hazard(s)).
3. The article of food is not a meat, poultry, or egg product inside a USDA-inspected facility. If the article of food is a meat, poultry, or egg product outside a USDA-inspected facility, consult with your supervisor.

If all of the above conditions are met, contact your supervisor and consider administrative detention.

#### 2.7.2.1.3 - MEAT AND POULTRY PRODUCTS

For detention of food subject to the [Federal Meat Inspection Act](#)<sup>28</sup> or the [Poultry Products Inspection Act](#)<sup>29</sup> the requirements are:

1. The article meets the jurisdictional requirements of section [304 of the FD&C Act](#)<sup>30</sup> and is in commercial channels.
2. The article is located in a facility that does not have USDA meat or poultry inspection service.

3. The article is intended for human food channels or could be readily diverted into such channels.
4. FDA has reason to believe the article is adulterated or misbranded under the FD&C Act.

NOTE: For any contemplated detentions of meat and poultry based on adulteration under section [402\(b\) of the FD&C Act](#)<sup>31</sup> [21 U.S.C. 342 (b)], check with your supervisor. These detentions should be cleared with the Center for Food Safety and Applied Nutrition.

#### 2.7.2.1.4 - EGG AND EGG PRODUCTS

For detention of products subject to the [Egg Products Inspection Act](#)<sup>32</sup> the requirements are:

1. The article, whether or not in interstate commerce, is located in a facility that does not have USDA Egg Products Inspection Service.
2. The article is intended for human food channels or could be readily diverted into such channels.
3. There is reason to believe the article is in violation of the Egg Products Inspection Act.

#### 2.7.2.1.5 – DRUGS

For detention of drugs under section 304(g) of the FD&C Act, the primary criteria are:

1. The article(s) meets the definition of drug in section 201(g)(1) of the FD&C Act.
2. You have reason to believe the drug(s) are adulterated or misbranded.

### 2.7.2.2 - Detention Procedure

After assuring that the criteria for detention are met, immediately advise your supervisor of the situation. The information you furnish should consist of that requested in blocks numbered 2, 4, 5, 7, 8, 10, 11, 13, 15, 19, 20, 21, 22, 24 and 26 on the Detention Order, FDA 2289. See IOM 2.7.2.3<sup>33</sup>.

For detention of I devices and drugs under section 304(g) the District director in whose District the device or drugs involved are located must approve the detention order in writing. For articles of food under section 304(h) of the FD&C Act, the District Director in whose District the article of food involved is located, or an FDA official senior to such director, must approve the detention order in writing. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

#### 2.7.2.2.1 - CONSIDERATIONS

If the article of food to be detained is in-transit aboard a conveyance, e.g., railcar, truck, or ship, be aware that that detention of food aboard a conveyance may impact other

activities of commerce that are dependent upon the ongoing operation of the conveyance.

FDA may allow the detained food to be removed from the conveyance to a storage facility. However, consult with your supervisor on this matter because the determination of whether the food can be moved from the conveyance to another location should be made based on considerations about the nature of the contaminant, security, preservation of the food, and accessibility to the food during the period of detention.

For all detentions, follow the guidance in IOM section 4.3.4 to determine when FDA may examine a package that is in the possession, control or custody of a common carrier. Guidance on resealing a conveyance is also found in IOM section 4.3.4.3.

If your supervisor instructs you to detain the article, proceed as in IOM 2.7.2.3, and 2.7.2.4.

### 2.7.2.2.2 - EXECUTING THE DETENTION

When you have been authorized to place a detention proceed as follows:

1. If the article is a food indicate the conditions that are to be maintained while the article is detained by checking the appropriate method in Block 28 on the Detention Order (Form FDA 2289). After a device, drug, or food is detained, it may not be moved unless specific procedures are followed. Consult your supervisor for guidance.
  - a. For detention of food under section 304(h), determine the storage conditions required, e.g., refrigeration, and whether movement to another facility is necessary to either provide the storage conditions required or for security purposes. Consult your supervisor for guidance. Indicate conditions that are to be maintained while the article of food is detained in the "Remarks" section of the detention notice (block #26). If applicable, also indicate that the movement of the food to another facility during detention has been authorized in writing by an authorized FDA representative, pursuant to [21 CFR 1.380](#) and [1.381](#).
  - b. Maintain surveillance on detained products, including the in-transit products, during their transfer and after the products are placed in storage if possible.
  - c. Ensure the custodian (i.e., the person in possession of the article when detained) places or maintains the detained product under the proper storage conditions.
  - d. If neither (a) nor (b) is possible, place product under detention and remove it to a proper storage facility. Notify the custodian of the place of storage (use block 16 on the FDA-2289) and advise your supervisor of the necessity for including this information in the letter to the custodian and/or owner of the article.

2. Personally inform the immediate custodian, at the highest management level, that the article is under FDA detention. If the article is a device, inform the custodian that the record keeping requirements of [21 CFR 800.55\(k\)](#)<sup>40</sup> are in effect. If the article is a drug, inform the custodian that the record keeping requirements of 21CFR 1.980(k) are in affect.

3. Prepare the Form FDA-2289, as instructed in IOM 2.7.2.3.1, and issue page 1, the original, to the custodian named. If the product is a device, a drug, or an article of food detained under section 304(h) of the FD&C Act, point out the appeal rights of the owner, of the article, which are listed on the back of Page 1 of the FDA-2289, and include the right to appeal with or without requesting an informal hearing.

4. Affix Detention Tags, FDA-2290 to the article in a manner to assure visibility. If necessary, a label other than the Detention Tag may be used to identify an article(s) of food that has been detained, provided the label includes all the information listed on the current FDA-2290.

### 2.7.2.3 - Detention Order (Form FDA 2289)

The Detention Order,(Form FDA 2289), is a pre-numbered five-part snap-out form, constructed and arranged to serve as the detention order as a report of the action and as a notice to the custodian of an opportunity for an informal hearing.

#### 2.7.2.3.1 - PREPARATION OF DETENTION ORDER NOTICE

Print or type the information in the appropriate blocks of the Form FDA 2289. The first page blocks which must be filled for detentions of foods in accordance with [21 CFR 1.382](#)<sup>41</sup> are those numbered 1, 3, 6, 9, 10, 11, 12, 15, 16, 017, and 18. Indicate the name and title of the person who approved the detention order and the manner in which the approval was obtained in blocks #17 and 18. For devices or drugs, mark #24 and #26 as N/A. For meat, poultry or egg products not being detained under the authority of [section 304\(h\) of the FD&C Act](#)<sup>42</sup>, mark #17 and 18 as N/A. Block 2 should also be completed. Once page 1 is completed, signed, and issued to the custodian of the product, it becomes an official document and the detention period begins.

You should immediately complete the additional pages of the Form FDA 2289 (Pages 2 through 5) and submit them to your supervisor, for processing the action. Blocks to be filled in on these pages are items 13, 14 and 19 through 28. These blocks should be completed as appropriate (e.g. if samples were collected) or according to the product being detained (e.g. device, drug, or food) if the pertinent information can be readily determined. See IOM Exhibit 2-2.

**2.7.2.3.2 - PREPARATION OF PAGE 1 (FDA 2289)**

Preparation of Page 1:

1. DISTRICT ADDRESS, PHONE NUMBER, FAX NUMBER, NAME OF DISTRICT and the DISTRICT DIRECTOR'S E-MAIL ADDRESS – This may be typed in advance. For detention of articles of food, the FDA District Director's email address and fax number must also be included in this block. For detentions under the FMIA, PPIA, and EPIA, this information should also be included.
2. NAME OF CUSTODIAN - Obtain the name of the highest-ranking official of the firm at the place of detention and issue to the official. Page 1 of the Form FDA 2289 is to be issued to the person named in this block.
3. DETENTION ORDER NUMBER - This is normally pre-stamped on each form. In the event that an electronic version of the form is used in the field, the detention number from a pre-printed detention form must be entered and the original pre-printed form bearing that number destroyed. Any correspondence or subsequent actions should reference this number.
4. TITLE OF CUSTODIAN - Insert proper official title such as president, warehouse manager, etc. Do not use courtesy titles.
5. TELEPHONE NO. - Insert the office telephone number, including area code.
6. DATE AND HOUR DETAINED - Insert actual date and time you hand the original to the custodian. The period of detention begins when you issue the original to that person.
7. FIRM NAME - Enter the legal name of the custodial firm.
8. ADDRESS - Use complete street name, city, state and Zip Code of custodial firm.
9. MAXIMUM DETENTION \_\_\_\_\_ DAYS - Enter "20" for detention of meat, poultry or egg products. Enter either "20" or "30", as instructed by your supervisor, for detention of devices under section 304(g) of the FD&C Act, for the detention of drugs under section 304(g) of the FD&C Act, or detention of articles of food under section 304(h) of the FD&C Act.
10. NAME OF DETAINED ARTICLE – Provide a complete list of the detained articles. Use the complete name of the product as labeled, e.g., "Beef Pot Pies with mushrooms", not just "Pies"; "Dr. Z's Tongue Depressors", not just "device". If there is insufficient space to list all the detained articles, attach Administrative Detention Continuation Form FDA 2289c to provide a complete list of all detained articles, and indicate in Block 10 that this list is attached. Be sure to record the Administrative Detention Order

number from the original FDA 2289 on the FDA 2289c to link the two forms.

11. SIZE OF DETAINED LOT - Indicate number of cases or other type container or article and subordinate containers, e.g., 2000 cases/24/#2 cans, 250 half sides pork carcasses, 500/fore quarters veal, 95 crates/50 lbs. whole fryers, 25/30 lb. cans frozen eggs, etc.
12. DETAINED ARTICLE LABELED - Quote enough labeling so the article can be positively identified. Include product numbers, lot numbers, serial numbers, control codes, grade marks, etc. Follow the instructions in #10 above about using the FDA 2289c if there is insufficient space for a complete list of the labels.
15. REASON FOR DETENTION - Give a brief, general statement of the reasons for detention, i.e., describe the apparent violation and briefly list evidence available to substantiate it. In the case of detention of food under section 304(h) of the FD&C Act, include information supporting the Agency's reason to believe the food is adulterated or, misbranded. If there are multiple reasons for the Agency's belief, list all the reasons and indicate if any reasons apply to a specific article or articles. If needed, use Form 2289c, the Administrative Detention Continuation Form, and note that the reasons are provided in the attached continuation form, and state at the top of the text block on 2289c that "The articles identified below from Box 10 were detained for the following reasons:"

Keep in mind that any classified information supporting the detention of food must be protected from unauthorized disclosure in the interest of national security. Consult with your supervisor for the requirement to protect classified information according to Executive Order 12958. If the product is a device or drug, always state not only the section of the FD&C Act the device or drug is believed to violate, but the particulars of the violation as well. Discuss the reasons for detention with your supervisor when you obtain the permission to detain a device or drug. See page 3 of IOM Exhibit 2-2.

16. DETAINED ARTICLE STORED AT - In most instances this will be the same as the custodial firm indicated in blocks 7 and 8. However, if the product has been moved to another location, enter the name and address of the firm and location where it finally comes to rest and will stay until the detention is terminated. Include any applicable conditions of transportation to the final storage locale. Once the product is detained, it is unlawful to move it without direct authority from FDA, except that devices may be moved and processed under 21 CFR 800.55(h)(2) pursuant to section 304(g)(2)(B) of the FD&C Act [21 U.S.C. 334 (g)(2)(B)] and drugs may be moved and processed under 21CFR1.980(h)(2) pursuant to section 304(g)(2)(B) of the FD&C Act [21 U.S.C. 334 (g)(2)(B)]. Articles of food detained under section 304(h) of the FD&C Act may only be moved if FDA approves a request to modify a detention order under 21 CFR 1.381(c).

17. Name and title of person who approved the detention order.

18. Indicate whether approval of the detention order was written or oral. If oral, you must obtain written confirmation of the approval as soon as possible. For detentions other than detention of food under section 304(h) of the FD&C Act, enter "N/A."

NAME OF FDA EMPLOYEE - Print or type.

SIGNATURE - Sign the form.

TITLE - Enter your title.

28. STORAGE OF DETAINED ARTICLES – Identify the appropriate storage conditions for the detained articles by checking the box marked either N/A, frozen, refrigerated or ambient, and, if conditions other than those which are temperate related are necessary, mark "other" and provide explanation.

**2.7.2.3.3 - PREPARATION OF PAGE 2 THROUGH 5 (FDA-2289)**

The blocks on pages 2 through 5 are identical and completion of these constitutes your report on the detention, unless directed otherwise by your supervisor.

13. APPROXIMATE VALUE OF LOT - This is the wholesale or invoice value of the merchandise. Estimate if there is no documentary reference you can quote.

14. SAMPLE NUMBER(S) - List numbers of any samples taken in connection with the detention.

19. NAME AND ADDRESS OF THE ARTICLE(S) OWNER – This will probably be the same as the custodian's. However, they may differ in the case of public warehouses or consigned goods. Enter the name and address, including zip code, of the actual owner. In the case of detention of food, if the owner of the article can be readily determined, you must issue a copy of the detention order to the owner as well as the custodian listed in block #2.

20. NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER - Enter name and address of person or firm who first shipped or sold the product.

21. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS - If products have passed through more than one firm prior to coming to your attention, list these firms and indicate transit points under their control.

22. NAME OF CARRIERS - List carrier or carriers involved, starting with the one who first picked up the article and indicate transit points under their control.

23. DATE LOT SHIPPED - Use date on a shipping document, not the invoice date.

24. NAME AND ADDRESS OF PACKING PLANT - Enter firm name and address of the plant where products were actually packed, processed, manufactured or assembled. For devices, drugs, or articles of food other than meat, poultry, and egg products, enter "N/A".

25. DATE LOT RECEIVED - Date the article was received by the firm at the location where currently detained.

26. PACKING PLANT USDA NO. - All plants under U.S. Department of Agriculture inspections are numbered. This number is placed on products packed or processed in that particular plant. Enter the complete number. For a device,

drug or article of food other than meat, poultry, and egg products, enter "N/A".

27. DESCRIPTION OF SAMPLE - Describe sample(s) collected in connection with the detention operations. This will be the same as on the C/R.

REMARKS -Use FDA Form 2289c to elaborate on items wherever necessary. List any recommendations you made to the custodian for special storage such as refrigerated, frozen, etc.

**2.7.2.3.4 - DISTRIBUTION OF FDA-2289**

Distribution of FDA-2289 - The five-part snap-out is distributed as follows:

1. Page 1, original - Give to custodian and, if applicable, give a copy of page 1 to the owner of the article. Give the two-sided text page listing statutory references to the owner of the article.
2. Page 2, 3, 4 - Turn in to your District immediately using the fastest means possible.
3. Page 5 - Retain in your possession.

**2.7.2.4 - Detention Tag FDA 2290**

This tag is a warning and identification device intended to be affixed to the detained products.

**2.7.2.4.1 - PREPARATION**

As soon as you have issued the Detention Notice, fill out Detention Tags, FDA 2290, following the instructions below. See IOM Exhibit 2-3.

**2.7.2.4.2 - FRONT OF TAG**

- "DETENTION DATE AND HOUR" - Copy the date and hour of detention from block #6 of the Detention Order ( FDA Form 2289).
- "DETENTION Order NO. DO" - Copy the exact number from block #3 of the Detention Order.
- "MAXIMUM DETENTION \_\_\_\_ DAYS" - Copy the number of days from block #9 of the Detention Order.
- "NAME FDA EMPLOYEE WHO ISSUED DETENTION Order" - Print or type.
- "SIGNATURE" - Sign.
- "TITLE" - Enter your title.
- "NAME OF THE EMPLOYEE AFIXING TAG (if different from issuing employee)"
- "SIGNATURE OF EMPLOYEE AFIXING TAG (if different from issuing employee)"
- "TITLE OF EMPLOYEE AFIXING TAG (if different from issuing employee)"

**2.7.2.4.3 - REVERSE OF TAG (FDA 2290)**

- "NAME OF DETAINED ARTICLE" - Enter the name exactly as in Block #10 of Detention Order.

- "DETAINED ARTICLE LABELED" - Copy enough from Block #12 of Detention Order to identify the product.
- "SIZE OF DETAINED LOT" - Copy from Block #11 of Detention Order.

#### 2.7.2.4.4 - USE OF TAG

Complete and affix tags so they are visible on several sides of the lot detained. Use sufficient tags to give adequate warning the lot is under U.S FDA Detention and must not be used, moved, or tampered with, in any manner.

Each tag has a self-locking pin, the point of which should be firmly inserted in an appropriate seam, border, flap, or other area of the container or product, and pulled sharply downward to engage the top curve of the pin. Do not just lay tags on the articles. Secure them to the containers or products. If locking pin cannot be used, tape or tie the tag firmly onto the container or item.

Advise the custodian that Detention Tags have been affixed, and of the reason for the detention. Also advise the custodian that the merchandise may not be moved without written permission of the Agency. In-process devices may be completed without permission. For devices, see [21 CFR 800.55\(h\)\(2\)](#)<sup>53</sup> for instructions. For drugs, see [21CFR 1.980\(h\)\(2\)](#) for instructions. For detention of foods, see [21 CFR 1.381\(c\)](#)<sup>54</sup>.

#### 2.7.2.5 - Termination of Detention

When final action has been taken on the detention, you will be authorized to terminate the detention. This will occur when one of the following conditions has been met.

1. For articles of food under detention, the article of food has been destroyed under appropriate supervision.
2. For drugs or devices, the product has been brought into compliance or destroyed under appropriate supervision. For meat, poultry, or egg products detained under authority of the [FMIA](#)<sup>55</sup>, [PPIA](#)<sup>56</sup>, or [EPIA](#)<sup>57</sup> the product has been brought into compliance, denatured or destroyed under appropriate supervision.
3. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, the USDA, state, county, or local authorities have accepted jurisdiction and control of the article.
4. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, it has been determined there is no significant violation of the FD&C Act, or of the EPIA, whichever is applicable, and the USDA has been notified that FDA intends to terminate the detention.
5. Twenty calendar days have expired ( or, if an additional ten calendar day detention period has been ordered, thirty calendar days have expired), counting from the day and hour of detention of the product. In this circumstance, no action is necessary on the part of the District.
6. A seizure action under section 304(a) of the FD&C Act has been instituted in court and the goods have been seized by the U.S. Marshals pursuant to a court issued

- warrant, or injunction action under section 302 of the FD&C Act has been instituted in Court.
7. The District director or the Regional Food and Drug Director order the termination.

#### 2.7.2.5.1 - REMOVAL OF DETENTION TAGS

As soon as you are authorized to terminate the detention, proceed to where the detained material is stored, personally remove and completely destroy all detention tags. Do not merely throw them in the trash.

#### 2.7.2.5.2 - ISSUANCE OF DETENTION TERMINATION NOTICE FDA 2291

Issuance of Detention Termination Notice FDA 2291 - As soon as you have removed all detention tags, tell the custodian the article is no longer under detention. Immediately prepare a Detention Termination Notice by filling out blocks 1 through 12, and the bottom of the form to include name, title, and signature. Give the original (page 1) to the custodian. This terminates the detention.

Complete the "Remarks" section to elaborate on pertinent information such as supervision, reconditioning, destruction accomplished, etc. The Detention Termination Notice, FDA 2291, together with Detention Notice, FDA 2289, will, unless instructed otherwise, constitute the complete report on the detention. See IOM Exhibit 2-4.

#### 2.7.3 - SAMPLING

Official samples of articles involved in this type of operation are collected, prepared, and submitted in the same manner as any other regulatory samples. In the case of food detained under [Section 304\(h\) of the FD&C Act](#)<sup>59</sup>, consult with your supervisor to determine whether the suspected contaminant in articles of food that have been detained makes it necessary to follow sampling procedures that may be different from those followed for routine regulatory samples.

#### 2.7.4 - SUPERVISION OF RECONDITIONING, DENATURING, OR DESTRUCTION

Methods and procedures for reconditioning, denaturing, or destruction, will be proposed to the District by the owner of the devices, drugs, or meat, poultry, or egg products. For food detained under [Section 304\(h\) of the FD&C Act](#)<sup>60</sup>, destruction will likely be the only option, and it can only be done after FDA approves in writing a request to modify the detention order. For all detentions, do not take any action on reconditioning, denaturing, or destruction unless you are authorized by your supervisor. The District officials will determine the adequacy of the proposed method. If satisfactory, you will be advised of the procedure and authorized to monitor the action.

When the operation is satisfactorily completed, and when authorized, terminate the detention as indicated in IOM 2.7.2.5.2<sup>61</sup>.

The results of the reconditioning, denaturing, or destruction may be described in the "Remarks" section on the Detention Termination Notice, FDA 2291, if desired. See IOM Exhibit 2-4<sup>62</sup>.

## 2.7.5 - REPORTING

Except in unusual situations, or unless instructed otherwise by your supervisor, the Detention Order, Form FDA 2289, the Detention Order Termination, Form FDA 2291, and the FACTS Collection Record are designed to provide all information required to report the action from detention to termination.

## SUBCHAPTER 2.8 - DENATURING

### 2.8.1 - OBJECTIVE

The basic purpose of denaturing is to prevent salvage or diversion of violative materials for human consumption.

### 2.8.2 - DIVERSION TO ANIMAL FEED

The indiscriminate use of contaminated food for livestock may constitute a hazard to such livestock, as well as humans. Due to this concern, all diversion request of this nature should be forwarded to Division Compliance for review and consultation with Center for Veterinary Medicine, Division of Compliance to determine if the product may be converted to animal feed.

#### 2.8.2.1 - Rodent or Bird Contaminated Foods

Diversion of rodent or bird contaminated foods for animal feed is authorized only when the contaminated product is treated by heat to destroy Salmonella organisms. In the case of wheat and other grains containing rodent excreta, a suitable heat process may be used or the product is examined bacteriologically and shown not to contain Salmonella.

#### 2.8.2.2 - Moldy Food

If processors insist on salvage of moldy grain or foods for animal feed use, it must be done under proper supervision, and provide for:

1. Treatment by dry heating to destroy viable spoilage microorganisms (generally, this will result in grain having a toasted color and odor), and
2. Evidence it does not contain mycotoxins, and
3. Evidence, by animal feeding studies, the product is safe for animal use.

### 2.8.2.3 - Pesticide Contamination

Foods contaminated by pesticides residues should not be diverted to animal food use unless a determination is made which assures illegal residues will not result in the food animal or their food products, e.g., meat, milk, eggs.

## 2.8.3 - DECHARACTERIZATION FOR NON-FOOD OR FEED PURPOSES

The choice of methods should be made by considering the type of the denaturant, the physical properties of the diverted material, and the ultimate use of the article.

## SUBCHAPTER 2.9 - REGULATORY SUBMISSIONS

Subchapter 2.9 provides information on the procedures for obtaining information and filing applications with the agency. These will be covered by Center. The filing and registration requirements are directed by the FD&C Act and its implementing regulations. They are filed, in most cases, by industry (e.g.: drug registration, LACF registration and process filing, ANDA's, etc.).

### 2.9.1 - CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

The FD&C Act and its regulations require the filing of certain forms by firms which produce human drugs and drug related products. The requirements and procedures for these are described below.

#### 2.9.1.1 - Registration and Listing

Owners or operators of all drug establishments not exempt under [Section 510\(g\) of the FD&C Act](#) [21 U.S.C. 360 (g)] or [21 CFR 207.13](#), that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, including blood products, and biological products regulated under section 351 of the [FD&C Act](#), are required to register each such establishment and to submit a list of every drug in commercial distribution, whether or not the output of such establishment or any particular drug so listed enters interstate commerce. This does not apply to owners and operators of establishments that collect or process human whole blood and blood products unless the establishment also manufactures, repacks, or relabels other drugs. Changes in the Act, resulting from the FDA Amendments Act of 2007 (PL 110-85) require drug establishment registration and drug listing information be submitted electronically unless a waiver is granted, effective June 1, 2009.

Registration and Listing are required whether or not interstate commerce is involved.

- **Drug Establishment Registration** - The guidance document on electronic submissions for drug



establishments' registration and drug product listing is available at:

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/guidances/ucm072339.pdf>.

General information and questions can be addressed by: Phone: 301-210-2840 or e-mail: eDRLS@fda.hhs.gov. See IOM Exhibit 5-12 for types for drug operations that require registration and listing.

- **Outsourcing Facility Registration - The guidance documents on electronic submissions for outsourcing facilities' registration and drug product reporting is available at: <https://www.fda.gov/media/87570/download> and <https://www.fda.gov/media/90173/download>.**

General information and questions concerning outsourcing facilities' registration and product reporting can be addressed by: [Compounding@fda.hhs.gov](mailto:Compounding@fda.hhs.gov).

### 2.9.1.2 - Investigational New Drug Application (IND)

An application which a drug sponsor must submit to FDA before beginning tests of a new drug on humans. The IND contains the plan for the study and is supposed to give a complete picture of the drug, including its structural formula, animal test results, and manufacturing information. Detailed instructions for the submission of INDs can be found in [21 CFR 312](#).

### 2.9.1.3 - New Drug Application (NDA)

A New Drug Application is an application requesting FDA approval to market interstate commerce a new drug for human use. The application must contain among other things, data from clinical studies needed for FDA review from specific technical viewpoints, including chemistry, pharmacology, biopharmaceutics, statistics, and anti-infectives, microbiology. Detailed instructions for the submission of NDAs can be found in [21 CFR 314](#).

### 2.9.1.4 - Abbreviated New Drug Application (ANDA)

A simplified submission permitted for a duplicate of an already approved drug. ANDAs are for products with the same or very closely related active ingredients, dose form, strength, administration route, use, and labeling as a product already shown to be safe and effective. An ANDA includes all the information on chemistry and manufacturing controls found in a new drug application (NDA), but does not have to include data from studies in animals and

humans. It must, however, contain evidence the duplicate drug is bioequivalent to the previously approved drug. Information concerning the submission of ANDAs can be found in [21 CFR 320](#).

## 2.9.2 - CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

The FD&C Act, its amendments, and the regulations promulgated under the Act, require the filing of certain forms and submission of certain data by those involved in the production (and in some cases the use) of medical devices and radiological products. Within the CDRH, the Division of Industry and Consumer Education (DICE) has been charged with responsibility for providing information and assistance to industry in complying with these requirements. The general requirements are discussed below, as are several issues unique to CDRH submissions.

### 2.9.2.1 - Device Registration and Listing

[Section 510 of the FD&C Act \[21 U.S.C. 360\]](#) and [21 CFR 807](#) describe the establishment registration, device listing, and premarket notification requirements and specify conditions under which establishments are exempt from these requirements.

Manufacturers of finished devices (including device specification developers, reproprocessors of single use devices), repackers and relabelers, foreign exporters and initial importers of medical devices, are required to register their establishments by submitting their registration and listing information via the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM). After initial submission, annual registration is accomplished by reviewing previously submitted registration and listing information via FURLS/DRLM. Component manufacturers are not required to register if the components are sold to registered device establishments for assembly into finished devices. Registration and listing is required, however, if the component is labeled for a health care purpose and sold to medical or clinical users. Optical laboratories, clinical laboratories, dental laboratories, orthotic and prosthetic appliance assemblers, hearing aid dispensers and others who, using previously manufactured devices, perform a service function for physicians, dentists, other licensed practitioners or their patients, are exempt from establishment registration if they are located in the United States. X-ray assemblers are exempt from establishment registration. An exemption from registration does not exempt an establishment from inspection under [Section 704 of the FD&C Act \[21 U.S.C. 374\]](#).

Each establishment, except initial importers of medical devices, required to register must list their devices. Device listing and updates to listing information are accomplished via FURLS/DRLM.

All foreign manufacturers are required to notify FDA of the name, address, telephone and fax numbers, and e-mail address of their United States agent. The United States agent must reside or have a physical place of business in the United States. Post office boxes, answering services and machines are not allowed.

Establishments are required to register and list, even if interstate commerce is not involved. Foreign establishments must register, list and identify a United States agent prior to exporting to the United States. See IOM Exhibit 5-13 for types of medical device operations, which require registration and listing.

An establishment must initially register by paying the annual Registration user fee and submitting their registration and listing information via FURLS/DRLM. Step-by-Step instructions explaining how to pay the annual registration user fee, register an establishment and list a device can be found on our website at <https://www.fda.gov/medical-device/how-to-study-and-market-your-device/device-registration-and-listing>. General registration and listing information and questions about FURLS/DRLM can be addressed by sending an e-mail message to [reglist@cdRH.fda.gov](mailto:reglist@cdRH.fda.gov). Policy questions can be addressed by sending an email to [device.reg@fda.hhs.gov](mailto:device.reg@fda.hhs.gov).

### 2.9.2.2 - Investigational Device Exemption/Humanitarian Device Exemption (IDE/HDE)

#### 2.9.2.2.1 - Investigation Device Exemption (IDE)

The IDE regulation in [21 CFR 812](#) contains requirements for sponsors, Institutional Review Boards (IRBs) and Clinical Investigators. Additional requirements are found in [21 CFR 50](#), Informed Consent, and [21 CFR 56](#), IRB's. All Sponsors of device clinical investigations must have an approved IDE, unless specifically exempted by the regulation. Sponsors who have an approved IDE are exempt from requirements on labeling, registration and listing, premarket notification, performance standards, premarket approval, GMPs except the design control provisions, banning of devices, restricted devices, and color additives.

Provisions for obtaining an IDE, and the sections of the regulations, with which sponsors, investigators, and IRBs must comply, differ according to the risks posed by the device. Sponsors of nonsignificant risk devices must obtain IRB approval, and are subject to a limited number of provisions; sponsors of significant risk (See [21 CFR 812.3\(m\)](#)) investigations are subject to the entire regulation.

There are investigations, described in [21 CFR 812.2\(c\)](#) that are exempt from the IDE regulation. Exempted investigations apply to devices and diagnostics, which meet the criteria in the regulation. These devices are, however,

still subject to other regulatory requirements of the Act, such as labeling, premarket approval of Class III devices, and GMPs (as stated in the preamble to the IDE regulation).

A Sponsor who knows a new device is not "substantially equivalent" to a preamendment device, or who is not sure if a device is "substantially equivalent" without conducting a clinical investigation, must obtain an approved IDE to conduct the clinical investigation. After collecting clinical data, a sponsor who desires to market a device must either submit a premarket notification (510k) or premarket approval application to FDA. A premarket notification may be submitted if the sponsor believes the data supports a finding of substantial equivalence.

Certain radiation-emitting electronic devices that are investigational are also subject to radiological health regulations, [21 CFR 1000 through 1050](#).

Transitional devices must have an approved IDE in order to be investigated.

Sponsors, Monitors, IRBs, Investigators, and Non-Clinical Toxicological Laboratories will be covered under the Bioresearch Monitoring Program. FDA has the authority to inspect and copy records relating to investigations. Records identifying patients by name will be copied only if there is reason to believe adequate informed consent was not obtained, or investigator records are incomplete, false, or misleading.

#### 2.9.2.2.2 – Humanitarian Device Exemption (HDE)

A humanitarian device exemption (HDE) is a device approved under Section 520(m) of the FD&C Act [21 U.S.C. 360j(m)]. The HDE standard for approval is exempt from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the FD&C Act, but is not exempt from the requirement for a reasonable assurance of safety. FDA approval of an HDE application authorizes an applicant to market a humanitarian use device in accordance with approved labeling and indication(s) for use, subject to certain profit and use restrictions set forth in section 520(m) of the FD&C Act. HDE approval for a device is initiated with the submission of an application to FDA. Refer to IOM Section 2.9.2.4, Premarket Approval.

### 2.9.2.3 - Premarket Notification - Section 510(k)

The Medical Device Amendments of 1976 require device manufacturers to notify the CDRH at least 90 days before commercially distributing a device. This is known as a "Premarket Notification" or a "510(k)" submission. "Commercial distribution", for practical purposes, means the device is held for sale. These 510(k) requirements do not apply to Class I devices unless the device is intended for a use which is of substantial importance in preventing

impairment of human health, or to any Class I device that presents a potential unreasonable risk of illness or injury. See [section 510\(l\) of the FD&C Act \[21 U.S.C. 360\(l\)\]](#)

A manufacturer must submit a Premarket Notification to FDA in any of the following situations:

1. Introducing a device into commercial distribution for the first time when a predicate device exists.
2. Introducing for the first time, a new device or product line which may already be marketed by another firm.
3. Introducing a device into commercial distribution when there is a modification to a previously cleared device that could significantly affect safety and/or effectiveness. Such changes or modifications could relate to design, material, chemical composition, energy source, manufacturing method, or intended use.
4. Introducing a device into commercial distribution when the device exceeds the limitations of exemption per .9 section of the associated regulation. (For example, 21 CFR 888.9 describes limitations of exemptions from section 510(k) for Orthopedic Devices.)

These requirements do not apply to "custom devices." A "custom device" is a device made exclusively for, and to meet the special needs of, an individual physician or health professional, or for use by an individual patient named in the order of a physician or dentist (such as specially designed orthopedic footwear). A "custom device" is not generally available in finished form for purchase; and is not offered through labeling or advertising for commercial distribution.

Refer to IOM Exhibit 5-13 for types of medical devices, which require 510(k) submissions. The investigator should document for CDRH review failures to submit required 510(k)s.

### 2.9.2.4 - Premarket Approval

Class III devices are required to undergo premarket approval (PMA) in accordance with the provisions of [Section 515 of the FD & C Act \[21 U.S.C. 360e\]](#). A PMA is initiated with the submission of an application to FDA. Prior to approval of a PMA application, or a PMA supplemental, FDA may inspect the applicant's facilities and records pertinent to the PMA.

Compliance Program 7383.001 "Medical Device PMA Preapproval and PMA Postmarket Inspections" provides instructions to FDA field and CDRH staff for PMA preapproval, PMA postmarket inspections, and regulatory activities associated with PMAs.

Requests for PMA inspections issue from CDRH Office of Regulatory Programs, DRP2: Division of Establishment Support, Regulatory Inspections and Audits Team. The assignments will request a comprehensive assessment of the firm's quality management system for compliance with the appropriate regulations.

### 2.9.2.5 - Classification of Devices

All medical devices subject to the FD&C Act will be classified as either Class I, Class II, or Class III medical devices.

Manufacturers who have questions regarding the classification of a device can write CDRH under [Section 513\(g\) of the FD&C Act \[21 U.S.C. 360c \(g\)\]](#) and request an opinion as to the status of the device.

#### 2.9.2.5.1 - CLASS I

Class I - General - Devices for which general controls (i.e., the controls in Section [501](#), [502](#), [510](#), [516](#), [518](#), [519](#) and [520](#) of the FD&C Act [21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j]) provide reasonable assurance of safety and effectiveness.

#### 2.9.2.5.2 - CLASS II

Class II - Special Controls - Devices for which the general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness of the device, and for which there is sufficient information to promulgate special controls, necessary to provide such assurance.

#### 2.9.2.5.3 - CLASS III

Class III - Premarket Approval - Devices which:

1. Cannot be placed into Class I or II because insufficient information exists to provide assurance of safety and effectiveness, and cannot be placed into Class II because too little data exists to support the promulgation of special controls, and
2. Are purported or represented to be for use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or
3. Presents a potentially unreasonable risk of illness or injury.

Unless they are determined substantially equivalent to devices distributed prior to the 1976 Medical Device Amendments, devices proposed for marketing after May 28, 1976, fall automatically into Class III. Class III medical devices marketed before May 28, 1976, and the substantially equivalent devices marketed after that date, remain subject to the premarket notification requirements until required to have an approved PMA. Petitioners can request to have such devices reclassified into Class I or II. Transitional devices, those regulated as new drugs before May 28, 1976, are automatically assigned to Class III.

### 2.9.2.6 - Requests for GMP Exemption and Variances

[Section 520f\(2\)\(A\) of the FD&C Act](#) [21 U.S.C. 360j (f)(2)(A)] allows manufacturers, trade organizations, or other interested persons to petition for exemption or variance from all or part of the GMP. Filing a petition does not defer compliance with the GMP requirements, and petitions will not be processed while an investigation is ongoing, or while regulatory action is pending.

Some Class I devices have been exempted from the GMP through the classification process. Each classification panel was required to consider the Class I devices reviewed by that panel and recommend if they should be exempt from the GMP. Devices exempted from the GMP by the classification process are published in classification regulations in the Federal Register.

Devices labeled or otherwise represented as sterile are not eligible for exemption from the GMP regulation. A sterile device is subject to all GMP requirements pertinent to sterility and sterilization processes.

No exemptions will be granted from [21 CFR 820.198](#) - Complaint Files, which requires the device manufacturer to have an adequate system for complaint investigation and follow-up. This Policy extends to [820.180](#) - General Requirements, which gives authorized FDA employees access to complaint files, device related injury reports, and failure analysis records for review and copying. When FDA has granted a manufacturer an exemption from one or more GMP requirements, the manufacturer still has the responsibility to implement appropriate quality control measures to assure the finished device has the quality it purports to possess, as stated in [Section 501\(c\) of the FD&C Act](#) [21 U.S.C. 351 (c)]. A manufacturer who has been granted a GMP exemption is still subject to inspection under [Section 704\(a\) of the FD&C Act](#) [21 U.S.C. 374 (a)], and may be subject to regulatory action if devices are adulterated or misbranded.

### 2.9.2.7 - Medical Device Reporting

The [Medical Device Reporting \(MDR\) regulation](#) and the changes mandated by the Safe Medical Devices Act of 1990 (SMDA) is a mandatory information reporting system. It requires manufacturers, importers, and users of medical devices to report to FDA certain adverse experiences caused or contributed to by their devices. This program is administered by the Center's MDR Policy Team in the Office of Regulatory Programs, Office of Surveillance and Biometrics. The regulation requires a report be submitted to FDA whenever a manufacturer or an importer becomes aware of information that its device:

1. May have caused or contributed to a death or serious injury, or
2. Has malfunctioned and, if the malfunction recurs, is likely to cause or contribute to a death or serious injury.

Under the Safe Medical Devices Act of 1990, user facilities must report device-related deaths to FDA and to the manufacturer, if known. User facilities must also report device-related serious illnesses and injuries to the manufacturer, or to FDA if the manufacturer is unknown. In addition, SMDA also requires user facilities to submit to FDA, on an annual basis, a summary of all reports submitted.

The CDRH Division of Industry and Consumer Education and the Office of Regulatory Programs should be contacted for further guidance about the MDR regulation. Inspections for compliance with the MDR regulation are conducted following the guidance contained in the Compliance Program 7382.845 - Inspection of Medical Device Manufacturers.

As of 8/2018, the agency's Voluntary Malfunction Summary Reporting program was implemented. It permits certain manufacturers an alternative method to submit MDRs for eligible product codes in summary form on a quarterly basis.

### 2.9.2.8 - Radiation Reporting

Prior to introduction of products into commerce, manufacturers of radiation-emitting electronic products must submit radiation safety Product Reports if the product is listed and marked in Table 1 of [21 CFR 1002.1](#). (Non-medical radiation products have NO registration and listing requirements, but the same type of information is included in these reports.) These are premarket documents but there is no timeframe for review and manufacturers do not have to wait for clearance. However, these documents must be processed by CDRH, OHT7: Office of Invitro Diagnostics and Radiological Health to provide rapid import entry of electronic products. Radiation Product Reports provide technical specifications, how products comply with standards, and radiation testing and quality control programs to support the firm's (self)-certification of compliance of each product.

In addition, manufacturers must file annual reports (if specified in Table 1), defect or noncompliance reports when appropriate (similar to recall notices), and accidental radiation occurrence reports when appropriate (similar to, and sometimes replaced by, Medical Device Reports (MDRs)).

## 2.9.3 - CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

The requirements for the registration and licensing of biological products fall under both the Public Health Service Act (PHS) and the FD&C Act.

### 2.9.3.1 - Registration and Listing

See also IOM 5.7.3.

CBER provides industry with registration and listing forms, [FDA 2830](#), Blood Establishment Registration and Product Listing, and [FDA 3356](#), Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS). Instructions for completing these documents are on the reverse side of these forms along with establishment and product definitions. Registration forms are available through the District office and through CBER's Office of Communication, Training and Manufactures Assistance, and from the [CBER website](#). Registration and listing is required whether or not interstate commerce is involved. (See IOM 5.7.3)

### 2.9.3.1.1 - HUMAN BLOOD AND BLOOD PRODUCTS

Human Blood and Blood Products:

1. Who must register - [Section 510 of the FD&C Act](#) and [21 CFR 607](#) delineate the requirements and exemptions relating to the registration of establishments engaged in the collection, manufacturing, preparation, or processing of human blood or blood products. Registration and listing are required whether or not interstate commerce is involved. Fixed blood collection sites that have supplies or equipment requiring quality control or have an expiration date, e.g., copper sulfate, centrifuges, etc., or are used to store donor records, must register. Temporary collection sites, to which all blood collection supplies are brought on the day of collection and are completely removed from the site at the end of the collecting period (except beds, tables, and chairs) and blood mobiles, are not required to register. All Military blood bank establishments are required to register. (MOU with Department of Defense [Federal Cooperative Agreements Manual] Regarding Licensure of Military Blood Banks.) Brokers, who take physical possession of blood products, such as in storage, pooling, labeling, or distribution, are required to register. Blood establishments located outside of the United States that import or offer for import blood products into the U.S. are required to register with FDA. They must also provide the name of the United States agent, the name of each importer, and each person who imports or offers for import these blood products.
2. When to register - Establishments must register within five days after beginning operations and must submit a list of blood products they distribute commercially. They must register annually thereafter.
3. How to register - Owners or operators of blood establishments register using the Form [FDA 2830](#). Refer to [Compliance Policy Guide \(CPG\) 230.110](#) for additional information on registration. These persons may complete and submit [Form FDA 2830 on the Internet](#) or may submit a paper form.
4. Where to mail completed paper forms - Mail completed legible forms to: Food and Drug Administration, Center for Biologics Evaluation and Research, Division of Blood Applications (HFM-370), 1401 Rockville Pike, 200N, Rockville, MD 20852-1448.
5. General Information and Questions:  
Phone: 301-827-3546

Email: [bloodregis@cber.fda.gov](mailto:bloodregis@cber.fda.gov)

Mail: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Avenue, WO7, G112, Silver Spring, MD 20993-0002.

### 2.9.3.1.2 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS):

1. Who must register - Establishment that manufacture HCT/PS that are regulated solely under the authority of [section 361 of the Public Health Service Act](#) (42USC264) (the PHS Act) must register and list with CBER whether or not the HCT/P enters into interstate commerce ([21 CFR 1271.1](#)). Establishments that manufacture HCT/PS that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug and Cosmetic Act, must register and list with CBER following procedures in [subpart B, 21 CFR 1271.21 thru 1271.37](#). Registration and listing are required if the establishment recovers, processes, stores, labels, packages, or distributes any human cell or tissue, or screens or tests the cell or tissue donor. Establishments exempted from registration are listed in [21 CFR 1271.15](#). Establishments that only have HCT/PS under premarket review (IND/IDE/BLA/PMA) do not have to register and list until the HCT/P has been licensed, approved or cleared by FDA.
2. When to register - Establishments must register within five days after beginning operations and must submit a list of each HCT/P manufactured.
3. How to register - To register a Form [FDA 3356](#) must be completed.
4. Where to mail completed forms - Mail completed legible forms to: Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, WO7, G112, Silver Spring, MD 20993-0002, Attention: Tissue Establishment Registration Coordinator. Or it may be submitted by FAX according to form instructions. Alternatively, establishments may now submit the information electronically via the [Electronic Human Cell and Tissue Establishment Registration \(eHCTERs\) page](#).
5. General Information and Questions:  
Phone: 301-827-6176 (Tissue Establishment Registration Coordinator)  
Email: [tissuereg@cber.fda.gov](mailto:tissuereg@cber.fda.gov)  
Mail: Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-775, 1401 Rockville Pike, 200N, Rockville, MD 20852-1448.

### 2.9.3.2 - Biologic License

[Section 351 of the Public Health Service Act](#) requires individuals or companies who manufacture biological products for introduction into interstate commerce to hold a

license for the products. Biologics licenses are issued by CBER and CDER (21 CFR 601.4).

What changes to an approved biologics license application are reportable - Applicants must inform the FDA about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application ([21 CFR 601.12](#)).

When to Report - Major changes require supplement submission and approval prior to distribution of products made using the change (21 CFR 601.12(b)). Certain changes require supplement submissions at least 30 days prior to distribution of the product made using the change, and other minor changes need only be described in an annual report (21 CFR 601.12(c) and (d)).

Where to send Reports - For licensed biological products regulated by CBER: Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, WO7, G112, Silver Spring, MD 20993-0002. For licensed biological products regulated by CDER: Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs (Specify OND Review Division) 5901-B Ammendale Road, Beltsville, MD 20705-1266. ([21 CFR 600.2](#))

## 2.9.4 - CENTER FOR VETERINARY MEDICINE (CVM)

Requirements for registration and filing of various applications by firms which manufacture animal drugs, feeds, and other veterinary products are required by the FD&C Act.

### 2.9.4.1 - Registration and Listing

Owners or operators of all drug establishments, not exempt under [section 510\(g\) of the FD&C Act](#) [21 U.S.C. 360 (g)] or [subpart D of 21 CFR 207](#), who engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs are required to register. Also, they must submit a list of every drug in commercial distribution, except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment, and there exists joint ownership and control among all the establishments.

Who must register - Owners and operators of establishments engaged in manufacture or processing of drug products must register and list their products.

When to register - The owner or operator of an establishment must register within 5 days after beginning of

the operation and submit a list of every drug in commercial distribution at that time. Owners or operators of all establishments engaged in drug activities described in [21 CFR 207.3\(a\)\(8\)](#) shall register annually.

The Guidance document on electronic submissions for drug establishment registration and drug product listing is available at:

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf>.

For information on registered animal drug firms contact CVM's Registration Monitor (HFV-212), 7519 Standish Place, Rockville, MD 20855 240-402-6816. You may make inquiries on registration status of individual firms through CVM's Registration Monitor.

For information on animal drug listing - CVM maintains its own database for animal drug listing. You may make inquiries for information via email [MedicatedFeedsTeamMail@fda.hhs.gov](mailto:MedicatedFeedsTeamMail@fda.hhs.gov).

### 2.9.4.2 - Medicated Feed Mill License (FML)

An approved medicated feed mill license is required for facilities that manufacture feed using Category II, Type A medicated articles; liquid and free-choice medicated feed containing a Category II drug; or liquid and free-choice medicated feed containing a Category I drug that follow an approved proprietary formula and/or specifications.

Licensed mills are required to operate in compliance with current Good Manufacturing Practices as described in [21 CFR 225](#) (225.10 – 225.115) and must undergo a pre-approval inspection prior to licensure. Licensed mills must also register as drug establishments with FDA per [21 CFR 207](#). Registration is completed electronically each year between October 1 and December 31. Information on how to complete registration and check registration status can be found on CVM's [Medicated Feeds](#) webpage.

To apply for a license, a completed [Form FDA 3448](#) should be mailed to the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 12225 Wilkins Avenue, Rockville, Maryland 20852. This form is also used for supplemental applications to update license information. For general information and questions, an email can be sent to the Medicated Feeds Team at [MedicatedFeedsTeamMail@fda.hhs.gov](mailto:MedicatedFeedsTeamMail@fda.hhs.gov).

### 2.9.4.3 - Abbreviated New Animal Drug Application (ANADA)

The Generic Animal Drug and Patent Term Restoration Act amended the FD&C Act to provide for the approval of generic copies of previously approved animal drug products. The generic product may be approved by providing evidence it contains the same active ingredients,

in the same concentration, as the approved article, and is bioequivalent. The information is submitted to the FDA in the form of an Abbreviated New Animal Drug Application or ANADA.

How to file - An ANADA must be submitted to FDA on the form [FDA 356V](#). The format and content of the application must be in accordance with the policies and procedures established by FDA's Center for Veterinary Medicine. The application must be filled out completely in triplicate and submitted to the address below.

Where to obtain forms - ANADA's also use the form FDA 356 which can be obtained from: Food and Drug Administration, Center for Veterinary Medicine (HFV-12), 7500 Standish Place, Rockville, MD 20855.

Where to mail completed forms - Completed legible applications should be mailed to: Food and Drug Administration, Center for Veterinary Medicine (HFV-199), 7500 Standish Place, Rockville, MD 20855.

General Information and Questions - Assistance and additional information can be obtained by calling 240-402-5674.

#### **2.9.4.4 - New Animal Drug Application (NADA)**

A new animal drug is any drug intended for use in animals other than man. Manufacturers of new animal drugs must complete a New Animal Drug Application (NADA), and receive approval prior to distribution.

How to file - Applications must be submitted on a form FDA 356. The applications must be signed by the applicant or by an authorized attorney, agent, or official. The application must be filled out completely, in triplicate, and submitted to the address below.

Where to obtain forms - NADAs use form FDA 356 which can be obtained from: Food and Drug Administration, Center for Veterinary Medicine (HFV-12), 7500 Standish Place, Rockville, MD 20855.

Where to mail completed forms - Completed NADAs should be mailed to: Food and Drug Administration, Center for Veterinary Medicine (HFV-199), 7500 Standish Place, Rockville, MD 20855.

General Information and Questions - General information or questions can be answered by calling 240-276-9300.

### **2.9.5 - CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)**

The FDA issued [21 CFR 1](#), an interim final regulation in [FR Vol. 68 No. 197](#) pgs. 58893-58974 on October 10, 2003 that

requires affected domestic and foreign facilities that manufacture/process, pack or hold food for human or animal consumption in the United States to register with the FDA by December 12, 2003. The interim final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). For more information see the [FDA/CFSAN website](#) on food firm registration.

The FD&C Act and its regulations require certain firms to register and to file scheduled processes, while other firms are requested to do this voluntarily. CFSAN provides guidance and assistance as described below.

#### **2.9.5.1 - Low Acid Canned Food (LACF) / Acidified Foods (AF) Food Canning Establishment (FCE) Registration**

Food Canning Establishments (FCE) (foreign and domestic) engaged in the manufacture of Low Acid Canned Food/Acidified Foods (LACF/AF) offering their products for interstate commerce within the United States are required by 21 CFR Parts [108](#), [113](#), and [114](#) to register their facility with the FDA as indicated below.

Who must register - All commercial processors of LACF and AF products located in the US, and all processors in other countries who export their LACF or AF into the US must register their processing plants with the FDA. Wholesalers, importers, distributors, brokers, shippers, etc. are not required to register and file scheduled process information. However, they must ensure the processing firms they represent comply with all registration and process filing requirements.

When to register - Commercial LACF and AF processors in the US must register with FDA not later than 10 days after first engaging in the manufacture, processing, or packing of AF or LACF. Processors in other countries must register before offering any such products for import into the US.

How to register - Processors must submit Form [FDA 2541](#) for each physical processing plant location [electronically](#) or on paper. The form includes information identifying a "facility contact person" (FCP) for each plant being registered. The FCP should be an authorized, responsible official of the commercial processor. For electronic submissions, the processor will immediately receive the FCE number, however, for paper submissions, a copy of the FCE Registration form will be returned to the firm's preferred mailing address, when applicable, upon FDA assigning the five-digit FCE number to the plant. For domestic plants, whether submitted electronically or on paper, a copy of the FCE Registration Form will be forwarded to the OEI Coordinator email inbox in the FDA District Office in which the plant is located. The OEI Coordinator sends a response notifying the LACF Registration Coordinator of the firm's assigned FEI and the LACF Coordinator will manually add the FEI to the

LACF system. For foreign plants, whether submitted electronically or on paper, a copy of the FCE Registration Form will be forwarded to the DIOP FEI Merge Request Inbox. An email response is sent notifying the LACF Registration Coordinator notifying the firm's assigned FEI and the LACF Coordinator will manually add the FEI to the LACF system.

FCE registration information changes - Manufacturers must notify the FDA of any changes to their FCE registration information. These notifications should be made using form FDA 2541 for changes in firm name, ownership, street name and number, or preferred mailing address. It would be marked as a "Change of Registration Information" and the type of change requested. Where to mail completed forms - Mail completed legible forms to: LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

General Information and Questions:

E-mail: [LACF@fda.hhs.gov](mailto:LACF@fda.hhs.gov)

### 2.9.5.2 - FCE Process Filing of LACF/AF Processors

In addition to processors registering their establishments with the FDA, processors must also submit and file scheduled process information for their LACF/AF products with the FDA. Processors may submit electronically or by paper using one or more of the follow forms depending on the products' processing method: Form FDA 2541d, FDA 2541e, FDA 2541f, or FDA 2541g. FDA encourages processors to submit electronically. Processes must be filed no later than 60 days after registration and prior to packing a new product or, in the case of firms in other countries, before importing their products into the United States.

It is the responsibility of the manufacturer and/or its authorized representative to ensure the design process used is safe from a standpoint of public health significance and will destroy or inhibit the growth of microorganisms. This is accomplished through the consultation of and recommendations by a process authority. Documentation that scheduled processes are delivered should be maintained through appropriate and accurate record keeping. Forms and documentation must be presented in English.

Process filing information consists of the following:

1. FCE number to the processing plant,
2. Submission Identifier (SID) number to identify a specific form submitted by the manufacturer,
3. Governing regulation (LACF - [21 CFR 108.35/113](#) or AF - [21 CFR 108.25/114](#)),
4. Food name or description, which includes form or style of the product (whole, sliced, diced, etc.) and packing medium (in water, in brine, in tomato sauce, etc.),
5. Container type,

6. Process Establishment Source, and
7. Container dimensions in inches and/or capacity.
8. Scheduled process, and
9. Other critical factors if applicable

### 2.9.5.3 – Cosmetics

#### VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS (21 CFR 710)

Who should register - The owner or operator of a cosmetic product establishment, which is not exempt under [21 CFR 710.9](#), and engages in the manufacture or packaging of a cosmetic product, is asked to register each such establishment, whether or not the product enters interstate commerce. This request extends to any foreign cosmetic product establishment whose products are exported for sale in any State as defined in [section 201\(a\)\(1\) of the FD&C Act](#) [21 U.S.C. 321 (a)(1)]. No registration fee is required.

Time for registration - The owner or operator of an establishment entering into the manufacture or packaging of a cosmetic product should register the establishment within 30 days after the operation begins.

How and where to register - The [FDA 2511](#) - Registration of Cosmetic Product Establishment is available from the FDA, CPK-2, Office of Cosmetics and Colors, Cosmetics Staff (HFS-125), 5100 Paint Branch Parkway, College Park, MD 20740-3835, or at any FDA District office. The completed form should be mailed to HFS-125. The form is also available online at [VCRP Online Forms](#). Establishments can also be registered online at [VCRP Online Registrations](#).

Information requested - The FDA 2511 requests information on the name and address of the cosmetic product establishment, including post office ZIP code; all business trading names used by the establishment; and the type of business (manufacturer and/or packer). The information requested should be given separately for each establishment.

General information and questions - Call 240-402-1345, or e-mail [ocacapp@fda.hhs.gov](mailto:ocacapp@fda.hhs.gov) at <https://www.accessdata.fda.gov/scripts/ocacapp/client/vcrp/contact/>. Instructions are sent with the forms.

#### VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENT (21 CFR 720)

Who should file - Either the manufacturer, packer, or distributor of a cosmetic product is requested to file a [FDA-2512](#) Cosmetic Product Ingredient Statement, whether or not the product enters interstate commerce. The request extends to any foreign manufacturer, packer, or distributor of a cosmetic product exported for sale in any State as



defined in [section 201\(a\)\(1\) of the FD&C Act](#) [21 U.S.C. 321 (a)(1)]. No filing fee is required.

Times for filing - The FDA 2512 should be filed for each cosmetic product being commercially distributed. The FDA-2512 should be filed within 60 days after the beginning of commercial distribution of any product.

How and where to file - The [FDA 2512](#) and [FDA 2512a](#) - Cosmetic Product Ingredient Statement are obtainable on request from the FDA, CPK-2, Office of Cosmetics and Colors, Cosmetics Staff (HFS-125), 5100 Paint Branch Parkway, College Park, MD 20740-3835 or at any FDA District office. The forms are also available online at [VCRP Online Forms](#). The completed form should be mailed or delivered according to instructions provided with the form to HFS-125. The FDA-2512 Cosmetic Product Ingredient Statement can also be filed online at [VCRP Online Registrations](#).

General information and questions - Phone: 240-402-1257, or e-mail at <https://www.accessdata.fda.gov/scripts/ocacapp/client/vcrp/contact/>.

#### 2.9.5.4 - Color Certification Program

Request for Certification - A request for certification of a batch of color additive (straight color, lake, repack) should be submitted online by logging in to the company account using the color certification portal or in writing using the formats found in 21 CFR 80.21. The fee prescribed in 21 CFR 80.10 should be submitted by following the banking instructions provided at the time the company account was established.

A sample accompanying a request for certification must be submitted and should be addressed to the Food and Drug Administration, Color Certification Branch (HFS-107), 4300 River Road, College Park, MD 20740.

Where to mail request - Mail or deliver the request to the Food and Drug Administration, Color Certification Branch (HFS-107) at the address above or send e-mail to [amelia.baldo@fda.hhs.gov](mailto:amelia.baldo@fda.hhs.gov).

Contact the Food and Drug Administration, Color Certification Branch (HFS-107) at the address above.

Costs - There is a fee for services provided (analytical work) which will vary based on type of color additive (straight color, lake, repack) and weight of batch. See 21 CFR 80.10.

#### 2.9.5.5 - Infant Formula

Who should register - There are three types of notifications:

1. First Notification - All manufacturers of infant formula sold in the US, and any manufacturer of a "new infant formula", must register with FDA no less than 90 days before it is introduced into interstate commerce. The first notification must include:

- a. The name and description of the physical form of the infant formula,
  - b. The explanation of why the formula is a new infant formula,
  - c. The quantitative formulation of the infant formula,
  - d. A description of any reformulation of the formula or change in processing of the infant formula, when applicable,
  - e. Assurances the infant formula meets the requirements for quality factors and nutrient content requirements,
  - f. Assurances the infant formula meets regulations and, as demonstrated by the testing required under regulations, and
  - g. Assurances the processing of the infant formula complies with regulations.
2. Second notification - This notification is given to FDA after the first production of an infant formula, and before it is introduced into interstate commerce. The manufacturer must submit a written verification that summarizes test results and records' demonstrating such formula complies with regulations.
  3. Third notification - This notification must be sent to FDA if the manufacturer determines a change in the formulation or processing of the formula may adversely affect the article.

Where to mail notifications - Notifications should be sent to: Food and Drug Administration, Office of Nutrition and Food Labeling, Infant Formula and Medical Foods Staff, HFS-850, 5001 Campus Drive, College Park, MD 20740-3835.

General information and questions phone: 240-402-2373.

#### 2.9.5.6 - Interstate Certified Shellfish (Fresh and Frozen Oysters, Clams, and Mussels) Shippers

Persons interested in receiving general information about the National Shellfish Sanitation Program - Contact: Food and Drug Administration, Division of Seafood Safety, HFS-325, 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-2300; FAX: 301-436-2601

Persons interested in technical assistance about the National Shellfish Sanitation Program - Contact: Food and Drug Administration, Retail Food & Cooperative Programs Coordination Staff (HFS-320), 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-2149; FAX: 301-436-2672

Persons interested in receiving the Interstate Certified Shellfish Shippers List (ICSSL) - Contact: Charlotte V. Epps. Mail: Food and Drug Administration, Retail Food & Cooperative Programs Coordination Staff (HFS-320), 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-2154; FAX: 301-436-2672

### 2.9.5.7 - Interstate Milk Shippers (IMS)

Rules for inclusion in the [IMS List](#) - All Grade A milk shippers certified by State Milk Sanitation Rating authorities as having attained an acceptable sanitation compliance and enforcement rating are include in the IMS list. These ratings are based on compliance with the requirements of the "USPHS/FDA Grade A Pasteurized Milk Ordinance (PMO) and/or the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey Ordinance (DMO)" and are made in accordance with the procedures set forth in "Methods of Making Sanitation Rating of Milk Shippers" and the "Procedures Governing the Cooperative State-Public Health Service/ Food and Drug Administration Program of the National Conference on Interstate Milk Shippers". The IMS List is published semi-annually and updated monthly on the FDA website.

To obtain a free copy of the IMS List contact:

Food and Drug Administration  
Dairy and Egg Branch (HFS-316)  
Division of Plant and Dairy Food Safety  
5100 Paint Branch Parkway  
College Park, MD 20740

General Information and Questions.

Contact: Dairy and Egg Branch (HFS-316), Division of Plant and Dairy Food Safety, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-1700

### 2.9.6 –CENTER FOR TOBACCO PRODUCTS

The FD&C Act and its amendment under the Family Smoking Prevention and Tobacco Control Act require manufacturers or importers to submit certain information to the FDA including: Tobacco Health Document Submission, Establishment Registration and Product Listing, and Listing of Ingredients in Tobacco Products.

General information regarding industry submissions or the process can be found at: <https://www.fda.gov/tobacco-products/compliance-enforcement-training/manufacturing>.

**2-1 INTERROGATION: ADVICE OF RIGHTS**

**YOUR RIGHTS**

Place \_\_\_\_\_  
Date \_\_\_\_\_  
Time \_\_\_\_\_

Before we ask you any questions, you must understand your rights.

You have the right to remain silent.

Anything you say can be used against you in court.

You have the right to talk to a lawyer for advice before we ask you any questions and to have him with you during questioning.

If you cannot afford a lawyer, one will be appointed for you before any questioning if you wish.

If you decide to answer questions now without a lawyer present, you will still have the right to stop answering at any time. You also have the right to stop answering at any time until you talk to a lawyer.

**WAIVER OF RIGHTS**

I have had read to me this statement of my rights and I understand what my rights are. I am willing to make a statement and answer questions. I do not want a lawyer at this time. I understand and know what I am doing. No promises or threats have been made to me and no pressure or coercion of any kind has been used against me.

Signed \_\_\_\_\_

Witness: \_\_\_\_\_

Witness: \_\_\_\_\_

Time: \_\_\_\_\_

INTERROGATORIO: NOTIFICACION DE LOS DERECHOS

**SUS DERECHOS**

Lugar \_\_\_\_\_  
Fecha \_\_\_\_\_  
Hora \_\_\_\_\_

Antes de hacerle pregunta alguna, Ud. debe entender lo que son sus derechos.

Ud. tiene el derecho de mantener silencio.

Cualquier cosa que diga Ud. puede ser usada en su contra en un tribunal.

Ud. tiene el derecho de consultar con un abogado para que éste le aconseje antes de que le hagamos las preguntas y también tiene derecho a la presencia del abogado durante el interrogatorio.

**Si Ud. no puede pagar los gastos de un abogado, se le asignara uno antes de iniciarse el interrogatorio, si así lo desea Ud.**

Si Ud. se decide a contestar las preguntas ahora sin la presencia del abogado, Ud. tiene todavía el derecho de negarse a contestar en cualquier momento. Ud. tiene también el derecho de interrumpir las contestaciones en cualquier momento hasta que haya consultado con un abogado.

**RENUNCIA A LOS DERECHOS**

Me han leído esta declaración de mis derechos y entiendo lo que son. Estoy dispuesto a hacer una declaración y a contestar las preguntas. No quiero que esté presente un abogado en este momento. Tengo conciencia de lo que hago. No se me han hecho ni promesas ni amenazas y no se has ejercido presión alguna en mi contra.

Firmado \_\_\_\_\_

Testigo: \_\_\_\_\_

Testigo: \_\_\_\_\_

Hora: \_\_\_\_\_

# 2-2 Detention Order

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION  <b>DETENTION ORDER</b>	1a. DISTRICT ADDRESS		1c. NAME OF DISTRICT DIRECTOR	
			1d. EMAIL ADDRESS	
	1b. PHONE NUMBER		1e. FAX NUMBER	
2. NAME OF CUSTODIAN TO:			3. DETENTION ORDER NUMBER <b>DO</b>	
4. TITLE OF CUSTODIAN		5. TELEPHONE NUMBER	6. DATE AND HOUR DETAINED	
7. FIRM NAME			a.m. p.m.	
8. ADDRESS (Street, City, State, ZIP Code)			9. MAXIMUM DETENTION _____ DAYS	
Pursuant to (Check applicable Section(s)) <input type="checkbox"/> Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), <input type="checkbox"/> Section 304(g) of the FD&C Act, <input type="checkbox"/> Sections 402 and 409b of the Federal Meat Inspection Act, <input type="checkbox"/> Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or <input type="checkbox"/> Sections 19 and 23(d) of the Federal Egg Products Inspection Act, the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).				
10. NAME OF DETAINED ARTICLE(S)			11. SIZE OF DETAINED LOT	
12. DETAINED ARTICLE(S) LABELED (Include Master Carton Label)				
15. REASON FOR DETENTION		16. DETAINED ARTICLE(S) STORED AT (Name, Address, ZIP Code)		
17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER			18. APPROVAL OF DETENTION ORDER <input type="checkbox"/> Written <input type="checkbox"/> Verbal	
28. STORAGE OF DETAINED ARTICLES (Select appropriate - Per 21 CFR 1.303(b)(7), the detained articles must be stored by only these methods.) <input type="checkbox"/> N/A <input type="checkbox"/> Frozen <input type="checkbox"/> Other (For non-temperature related storage conditions; specify): _____ <input type="checkbox"/> Refrigerated at _____ °F <input type="checkbox"/> Ambient				
NAME OF FDA EMPLOYEE (Type or print)		TITLE (FDA Employee)	SIGNATURE (FDA Employee)	

See instructions following page 5 in this electronic form version.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION  <b>DETENTION ORDER</b>	1a. DISTRICT ADDRESS		1c. NAME OF DISTRICT DIRECTOR	
			1d. EMAIL ADDRESS	
	1b. PHONE NUMBER		1e. FAX NUMBER	
2. NAME OF CUSTODIAN TO:			3. DETENTION ORDER NUMBER <b>DO</b>	
4. TITLE OF CUSTODIAN		5. TELEPHONE NUMBER	6. DATE AND HOUR DETAINED	
7. FIRM NAME			a.m.	p.m.
8. ADDRESS (Street, City, State, ZIP Code)			9. MAXIMUM DETENTION _____ DAYS	
Pursuant to (Check applicable Section(s)) <input type="checkbox"/> Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), <input type="checkbox"/> Section 304(g) of the FD&C Act, <input type="checkbox"/> Sections 402 and 409b of the Federal Meat Inspection Act, <input type="checkbox"/> Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or <input type="checkbox"/> Sections 19 and 23(d) of the Federal Egg Products Inspection Act, the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).				
10. NAME OF DETAINED ARTICLE(S)			11. SIZE OF DETAINED LOT	
12. DETAINED ARTICLE(S) LABELED (Include Master Carton Label)			13. APPROXIMATE VALUE OF LOT	
			14. SAMPLE NUMBER	
15. REASON FOR DETENTION		16. DETAINED ARTICLE(S) STORED AT (Name, Address, ZIP Code)		
17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER			18. APPROVAL OF DETENTION ORDER <input type="checkbox"/> Written <input type="checkbox"/> Verbal	
19. NAME AND ADDRESS OF ARTICLE(S) OWNER		20. NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER		
21. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS (Continue in Remarks, if necessary)		22. NAME OF CARRIERS		
		23. DATE LOT SHIPPED		
24. NAME AND ADDRESS OF PACKING PLANT		25. DATE LOT RECEIVED		
		26. PACKING PLANT USDA NUMBER		
27. DESCRIPTION OF SAMPLE				
28. STORAGE OF DETAINED ARTICLES (Select appropriate -- Per 21 CFR 1.303(b)(7), the detained articles must be stored by only these methods.) <input type="checkbox"/> N/A <input type="checkbox"/> Frozen <input type="checkbox"/> Other (For non-temperature related storage conditions; specify): _____ <input type="checkbox"/> Refrigerated at _____ ° F <input type="checkbox"/> Ambient				
NAME OF FDA EMPLOYEE (Type or print)		TITLE (FDA Employee)	SIGNATURE (FDA Employee)	

*Section 304(h) of the Food, Drug and Cosmetic Act is quoted below:*

**“(h) Administrative Detention of Foods.**

**(1) Detention Authority.**

**(A) In general.** An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.

**(B) Secretary's approval.** An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

**(2) Period of detention.** An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

**(3) Security of detained article.** An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

**(4) Appeal of detention order.**

**(A) In general.** With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

**(B) Effect of instituting court action.** The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved.”

Please see 21 CFR 1.402 (copied here) for the requirements for submitting an appeal for administrative detention of foods. If you decide to appeal the detention order, you may also request a hearing as part of the appeal by filing a timely notice of intent to request a hearing and then noting your request for a hearing as part of your appeal. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Presiding Officer determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. If you request a hearing as part of your appeal, you should submit with your appeal and request for a hearing the materials, data, and information that you believe shows there is a genuine and substantial issue of fact regarding the propriety of the detention and any other information you would like the presiding officer to consider when deciding your appeal and request for a hearing. If your appeal is denied, written notice of a determination of summary judgment will be provided, explaining the reasons for denial. If you do not request a hearing as part of your appeal, you should submit with your

appeal all of the materials, data and information that you would like the Presiding Officer to consider when deciding your appeal.

*Section 1.401 and 1.402 of Title 21, Code of Federal Regulations, are quoted below as notice of opportunity for appeal and a regulatory hearing for administrative detention of foods:*

**“Section 1.401 Who is entitled to appeal?**

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the FD&C Act, may appeal a detention order as specified in section 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the FD&C Act are governed by Supplemental Rule C to the “Federal Rules of Civil Procedure.”

**Sec. 1.402 What are the requirements for submitting an appeal?**

**“(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA District Director, in whose district the detained article of food is located, at the mailing address, e-mail address, or fax number identified in the detention order according to the following applicable timeframes:**

**(1) Perishable food:** If the detained article is a perishable food, as defined in section 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.

**(2) Nonperishable food:** If the detained article is not a perishable food, as defined in section 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order. **(b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the Federal Rules of Civil Procedure.**

**(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the FD&C Act or an injunction under section 302 of the FD&C Act (21 U.S.C. 276) regarding the article of food involved in the detention order.**

**(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed.”**

Any informal hearing of a detention order for food must be conducted as a regulatory hearing under 21 CFR Part 16 as modified by section 1.403.

For more information, please see 21 CFR Part 1, subpart K and 21 CFR Part 16.

*Section 304(g) of the Food, Drug and Cosmetic Act is quoted below:*

**(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device, drug, or tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device, drug, or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device, drug, or tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device, drug, or tobacco product during the period of its**

*(Continued on the reverse of this page)*

detention for the purpose of identifying the device, drug, or tobacco product as detained. Any person who would be entitled to claim a device, drug, or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of such device, drug, or tobacco product under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

“(2)(A) Except as authorized by subparagraph (B), a device, drug, or tobacco product subject to a detention order issued under paragraph

(1) shall not be moved by any person from the place at which it is ordered detained until -

“(I) released by the Secretary, or

“(II) the expiration of the detention period applicable to such order, whichever occurs first.

“(B) A device subject to a detention order under paragraph (1) may be moved -

(1) may be moved -

“(I) in accordance with regulations prescribed by the Secretary, and

“(II) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.”

**Section 800.55(g)(1)-(2) of Title 21, Code of Federal Regulations, is quoted below as notice of opportunity for appeal and a regulatory hearing:**

“(g) Appeal of a detention order.

(1) A person who would be entitled to claim the devices, if seized, may appeal a detention order. Any appeal shall be submitted in writing to FDA District Director in whose district the devices are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in Section 201(y) of the Act, the appellant shall request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which shall not be later than 20 calendar days after receipt of the detention order.

(2) The appellant of a detention order shall state the ownership or proprietary interest the appellant has in the detained devices. If the detained devices are located at a place other than an establishment owned or operated by the appellant, the appellant shall include documents showing that the appellant would have legitimate authority to claim the devices if seized.”

Any informal hearing on an appeal of a detention order for devices shall be conducted as a regulatory hearing under 21 CFR Part 16, with certain exceptions Described in 21 CFR § 800.55(g)(3).

**Sections 402 and 408(b) of the Federal Meat Inspection Act is quoted below:**

“Sec. 402. Whenever any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines or any product exempted from the definition of a meat food product, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to Title I of this Act, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of Title I of this Act or of any other Federal law or the laws of any State or Territory or the District of Columbia, or that such article or animal has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under Section 403 of this Act or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or animal, and shall not be moved by any person, firm, or corporation from the place at which it is located when so detained, until release by such representative. All official marks may be required by such representative to be removed from such article or animal before it is released unless it appears to the satisfaction of the Secretary that the article or animal is eligible to retain such marks. (21 U.S.C. 672.)

Sec. 409.

(b) The detainer authority conferred by Section 402 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal, Food, Drug, and Cosmetic Act with respect to any carcass, part thereof, meat, or meat food product of cattle, sheep, swine, goats, or equines that is outside any premises at which inspection is being maintained under this Act, and for such purposes the first reference to the Secretary in Section 402 shall be deemed to refer to the Secretary of Health and Human Services. (21 U.S.C. 679)”

**Sections 19 and 24(b) of the Poultry Products Inspection Act is quoted below:**

“Sec. 19. Whenever any poultry product, or any product exempted from the definition of a poultry product, or any dead, dying, disabled, or diseased poultry is found by an authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to this Act, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of this Act or of any other Federal law or the Laws of any State or Territory, or the District of Columbia, or that it has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under Section 20 of this Act or notification of Any Federal, State, or other governmental authorities having jurisdiction over such article or poultry, and shall not be moved by any person, from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or poultry before it is released unless it appears to the satisfaction of the Secretary that the article or poultry is eligible to retain such marks.”

Sec. 24.

(b) The detainer authority conferred by Section 19 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal Food, Drug and Cosmetic Act with respect to any poultry carcass, or part or product thereof, that is outside any official establishment, and for such purposes for first reference to the Secretary in Section 19 shall be deemed to refer to the Secretary of Health and Human Services.”

**Sections 19 and 23(d) of the Egg Products Inspection Act is quoted below:**

“Sec. 19. Whenever any eggs or egg products subject to the Act, are found by any authorized representative of the Secretary upon any premises and there is reason to believe that they are or have been processed, brought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of this Act or that they are in any other way in violation of this Act, or whenever any restricted eggs capable of use as human food are found by such a representative in the possession of any person not authorized to acquire such eggs under the regulations of the Secretary, such articles may be detained by such representative for a reasonable period but not to exceed twenty days, pending action under Section 20 of this Act or notification of any Federal, State, or other governmental authorities having jurisdiction over such articles and shall not be moved by any person from the place at which they are located when so detained until released by such representative. All official marks may be required by such representative to be removed from such articles before they are released unless it appears to the satisfaction of the Secretary that the articles are eligible to retain such marks.”

“Sec. 23(d). The detainer authority conferred on representatives of the Secretary of Agriculture by Section 19 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for the purposes of paragraph (d) of Section 5 of this Act, with respect to any eggs or egg products that are outside any plant processing egg products.”

(Continued on next page)




*Section 1.980(g)(1)-(2) of Title 21, Code of Federal Regulations, is quoted below as notice of opportunity for appeal and a regulatory hearing for administrative detention of drugs"*

"(g) Appeal of a detention order. (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA District Director in whose district the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized."

Any informal hearing on an appeal of a detention order for drugs shall be conducted as a regulatory hearing under 21 CFR Part 16, with certain exceptions described in 21 CFR § 1.980(g)(3)."

2-3 Detention Tag



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

---

**U.S. DETAINED**

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The Lot of goods to which this tag is affixed is  
**DETAINED BY THE UNITED STATES GOVERNMENT**

In accordance with the provisions of Section 304(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); Section 304(g) of the FD&C Act; Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; or Sections 19 and 23 (d) of the Egg Products Inspection Act, the merchandise listed below is hereby detained for the period indicated. The merchandise must not be used, moved, altered or tampered with in any manner during that period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to section 304(g)(2)(B) of the FD&C Act, a device may be moved and processed under 21 CFR 800.55(h)(2) and a drug may be moved and processed under 21 CFR 1.990(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).

**WARNING:** Removal, alteration or mutilation of this Tag or Violation of any of the above conditions is punishable by fine or imprisonment or both.

---

**SEE REVERSE OF THIS TAG FOR  
DESCRIPTION OF DETAINED MERCHANDISE**

DETENTION DATE &	HOUR	DETENTION NOTICE NO.
	a.m.	<b>DN</b>
	p.m.	

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MAXIMUM DETENTION \_\_\_\_\_ DAYS

NAME FDA EMPLOYEE ISSUING DETENTION NOTICE *(Print or type)* \_\_\_\_\_

SIGNATURE FDA EMPLOYEE ISSUING DETENTION NOTICE \_\_\_\_\_

TITLE FDA EMPLOYEE ISSUING DETENTION NOTICE \_\_\_\_\_


NAME FDA EMPLOYEE AFFIXING TAG *(If different from issuing employee)* \_\_\_\_\_

SIGNATURE FDA EMPLOYEE AFFIXING TAG \_\_\_\_\_

TITLE FDA EMPLOYEE AFFIXING TAG \_\_\_\_\_

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**FORM FDA 2290 (9/14) Prev. Ed. May NOT Be Used  
DETENTION TAG**



**U.S. DETAINED**

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NAME OF DETAINED ARTICLE \_\_\_\_\_

---

DETAINED ARTICLE LABELED \_\_\_\_\_

---

SIZE OF DETAINED LOT \_\_\_\_\_


---

**SEE REVERSE**

---

FORM FDA 2290 (9/14) 17

## 2-4 Detention Termination Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION  <b>DETENTION TERMINATION NOTICE</b>		1a. DISTRICT ADDRESS 850 Third Ave. Brooklyn, NY 11232 1b. PHONE NUMBER 718-340-7000	1c. NAME OF DISTRICT DIRECTOR Thomas Gardine 
TO:	2. NAME OF CUSTODIAN Mr. William Jantz	3. DETENTION NOTICE NUMBER DN 60006	
4. TITLE OF CUSTODIAN Warehouse Manager, Division II		5. DATE AND HOUR DETAINED 12-29-05	10:45 a.m. p.m.
6. FIRM NAME Amoure Cold Storage Co., Inc.		7. DATE AND HOUR DETENTION TERMINATED 1-6-06	8:35 a.m. p.m.
8. ADDRESS (Street, City, and State) 245 Dockage St. Buffalo, NY			9. ZIP CODE 14206
The merchandise listed below which, pursuant to Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; Sections 19 and 23(d) of the Egg Products Inspection Act; or Section 304(g) of the Federal Food, Drug, and Cosmetic Act, was detained on the above date and bears the above detention number, is hereby released and the detention is terminated.			
10. NAME OF DETAINED ARTICLE Beefy Brand Beef Pot Pie with Mushrooms		11. SIZE OF DETAINED LOT 1600cs/24 – 1 lb. 2 oz tins	
12. DETAINED ARTICLE LABELED (Include Master Carton Label) Tins labeled in part with paper labels: "Beefy Brand Pot Pie***ingredients: Selected beef, choice green peas, carrots, selected Idaho potatoes, Mushrooms***Gravy composed of: Water, beef stock, and flour***Net Wt. 1 lb. 2 oz.***Packed by Burly Products Co.***General Offices Kansas City, MO EST 223" Tins in cases labeled in part: "***24/ 1 lb 2 oz tins Beefy Pot Pies***EST 223***"			
NAME OF FDA EMPLOYEE (Type or Print) Sylvia A. Rogers	SIGNATURE (FDA Employee) <i>Sylvia A. Rogers</i>	TITLE (FDA Employee) Investigator	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION  <b>DETENTION TERMINATION NOTICE</b>		1a. DISTRICT ADDRESS 850 Third Ave. Brooklyn, NY 11232	1c. NAME OF DISTRICT DIRECTOR Thomas Gardine
		1b. PHONE NUMBER 718-340-7000	
TO:	2. NAME OF CUSTODIAN Mr. William Jantz	3. DETENTION NOTICE NUMBER <b>DN 60006</b>	
4. TITLE OF CUSTODIAN Warehouse Manager, Division II		5. DATE AND HOUR DETAINED 12-29-05	10:45 <small>a.m.</small>
6. FIRM NAME Amoure Cold Storage Co., Inc.		7. DATE AND HOUR DETENTION TERMINATED 1-6-05	8:35 <small>a.m.</small>
8. ADDRESS (Street, City, and State) 245 Dockage St. Buffalo, NY			9. ZIP CODE 14206
The merchandise listed below which, pursuant to Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; Sections 19 and 23(d) of the Egg Products Inspection Act; or Section 304(g) of the Federal Food, Drug, and Cosmetic Act, was detained on the above date and bears the above detention number, is hereby released and the detention is terminated.			
10. NAME OF DETAINED ARTICLE Beefy Brand Beef Pot Pie with Mushrooms		11. SIZE OF DETAINED LOT 1600cs/24 – 1 lb. 2 oz tins	
12. DETAINED ARTICLE LABELED (Include Mosaic Carton Label) Tins labeled in part with paper labels: "Beefy Brand Pot Pie***ingredients: Selected beef, choice green peas, carrots, selected Idaho potatoes, Mushrooms***Gravy composed of: Water, beef stock, and flour***Net Wt. 1 lb. 2 oz. ***Packed by Burly Products Co. ***General Offices Kansas City, MO EST 223" Tins in cases labeled in part: "****24/ 1 lb 2 oz tins Beefy Pot Pies***EST 223***"			
REMARKS The Culmore County Health department assumed jurisdiction of the product at 8:35 AM on 1-6-06 when it was released from US detention. The entire 1600 case lot was hauled on 1-6-06 by the ACE Trucking Co., 2993 Longway Place, Buffalo, NY, from Amoure Cold Storage Co., Warehouse #3B, 321 Dockage St., Buffalo, NY, to the county landfill at Port Road and Culmore County Road #8 where the lot was dumped, crushed by bulldozers, buried in a ditch, and covered with approximately five feet of earth. The entire operation was supervised by Culmore County Health Department Inspectors Robert J. Sandi and Henry D. Larky and FDA Investigator Sylvia A. Rogers. FDA supervision time and expenses: Inspectional time – 6 hours Mileage – 22 miles in US Gov't car G11-396  <p style="text-align: right;">Sylvia A. Rogers Sylvia A. Rogers Investigator</p>			
NAME OF FDA EMPLOYEE (Type or Print) Sylvia A. Rogers		SIGNATURE (FDA Employee) Sylvia A. Rogers	TITLE (FDA Employee) Investigator

# CHAPTER 3 - FEDERAL AND STATE COOPERATION

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Follow District policy regarding contacts with appropriate federal, state, county and local officials to exchange information, coordinate operations, and arrange joint inspections. If an assignment calls for joint work with state or local inspectors, make every effort to accomplish this work. See IOM 3.3.1. When you travel internationally, follow policy established in the "GUIDE TO INTERNATIONAL INSPECTIONS AND TRAVEL."

**3.1.2 - LAWS, CODES, AGENCIES**

Many states have enacted the basic Uniform Food, Drug, and Cosmetic Bill, and others have adopted at least a part of the Uniform Bill. The provisions of these laws are very similar to the 1938 provisions of the Federal Food, Drug, and Cosmetic Act. A few states have enacted the Pesticide Food and Color Additives or Kefauver-Harris type amendments. See IOM 3.3.3.

Most states without the Uniform FD&C Act, have laws based on the 1906 Food and Drug Act. Most larger cities have their own ordinances and regulations. A portion of the food supply of the United States is consumed within the state in which it is produced, and is therefore, not directly under the jurisdiction of the Federal Food, Drug and Cosmetic Act as amended. Thus, the various state and local agencies are solely responsible for policing this supply.

The departments of the executive branch of the federal government operate under the laws and regulations which they are specifically responsible for enforcing. Since responsibilities may overlap and be duplicated, operating agreements and liaison between agencies is essential for smooth and efficient governmental operation. Section 702(c) of the FD&C Act [[21 U.S.C. 372\(c\)](#)] recognizes this by providing that the records of any department in the executive branch shall be open to inspection by authorized DHHS personnel.

District management is responsible for maintaining official liaison between FDA and other federal agencies. However, for day by day operations, personal contact between various operating federal investigators, inspectors, and agents is desirable and encouraged.

**3.1.2.1 - Agreements and Memoranda of Understanding (MOU)**

It is FDA's policy to enter into MOUs with other entities in situations in which there are a need to define lines of authority or responsibility, or to clarify cooperative procedures (see SMG 2820.1). FDA and various agencies often enter into formal or informal agreements, and/or understandings to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities. These agreements and understands specify areas of primary responsibility.

Prior to disclosing FDA's information, ensure that the

**SUBCHAPTER 3.1 - COOPERATIVE EFFORTS**

**3.1.1 - POLICY**

The scope of consumer protection is extended by cooperative efforts of federal, state, and local agencies and international cooperation. Procedures to appropriately share responsibilities and cooperate with our consumer protection partners are essential.

Federal, state, and local cooperation shall be fostered whenever possible. The Agency issues the IOM as well as other FDA manuals to international regulators and conformity assessment bodies, and state and local inspectors. FDA fosters cooperation through correspondence, FDA testimony, press releases, reprints from the Federal Register, and distribution of all pertinent policy and regulations issued by FDA which have significance in other regulatory jurisdictions. The Agency may share FDA's non-public information as long as the sharing complies with the Agency's confidentiality laws and procedures.

Districts, headquarters' offices, and resident post personnel in particular, should maintain liaison with federal, state and local officials.

Agreement and MOU contain confidentiality provisions that comply with FDA's information disclosure laws and procedures (e.g., sharing with the public (FOI), federal government officials [21 CFR 20.85](#), state/local [21 CFR 20.88](#), foreign [21 CFR 20.89](#)). Contact DIDP's ORA OSPOP Testimony – Info Sharing Team [ORainfoshare@fda.hhs.gov](mailto:ORainfoshare@fda.hhs.gov) when encountering an MOU for the first time, drafting an MOU, or for clarification of disclosure

**A complete listing (domestic, academia and non-profit) is publicly available on the [FDA MOUs page](#)**

### 3.1.3 - OTHER GOVERNMENT INSPECTION

General procedures regarding cooperation with other federal, state, and local officials are furnished below.

During establishment inspections determine the specific type of inspection service and inspecting units, such as the name of the federal, state, county, or city health agency or department. Obtain the name and title of the inspectional official, and general method of operation. IOM 5.4.9.3 discusses coverage of grade A Dairy Plants.

#### 3.1.3.1 - Federal

Compulsory Continuous Inspection - Do not inspect firms, or that portion of a plant, under compulsory, continuous inspection under United States Department of Agriculture's (USDA) Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act, except on specific instructions from your supervisor or assignment document.

Ingredients or manufacturing processes common to both USDA and FDA regulated products should be inspected by FDA. See IOM 3.2.1.3 for FDA/USDA Agreements in specific areas.

Provide routine FDA coverage of such firms as breweries and wineries, which may be intermittently inspected on a compulsory basis by the U.S. Treasury Department, U.S. Public Health Service, or other agencies.

Voluntary - All products inspected under the voluntary inspection service of the Agriculture Marketing Service (AMS), USDA, and the National Marine Fisheries Service (NMFS), US Department of Commerce, are subject to FDA jurisdiction and are usually given routine coverage; however, formal written Agreements or a MOU between FDA and other agencies are often executed and may govern the agreeing agencies' operations on these types of inspected plants.

#### 3.1.3.2 - Discussion with Federal Inspector

If you are assigned to cover a federally inspected plant which is under either compulsory or voluntary inspection,

check to see if an Agreement or a MOU exists between FDA and the agency involved to determine the obligations of both agencies. When you arrive at the firm:

1. Identify yourself to the inspector(s) and invite him/her to accompany you on the inspection but do not insist on their participation.
2. At the conclusion of the inspection, offer to discuss your observations and provide the in-plant inspector with a copy of your Inspectional Observations (FDA 483).

#### 3.1.3.3 - State and Local

State and local officials usually have extensive regulatory authority over firms in their area regardless of the interstate movement or origin of the food products involved. Joint FDA-State or local inspections are occasionally conducted. These are usually arranged by district administrative or supervisory personnel. See IOM 3.3.1.

## SUBCHAPTER 3.2 - FEDERAL AGENCY INTERACTION

This subchapter deals with the interaction of the FDA with other federal agencies. This interaction will be discussed below. Each agency with which FDA has agreements or an MOU is listed separately. Information regarding MOUs and other interactions are discussed as appropriate. Information about the complete MOU or agreement can be found in the appropriate Cooperative Agreements Manual. Listings of all Liaison Officers are included below.

### 3.2.1 - U. S. DEPARTMENT OF AGRICULTURE (USDA)

See IOM 3.1.3 for procedures to be followed when making inspections of firms under USDA inspection or subject to inspection by USDA.

#### 3.2.1.1 - Foods Rejected by USDA

All procurement and processing contracts administered by USDA for edible food products require compliance with FDA regulations. The USDA routinely reports to the FDA its findings on lots of flour, cereal, or other products which have been rejected for acceptance into USDA-sponsored programs, based on FDA guidelines. This notification of rejection is routinely furnished to the involved District office. When a District office receives such notification, it will determine appropriate follow-up by evaluating the reason for rejection, current priority assignments, and workload.

Samples should not be routinely collected from the USDA rejected material. If a follow-up inspection is made the District will then determine the need for samples or additional action.

### 3.2.1.2 - USDA Complaints

Whenever a complaint is received involving any meat-containing product, including such items as soups, combination infant foods, frozen dinners, etc., evaluate the need to contact USDA. Most products containing red meat or poultry are regulated by USDA. The exceptions include:

1. Products containing meat from game animals, such as venison, rabbits, etc.
2. Meat-flavored instant noodles
3. The product "pork and beans" which contain only a small amount of pork fat and for historic reasons is regulated by FDA.

Determine from the consumer whether there is a round "shield" on the label with the USDA establishment number. Alternatively, the establishment number may be identified in the lot number. Red meat products under USDA jurisdiction will often contain the abbreviation "EST" followed by a one to four-digit number; poultry products under USDA jurisdiction will contain the letter "P" followed by a number.

FDA reports suspected outbreaks to USDA and CDC. In addition, FDA and CDC have an agreement that FDA will be immediately advised whenever CDC ships botulism antitoxin anywhere in the United States or its possessions. See IOM 3.2.4.3 regarding interaction with CDC.

USDA and FDA have an agreement whereby FDA informs a designated USDA Compliance and Evaluation Area Office about any foodborne disease where a meat or poultry product is suspected. Conversely, USDA will alert the FDA District office on suspected products subject to FDA jurisdiction. In order for your District to alert USDA promptly, check with your supervisor immediately if meat or poultry products are involved in an outbreak you are investigating, or which comes to your attention.

### 3.2.1.3 - USDA Acts

The following USDA Acts under which FDA has been delegated detention authorities for products subject to USDA inspection are:

1. Federal Meat Inspection Act (FMIA) see IOM 2.7.1.2.2
2. Poultry Products Inspection Act PPIA see IOM 2.7.1.2.3
3. Egg Products Inspection Act (EPIA) see IOM 2.7.1.2.4

See IOM 2.7.1 for additional information. See IOM Exhibit 3-1 for a chart depicting jurisdictional lines for products regulated by FDA and USDA.

### 3.2.1.4 - FDA-USDA Agreements & MOUs

MOUs and Agreements with USDA and its various units will be listed and, in some cases, described below. This first subsection covers MOUs with the USDA, USDA/other agency, and FDA. The following subsections provide information about MOUs with other USDA units.

MOU with:

1. US Department of Commerce and USDA Concerning Inspection of Industrial Fishery Products Intended for Animal 315 Feed Use ([225-75-7001](#)).
2. USDA, NIH Regarding Importation of Biological Specimens under US/USSR Scientific Exchange Agreement ([225-74-1010](#)).
3. USDA and DHHS Regarding General War Food Inspection ([225-75-8004](#)).
4. USDA Concerning the trade facilitation of milk and milk products exported from the United States ([225-20-017](#)).

### 3.2.1.5 - Agricultural Marketing Service (AMS)/ USDA (MOUs)

MOU with:

1. AMS Concerning the Inspection and Grading of Food Products (225-72-2009).

This MOU has extensive separation of duties between AMS and FDA.

Both agencies agree to maintain a close working relationship, in the field as well as headquarters. Both agencies will work with industry toward greater efficiency connected with improvement of coding methods. Each agency will designate a central contact point to which communications dealing with this agreement or other issues may be referred to for attention.

The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).

The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).

2. AMS Regarding the Egg Products Inspection Act. FDA has exclusive jurisdiction over restaurants, institutions, food manufacturing plants, and other similar establishments, that break and serve eggs or use them in their products (225-75-4003).

AMS shall notify FDA whenever it has reason to believe that shell eggs or egg products have been shipped in commerce in violation of the act to a receiver for which FDA has exclusive jurisdiction, and notify FDA when applications are made to import shell eggs into the U.S. FDA will notify AMS so that they can check on the seller of any restricted eggs when it is determined that more restricted eggs than are allowed in U.S. Consumer Grade B. are encountered. FDA will also notify AMS of any unwholesome egg products it encounters, including imported shell eggs which contain restricted eggs not in accordance with USDA regulations and labeling requirements.

The FDA Liaison Officer is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).

The FDA Liaison Officer for imported shell eggs is the Branch Chief, Import Product Adulteration Branch, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-606 (1-888-723-3366).

The USDA Liaison Officer is the Deputy Administrator, Poultry Program, Agricultural Marketing Service (202-



- 720-4476).
3. AMS Concerning Imported Dates and Date Material (225-72-2001).  
 FDA inspects samples and examines imported dates and date products intended for processing to determine whether they are in compliance with the statute. AMS, upon request, will provide FDA with a copy of each examination report which will contain information such as that in the FDA Technical Bulletin Number 5, Microanalytical Procedures Manual.  
 The FDA Liaison Officer is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).  
 The USDA Liaison Officer is the Chief, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service (202-720-4693).
  4. AMS Concerning Cooperative Efforts for Inspection, Sampling, and Examination of Imported Raisins (225-73-2007).  
 AMS evaluates raisins for grade condition requirements and at the time and place of entry all lots of imported raisins. Upon completion of the examination, AMS promptly notifies the appropriate FDA District Office of any lots found not to meet minimum acceptance criteria because of insect infestation, filth, etc., and any questionable cases regarding the laboratory examination results. At the end of the season, the AMS provides FDA with a copy of each examination report. FDA accepts, unless it notifies USDA to the contrary, AMS findings on any lot of raisins sampled and inspected by them. FDA will detain any lots of raisins rejected by USDA because they contain insect infestation, etc. See the cooperative agreement manual for details of responsibilities.  
 The FDA Liaison Officer is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).  
 The USDA Liaison Officer is the Chief, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service (202-720-4693).
  5. AMS Regarding Aflatoxin Testing Program for In-Shell Brazil Nuts (225-96-2002).  
 Importers of Brazil Nuts voluntarily offer for USDA inspections before introducing them into U.S. commerce. USDA is responsible for sampling and testing each lot for aflatoxin in accordance with procedures prescribed by FDA and for issuing an analysis certificate for each lot. The Agricultural Marketing Service (AMS) will forward a copy of each certificate to the appropriate FDA District office. FDA accepts the certificate and then allows entry of the lots into U.S. commerce provided the aflatoxin level does not exceed the current action level prescribed by FDA.  
 The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).  
 The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).
  6. AMS Concerning Aflatoxin in Peanuts (225-96-2001).  
 AMS will use FDA administrative guidelines on objective samples to certify peanuts, recognizing that GMPs remove significant quantities of unfit peanuts and that levels of aflatoxin are reduced by heating. USDA will provide FDA with a copy of the analytical certificate and identification of the applicant on each lot found to exceed 25 ppb of aflatoxin and the analysis certificate on any lot on request. FDA will routinely confirm chemical assays in finished product at 20 ppb by bioassay procedures.  
 FDA will not formally object to the offering of lots of peanuts to processors where certificates show levels of aflatoxin above 25 ppb but will examine finished products from such lots. Such lots of raw peanuts may be subject to appropriate action in cases where there is lack of assurance that the finished product will comply with current standards.  
 The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).  
 The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).
  7. AMS and FSIS and EPA re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8910).  
 Parts of this MOU are discussed below. Information about the complete MOU can be found in the appropriate Cooperative Agreements Manual. The contact offices are as follows:  
 The FDA Liaison Office is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).  
 The USDA Liaison Office is the Administrator, Food Safety and Inspection Service (202-720-7025).  
 The EPA Liaison Office is the Office of Pesticide Programs, (703-305-7090), or Health Effects Division, (703-305-7351).
  8. AMS Concerning Salmonella Inspection and Sampling Coverage of Dry Milk Plants (225-75-4002).  
 Parts of this MOU are discussed below. Information about the complete MOU can be found in the appropriate Cooperative Agreements Manual.  
 USDA has two types of voluntary inspection programs: Plant Inspection Program for USDA Approved for Grading Services, and their Resident Inspection and Grading Program.  
 Plant Inspection Program (PIP). Under the PIP, dry milk plants are surveyed for approval every three months. This includes a salmonella surveillance testing of the plant's product and environmental material. Product inspection and grading is provided on request and dry milk products produced under this program are eligible to bear the USDA shield.  
 FDA will accept the AMS Salmonella Surveillance Program results on such plants and the finished dry milk products after shipment from those plants will not be sampled by FDA for Salmonella examinations. This does not preclude FDA sampling dry milk at manufacturing plants using dry milk as an ingredient as a follow-up to consumer complaints, or where the dry milk may have become contaminated or adulterated

after leaving the dry milk manufacturer's control. Neither will it preclude FDA inspections of any plant for problems other than Salmonella whether or not such plant produces dry milk products under USDA inspection, or the sampling of their products, including dry milk products, for problems other than Salmonella. The FDA Liaison Office is the Director, Office of Emergency Operations, HFA-615, (866-300-4374). The USDA Liaison Office is the Chief, Grading Branch, Dairy Division, Agricultural Marketing Service, (202-720-3171) or Chief, Standardization Branch, (202-720-7473).

### 3.2.1.6 - Animal Plant Health Inspection Service/USDA (APHIS)

MOU with APHIS Concerning Mutual Responsibilities for Regulating Biological Products (225-82-7000).

Referral and exchange information for purposes of investigation and appropriate legal action. To coordinate investigations and enforcement actions and to avoid duplication of effort, FDA and USDA agree to provide each other with any information which may be germane to either agency's enforcement functions. Information regarding pending investigations and enforcement actions shall be provided to the liaison officers noted below on a regular basis.

The FDA Liaison Office is the Director, Office of Surveillance and Compliance, Center for Veterinary Medicine, HFV-200, (240-453-6830).

The USDA Liaison Office is the Director, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, (301-734-8245).

APHIS and NIH Regarding the Care and Welfare of Laboratory Animals.

### 3.2.1.7 - Federal Grain Inspection Service/USDA (FGIS)

MOU with FGIS Concerning Inspection of Grain, Rice, Pulses, and Food Products (225-80-2000).

During an FDA inspection of any facility that processes, packs, or holds agricultural products, the investigator and or inspector will request that the FGIS inspector or licensee stationed at a facility accompany him/her during the inspection.

The inspector/investigator will request from FGIS any information concerning quality determinations of specific lots of products against which FDA has taken or may take action.

FDA will notify FGIS of any details concerning serious objectionable conditions found by FDA to exist in processing plants, packing plants, grain elevators, or any other facility where FGIS provides official services.

General matters involving this agreement may be referred to the agencies' liaison officers.

The FDA Liaison Office is the Director, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, HFS-300, (240-402-1488) or Director, Division of Programs and Enforcement Policy, Center for Food Safety and Applied Nutrition, HFS-305, (240-402-1988).

The USDA Liaison Office is the Director, Field Management Division, Federal Grain Inspection Service, Grain Inspection, Packers and Stockyards Administration (202-720-0228).

### 3.2.1.8 - Food Safety and Inspection Service/USDA (FSIS)

1. FSIS Pertaining to Class I and Class II Recalls of Food Products that Contain Poultry and/or Meat Products that have been Manufactured in a FSIS Inspected Establishment (225-75-4072);

FDA and FSIS agree that they will keep the customary records and make those related to the operation of this agreement available to the other agency. Both agencies will furnish reports of the progress of the work and such other reports as may be mutually agreed upon from time to time between cooperating parties.

The FDA Liaison Officer is the Director, Office of Emergency Operations, HFA-615, (866-300-3474). The USDA Liaison Officer is the Director, Emergency Planning Office, Food Safety and Inspection Service (301-504-2121)

2. FSIS Concerning Inspection of Food Manufacturing Firms FDA investigators will attempt to contact any on-site FSIS inspectors when they arrive at a plant, invite them to participate in the inspection and discuss with or report any adverse findings involving meat and poultry products to that inspector prior to leaving the premises (225-99-2001).

When report findings are classified "indicated" FDA will provide FSIS with a copy when the plant is also inspected by FSIS.

If the FDA investigator has found unsanitary conditions or otherwise adulterated products, the appropriate FSIS office should be informed by telephone unless the FDA investigator has already reported his findings to the FSIS inspector at the plant.

To any extent possible, consider information provided by FSIS to minimize duplication of effort.

The FDA Liaison Office is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).

The USDA Liaison Office is the Deputy Administrator, Field Operations, Food Safety and Inspection Service (202-720-8803).

3. FSIS and AMS and EPA re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8400).
4. FSIS (NE and SE Regional Offices), DE Department of Agriculture, MD Department of Agriculture, PA Department of Agriculture, VA Department of Agriculture and Consumer Services, WV Department of Agriculture Regarding Regulatory Investigations Involving Drug, Pesticide, and Industrial Chemical Residues in Animal Feeds and Meat and Poultry (225-76-4002).
5. FSIS and GA Department of Agriculture Regarding Regulatory Investigations Involving Drug, Pesticide, and Toxic Chemical Residues in Animal Feeds and in Meat Tissues (225-91-4000).

### **3.2.1.9 - Science and Education Administration/USDA (SEA)**

MOU with SEA Concerning Educational Programs in the Use of Animal Drugs (225-78-1002).

### **3.2.2 - U.S. DEPARTMENT OF COMMERCE (DOC)**

#### **3.2.2.1 - Commerce (DOC)**

MOUs with DOC and USDA Concerning Inspection of Industrial Fishery Products Intended for Animal Feed Use.

#### **3.2.2.2 - National Oceanic and Atmospheric Administration (NOAA) - National Marine Fisheries Service (NMFS)**

MOU with:

1. NOAA/NMFS Regarding Inspection Programs for Fishery Products (225-76-2001) - The National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA), Department of Commerce, operating under the authority of the Agriculture Marketing Act and the Fish and Wildlife Act is responsible for the development and advancement of commercial grade standards for fishery products and better health and sanitation standards in the industry and for furnishing inspection, analytical, and grading services to interested parties. The major purpose is to encourage and assist industry in improving the quality and safety of its products. This MOU outlines joint responsibilities between NOAA and FDA. See IOM 3.1.3 for guidance on joint inspections when inspecting firms under the voluntary NMFS program.  
The FDA Liaison Office is the Policy Guidance Branch, Division of Programs and Enforcement Policy, Office of Seafood, Center for Food Safety and Applied Nutrition, HFS-416 (240-402-2545).  
The NMFS Liaison Office is the Seafood Inspection Program, Department of Commerce, NOAA (301-713-2355).
2. NOAA/NMFS Concerning Enforcement of Laws (225-86-2000) - Against Illegal Commerce in Molluscan

Shellfish.

FDA will support NMFS Lacey Act investigations to the extent that regulatory authority and resources allow. This may include conducting food sanitation inspections of suspect shellfish shippers, reviewing interstate shipping records and obtaining affidavits to the extent possible, collecting and analyzing shellfish samples to be used as evidence of violations, and removing adulterated shellfish from the marketplace. Refer to the appropriate Cooperative Agreements manual for further discussion of this MOU.

The FDA Liaison Office is the Policy Guidance Branch, Division of Programs and Enforcement Policy, Office of Seafood, Center for Food Safety and Applied Nutrition, HFS-416 (240-402-2545).

The NMFS Liaison Office is the Seafood Inspection Program, Department of Commerce, NOAA (301-713-2355).

### **3.2.2.3 - U.S. Patent and Trademark Office (USP&TO) (DOC)**

MOUs with:

1. USP and TO/DOC Concerning Orphan Drugs (225-84-8000).
2. USP and TO/DOC to Establish a Product's Eligibility for Patent Term Restoration (225-86-8251).
3. DOD Concerning Food Protection (Food Safety and Food Defense) (225-16-020)

### **3.2.3 - DEPARTMENT OF DEFENSE (DOD)**

FDA has a number of MOUs with DOD and its various elements.

#### **3.2.3.1 - DOD MOUs**

1. DOD Concerning Licensure of Military Blood Banks (225-74-1017).
2. DOD Concerning FDA Responsibility for Quality Assurance of DOD Procured Drugs and Biologics (225-97-4000).
3. DOD Concerning Food Protection (Food Safety and Food Defense) (225-16-020).

FDA also has a number of Interagency Agreements (IAG) with DOD to include IAG with:

1. DOD Concerning Investigational Use of Drugs, Antibiotics, Biologics, and Medical Devices by DOD (224-75-3003).
2. DOD Regarding FDA Quality Assurance Responsibility for DOD Contracts for Medical Devices (224-82-4001).

#### **3.2.3.2 – U.S. Army Corps of Engineers (DOD)**

MOU with US Army/Corps of Engineers Concerning Consumer Protection During Natural Disasters.

### 3.2.3.3 – U.S. Army Medical Research and Development Command (DOD)

MOU with U.S. Army Medical Research and Development Command Regarding Quality Assurance Support for Medical Material Having Military Application (225-99-4000).

### 3.2.3.4 - Defense Personnel Support Center (DPSC)

1. MOU with DPSC Concerning Exchange of Information Regarding Food and Cosmetic Recalls and Hazardous Food Situations (225-82-4003).
2. The Defense Personnel Support Center purchases vast quantities of foods and drugs for use by the Armed Forces. The products are purchased on contract and must meet standards and contract specifications to be accepted. Any products failing to meet these specifications are rejected. These are mentioned in IOM 3.2.3.1 above.

FDA, under the Government-Wide Quality Assurance Program (GWQAP), furnishes information to the military regarding the capabilities of firms bidding or desiring to bid on government contracts. Occasionally Districts may be requested by the OO/OEIO/DCS/Enforcement Systems Branch to make inspections or collect samples in support of the GWQAP. When this is necessary, OO/OEIO/DCS/Enforcement Systems Branch will provide the District with specific procedures and instructions. DoD depots and hospitals must notify their command centers prior to release of their stocks. For this reason, prior to visiting a U.S. Government installation to collect samples of food, drugs or medical devices, Districts should contact OO/OEIO/DCS/Enforcement Systems Branch (see Directory, ORA Headquarters Directory, Office of Enforcement and Import Operations, Division of Compliance Systems).

### 3.2.3.5 - Department of Navy/Bureau of Medicine and Surgery

MOU with Dept. of the Navy/Bureau of Medicine and Surgery Regarding the Microwave Oven Survey (225-77-1001).

### 3.2.3.6 - Defense Health Agency (DHA), Public Health Division, Veterinary Services Branch (DHA VS) (DoD)

MOU with DoD Concerning Food Protection (225-16-020) establishes a mutually acceptable understanding between DoD and FDA that aims to strengthen global food protection programs and supports the medical readiness of the US Armed Forces. Both agencies have agreed to develop information-sharing networks and processes to share information on facility audits; recalls and/or advisories, import alerts, adverse food and supplement events, laboratory findings or methods and other food protection

procedures. Both agencies have further agreed to share laboratory data and research related to food protection including Food Emergency Response Network (FERN) and electronic Laboratory Exchange Network. DoD and FDA are collaborating in the development of food protection capabilities that include: joint inspections; training exercises; meetings and conferences; risk communications; and assessment of risk. All activities are coordinated by the agency Liaisons as per IOM section

### 3.2.3.6.1 – DoD/FDA Liaisons

FDA's MOU with DoD Concerning Food Protection (225-16-020) requires both agencies to identify and provide points of contact (POCs)/liaisons between DoD and FDA for both routine and emergency situations and exercises.

1. DoD designates the Chief, Inter-Agency Coordination (Food Protection) Officer
2. The FDA Liaison to DoD is Kathryn A. Nagy, 404-253-1225.

### 3.2.4 - DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

This Agency has a number of MOUs with the Department and other HHS units.

#### 3.2.4.1 - HHS MOUs

MOU with USDA and HHS Regarding General War Food Inspection (225-75-8004).

#### 3.2.4.2 - Administration for Children, Youth and Families (ACYF)

A MOU with ACYF to Assure the Feeding Programs in Head Start Centers Conform to Federal Food Safety and Sanitation Responsibilities (225-89-2000).

#### 3.2.4.3 - Centers for Disease Control and Prevention (CDC)

MOU with:

1. CDC Concerning In-Vitro Diagnostics (225-75-5012).
2. CDC Regarding Radiation Emergencies (225-81-6000).
3. CDC Regarding Exchange of Information and Coordination of Actions (225-82-8000).

Additional information is being provided here because of the close working agreement to assure the prompt exchange of information on suspected foodborne outbreaks.

Since it is essential that any suspected outbreaks be reported promptly to CDC, communicate any information you may learn in connection with foodborne outbreaks to your supervisor as soon as possible. Botulism Antitoxin

Shipments - CDC is responsible for maintaining and shipping necessary supplies of botulinum antitoxin. When CDC makes a shipment of botulinum antitoxin, CDC will immediately, regardless of the day or time, phone the Office of Emergency Operations (OEO), HFA-615, (866-300-4374). The OEO contact will immediately phone the consignee District to advise them of the shipment.

1. Outbreaks on Foreign Flag Vessels - If an outbreak involving a foreign flag vessel or a US Flag vessel with an international itinerary comes to your attention, report it to your supervisor immediately who will then report it to OEO 866-300-4374. This situation falls under the jurisdiction of the Vessel Sanitation Program of the Centers for Disease Control and Prevention (CDC) Atlanta, Ga.
2. Outbreaks Involving Interstate Conveyances - Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are the responsibility of FDA.

When a report of illness is received, you are encouraged to share it with state and local public health officials in case they received additional illness reports. Additionally, the procedures outlined in this Subchapter are to be followed including the following 5 items:

### 3.2.4.3.1 - INTERVIEWS

Interviews with the ill passenger, family members and/or physician (as applicable), should be in-depth enough to hypothesize whether the carrier may be related to the illness. Factors such as time of onset of symptoms, history of eating suspect foods, and other potential exposures should be considered. The carrier should also be contacted to determine whether other reports of illness have been received. The information developed should be evaluated to determine whether further follow-up is necessary (i.e., the carrier suspect). On those carriers where a reservation system is used, the names and phone numbers of passengers should be obtained to determine if other individuals became ill. It may be necessary to contact other passengers to determine if they consumed any food or water on the trip, and if they became ill in the time period associated with the original complaint. When a report of additional related or similar illnesses is received, immediately contact the Office of Emergency Operations, ORO, HFA-615, 866-300-4374 and relay the information. Also contact the state epidemiologist of the affected state to report the details of the illness. It may be advantageous to request assistance from them in the epidemiological investigation, particularly if patient specimens are needed to determine the cause.

### 3.2.4.3.2 - INFORMATION EXCHANGE AND COORDINATION

Recently FDA revised the MOU between FDA and CDC regarding exchange of information and coordination of actions. This MOU provides a framework for coordination and collaborative efforts between the two agencies. It also

provides the principles and procedures by which information exchanges between FDA and CDC will take place. The new memorandum supersedes the MOU between CDC and FDA dated 4/1/82. When receiving a request for information from the CDC immediately notify the Director of the Office of Emergency Operations, HFA-615, 866-300-4374.

"FDA and CDC agree that the following principles and procedures will govern the exchange of nonpublic information between the two agencies. Although there is no legal requirement the FDA and CDC exchange information in all cases, FDA and CDC agree that there should be a presumption in favor of full and free sharing of information between FDA and CDC. Both agencies recognize and acknowledge however that it is essential that any confidential information that is shared between FDA and CDC must be protected from unauthorized public disclosure. See e.g., 21 USC sec. 331(j); 18 USC sec. 1905; 21 CFR Parts 20 and 21; 42 CFR Parts 5 and 5b; and, 42 USC sec. 301(d). Safeguards are important to protect the interests of, among others, owners and submitters of trade secrets and confidential commercial information; patient identities and other personal privacy information; privileged and/or pre-decisional agency records; and information protected for national security reasons. Any unauthorized disclosure of shared confidential information by the agency receiving the information shall be the responsibility of that agency.

### 3.2.4.3.3 - ROUTINE REQUESTS FOR INFORMATION

Routine Requests for Information:

1. The requesting agency must demonstrate, in writing, why it is necessary for it to obtain the requested information.
2. The agency receiving the request for information shall, based upon the sufficiency of the need-to-know demonstration described in section 1 above, determine whether it is appropriate to share the requested information with the requesting agency.
3. The requesting agency agrees that:
  - a. It shall limit the dissemination of shared information it receives to internal agency offices and/or individuals that have been identified in its written request and/or have a need-to-know;
  - b. Agree in writing not to publicly disclose any shared information in any manner including publications and public meetings without written permission of the agency that has shared the information;
  - c. If the requesting agency receives a Freedom of Information Act (FOIA) request for the shared information, it will refer the request to the information-sharing agency; and,
  - d. It shall promptly notify ORA's DIDP at ORA OSPOP Testimony – Info Sharing Team [ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov](mailto:ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov) when there is any attempt to obtain shared information by compulsory process, including but not limited to a FOIA request,

subpoena, discovery request, or litigation complaint or motion.

4. The agency that shares information with the requesting agency shall include a transmittal letter, along with any agency records exchanged, indicating the type of information.

### 3.2.4.3.4 - EMERGENCY REQUESTS FOR CONFIDENTIAL INFORMATION

In cases in which the requesting agency has a need to obtain certain information as soon as possible due to emergency circumstances, such as a foodborne illness outbreak, FDA and CDC may utilize the following procedures:

1. The requesting agency shall indicate orally or in writing to the agency in possession of the relevant information that it has the need to obtain certain identifiable information as soon as possible due to the existence of emergency circumstances and describe what the emergency circumstances are.
2. The requesting agency shall verbally agree to protect from unauthorized public disclosure any and all information that is shared, according to all applicable laws and regulations.
3. The existence of an actual emergency situation shall warrant, as determined by the agency in possession of the requested records, the waiver of the need-to-know demonstration and determination described in sections 1 and 2 (Routine Requests for Information) above. However, once the requesting agency has obtained the information it seeks, it shall comply with those procedures set forth in section 3 (Routine Requests for Information) above.

### 3.2.4.3.5 - LIAISON OFFICERS

Liaison Officers

1. For FDA:
  - Office of Commissioner
  - Contact: Mark Russo, Acting Director, Office of Crisis Management
  - Food and Drug Administration
  - 12903 New Hampshire Ave.
  - White Oak, Bldg., 32, Room 1352, HFA-600
  - Silver Spring, MD 20993
  - 866-300-4374
2. For CDC:
  - Associate Director for Science
  - Harold W. Jaffee, MD, MA
  - Centers for Disease Control
  - Public Health Service
  - Department of Health and Human Services
  - Atlanta, GA 30333 404-639-7240

### 3.2.4.4 - Centers for Medicare and Medicaid Services (CMS)

MOU with Centers for Medicare and Medicaid Services (CMS) Concerning Blood Banking and Transfusion Programs (225-80-4000).

### 3.2.4.5 - Health Services Administration (HSA)

MOU with HSA Concerning Quality Assurance for Drugs, Biologics, Chemicals and Reagents Procured by HSA (225-75-8002).

### 3.2.4.6 - National Center for Health Statistics (NCHS)

A MOU with NCHS Regarding Exchange of Information (225-83-6000).

### 3.2.4.7 - National Institute of Drug Abuse (NIDA)

MOUs with:

1. NIDA Regarding Methadone Mutual Responsibilities in Implementing the Jointly Published Narcotic Addict Treatment Regulations (225-81-3000).
2. NIDA Concerning Cooperative Interaction in Expediting Domestic Scheduling of Drugs of Abuse (225-85-8251).

### 3.2.4.8 - National Institutes of Health (NIH)

MOU with:

1. NIH Regarding Anticancer Drugs (225-75-3001).
2. NIH and USDA Regarding Importation of Biological Specimens under US/USSR Scientific Exchange Agreement (225-74-1010).
3. NIH and APHIS Regarding the Care and Welfare of Laboratory Animals (225-83-8400).

## 3.2.5 - DEPARTMENT OF HOMELAND SECURITY

### 3.2.5.1 - U.S. Customs and Border Protection

MOU with:

1. Customs Service and the FDA Regarding Identifying Roles and Authority Concerning Electronic Products (225-74-6004).
2. Customs Service to Establish a Working Relationship for Cooperative Enforcement (225-79-4003).
3. Customs Services Regarding the Needs of the Trading Public in Expediting the Collection, Processing and the Use of Import Information (225-91-4003).

### 3.2.5.2 - Secret Service

The Secret Service operates under the Department of Homeland Security and is charged with the responsibility of protecting the President of the United States and certain other prominent persons. They also enforce the laws and regulations relating to currency, coins, and obligations and securities of the U.S. and foreign governments.

Authority for Secret Service to request FDA assistance, and for FDA to respond, is derived from the "Presidential Protection Assistance Act of 1976", P.L. 94-524 (90 Stat. 2475-7), Sections 1-10. Section six states in part:

"Executive Departments and Executive Agencies shall assist the Secret Service in the performance of its duties by providing services, equipment, and facilities on a temporary and reimbursable basis when requested by the Director and on a permanent and reimbursable basis upon advance written request of the Director; except that the DOD and the Coast Guard shall provide such assistance on a temporary basis without reimbursement when assisting the Secret Service in its duties directly related to the protection of the President or the Vice President or other officer immediately next in order of succession to the office of the President."

Note: At the present time the Agency is not claiming reimbursement from Secret Service until a study of total costs of our support function is completed.

FDA's authority for entry and inspection is derived from Secret Service authority and its request for FDA assistance. When called upon by the Secret Service to assist with a food service function, FDA's response is that of an advisor. Authority for decisions regarding food and beverages to be consumed by protectees is retained by the Secret Service.

Note: Do Not issue a Notice of Inspection - FDA 482 unless the investigation evolves into the collection of a sample for the enforcement of the FD&C Act. You are in the firm under the Secret Service authority.

FDA may initiate action against products encountered which are suspected of being in violation of the FD&C Act or the FPLA.

### 3.2.5.2.1 - LIAISON

The Secret Service and FDA have an arrangement whereby FDA district officials are alerted by the Secret Service when the President, Vice President or other Protectees are to visit their areas and are to consume prepared meals and Secret Service wants the food service facilities inspected. This is to assure that proper precautions are taken if any meals are to be consumed by these individuals during the stay.

If you are alerted by Secret Service Agents that the President, Vice President or other protectees will visit the area, immediately advise your supervisor in person or by telephone. Since the lead time is often short, the district must be alerted at once so proper arrangements can be made for issuance of inspectional or investigational assignments. Because of security procedures you are not to contact the Secret Service concerning protectee travel prior to notification by them even though you may hear from other sources that a protectee is to visit your area.

As part of this arrangement FDA supplies current rosters, office addresses, and telephone numbers of Regional Food

and Drug Directors, District Directors, Station Chiefs, and Residents to the Secret Service Headquarters for dissemination to their field agents.

### 3.2.5.2.2 - DEFINITIONS

Definitions:

1. Advanced Prepared Food means food that was prepared on location at the food service establishment prior to arrival of the Lead Investigator.
2. Food Service Function means a public event where food will be provided to a protectee.
3. Lead Advance Agent means the Secret Service Agent in charge of all security arrangements. This person is responsible for all sites to be visited by the protectee, and is a representative of the Office of Protective Operations (Secret Service Headquarters).
4. Lead Investigator means the FDA person designated by the FDA District/region to coordinate the investigational activities at the site of a food service function.
5. Person-in-Charge means the available person in the food service establishment authorized to make necessary changes/decisions such as the general manager, executive chef, banquet manager, caterer's representative or other management person.
6. Pre-prepared Food means potentially hazardous food that was received at the food service establishment in a prepared form. Examples would include chicken salad, liver pate, gefilte fish, hors d'oeuvres, etc. which were prepared at another location, and then transported to the food service establishment providing food for the event.
7. Protectee means any person eligible to receive the protection authorized by law.
8. Protective Detail means a team of Secret Service agents responsible for security surrounding public events to be attended by a protectee during a trip. Protective details are assigned and coordinated by Secret Service Headquarters but may include Secret Service field representatives.
9. District Contact means the Director, Investigations Branch.
10. Site Advance Agent means the Secret Service person responsible for security arrangements at a specific site to be visited by the protectee. This person is part of the protective detail headed by the Lead Advance Agent. Note: the term Site Advance Agent will include any agent designated by the Site Advance Agent to be the contact with the FDA Lead Investigator.
11. Support Personnel means FDA persons deemed necessary by FDA in order to properly inspect a food service function.

### 3.2.5.2.3 - PURPOSE

FDA's primary purpose in support of Secret Service is to minimize the possibility of the protectee becoming ill from a food intoxication or foodborne infection resulting from inadequate knowledge of food safety requirements by food service personnel, inadequate facilities, improper operating procedures, or carelessness. FDA is further concerned that

food have no visible signs of filth, and that it is prepared in a clean environment.

FDA personnel are not trained to detect deliberate attempts to harm persons by the addition of poisonous or toxic substances to food. The Secret Service retains responsibility for matters involving criminal intent. However, FDA personnel should immediately report to the Site Advance Agent peculiar behavior or suspicious conditions observed during their investigation.

### **3.2.5.2.4 - CRITERIA FOR REQUESTING FDA ASSISTANCE**

The decision to request FDA assistance is made by Secret Service Office of Protective Operations (Headquarters). FDA has provided certain criteria to aid Secret Service in determining how they might derive maximum benefit from FDA. Regardless what criteria are used, FDA should always respond to Secret Service requests for assistance. Secret Service considers factors other than the FDA supplied criteria in making its judgment regarding requests for assistance.

### **3.2.5.2.5 - SCOPE OF INVESTIGATION**

The focus of the FDA investigation should be on the menu items that the protectee will be served, or from which the protectee will make a selection. Food, facilities, personnel, procedures, etc. are only considered by FDA as they relate to the specific food and beverage items which may be consumed by the protectee. Do not conduct a traditional regulatory type food service inspection. The Food Service EIR (FDA 2420) will not normally be part of the report prepared following this special investigation. State/local regulatory authorities have jurisdiction over food establishments and have a primary responsibility for public health protection of the general public or participating members or guests of the organization sponsoring the event.

### **3.2.5.2.6 - INTERAGENCY COOPERATION**

Upon contact by Secret Service and after contacting your supervisor to apprise district management of the Secret Service request, the appropriate state/local regulatory authority should be contacted and encouraged to participate prior to and during the food service function. These officials may offer invaluable assistance because of their familiarity with the establishment and because of their regulation over the establishment on a long-term basis.

### **3.2.5.2.7 - DISTRICT CONTACT**

The district contact should receive Secret Service requests for assistance and initiate the FDA response. If a resident post is contacted directly for assistance, immediately contact your supervisor who will notify the director investigations branch. The director investigations branch will designate the lead investigator and arrange for

assignment of support personnel and equipment as required. The lead investigator could be on district or region staff according to district/region policy.

### **3.2.5.2.8 - LEAD INVESTIGATOR QUALIFICATIONS**

The best suited investigator (criteria optional) assigned to coordinate investigation of these food service functions should be one who:

1. Possesses OPM "Critical Sensitive" security clearance.
2. Is standardized in the use of the FDA Food Code.
3. Is experienced in Secret Service food service functions, if possible. New personnel should accompany experienced personnel before being assigned as Lead Investigator, if at all possible.
4. Is able and authorized to quickly mobilize an investigational team (FDA/State/Local).
5. Is able and authorized to make quick decisions on important food protection/sanitation questions.
6. Has a background in food microbiology.

### **3.2.5.2.9 - STEPS FOR CONDUCTING A SPECIAL SECRET SERVICE INVESTIGATION**

Steps for Conducting a Special Secret Service Investigation (District Contact/Lead Investigator).

Verify the call with the Secret Service and obtain from them:

1. Information about the site advance agent with whom FDA is to coordinate its activities. This should include the name(s) of agent(s) assigned, location(s) and telephone number(s).
2. Information about the firm(s) providing food for the food service function, to include:
  - a. Names of persons-in-charge of food service establishment and caterers.
  - b. Telephone numbers.
  - c. Addresses of firm(s).
  - d. Location where food service function will be held (if different).
  - e. Date of function.
  - f. Time of food events during function.

Obtain through means prearranged and agreed upon by FDA district/region management:

1. FDA support personnel needed.
2. Equipment required to conduct special investigation.

Contact the person-in-charge at the facility to:

1. Introduce the lead investigator.
2. Advise of purpose and scope of special investigation.
3. Arrange for personal interview to discuss menu, food preparation schedule and history (times/specific locations in establishment), and any intended use of pre-prepared foods.
4. Obtain telephone number(s) at the site(s) where FDA lead investigator may be reached while on location.



Contact state and local regulatory agencies responsible for retail food protection and sanitation. Request participation by inspectional personnel of the local office which provides routine inspectional coverage of the facility where the food service function is being held.

Meet with person-in-charge on location, in order to:

1. Be introduced to other key employees who have responsibility for the target meal or kitchen facilities, i.e. banquet manager, executive chef, maintenance supervisor, etc.
2. Inform person-in-charge of the names of other FDA, state, or local regulatory personnel to be involved.
3. Obtain the use of an area within the establishment that will become an FDA base of operations. The location should have convenient access to a telephone but may not be necessary for small functions.

Coordinate with Secret Service command post on location, in order to:

1. Inform site advance agent of the names of other FDA, state or local regulatory personnel to be involved.
2. Determine method for final selection of specific meal(s) to be served to protectee(s).

Carry out investigation by:

1. Basing judgments on the provisions of the FDA Food Code. In consideration of food sources, food protection, personnel, food equipment/utensils, water, waste disposal, vermin control, storage and use of toxic materials, and other code items as they relate to the food items to be served to the protectee.
2. Taking the history of each item on the menu to be served to the protectee. The history for each potentially hazardous food (including advance prepared and pre-prepared Food) must be detailed. Include timetables for preparation and storage, and the names of specific employees involved in its preparation. This will immediately establish parameters needed for FDA to complete a comprehensive, but well focused investigation (See IOM 3.2.5.2.3 above. Though every effort should be made by the lead investigator to help the person-in-charge and the Secret Service in their efforts to assure that preparation and arrangements for the food service function flow smoothly and efficiently, FDA personnel must be aware that their responsibility is for assuring that all prudent steps have been taken to minimize the risk of foodborne illness to the protectee.

### 3.2.5.2.10 - SAMPLING

Samples shall be collected at the discretion of the lead investigator. Two types of samples should be considered.

1. Typical Meal - In the unlikely event that a protectee (or others) becomes acutely or seriously ill during the hours following a food service function, it could be very helpful to have samples of meals served for analysis. Should this happen, FDA's response should be coordinated with the FDA Office of Emergency Operations at 866-300-4374.

FDA under Secret Service authority should request that two complete meals, including beverages, be randomly selected from the meals being served to the head table. This selection should be made by the same person and at the same time head table meals are selected.

If a reception is a planned part of the event, an example of each type of hors d'oeuvres should also be retained. These meals should be kept intact, covered, and retained under refrigeration by the person-in-charge for 72 hours following the event. Cost of the meals may, at the establishment's option, be invoiced to the organization sponsoring the food service function.

Note: Examples of food items selected in this manner cannot be considered a representative sample of food offered at the function. However, such food examples could be an aid to the FBI and food regulatory personnel, should a suspected food related illness occur.

2. Food Samples - Occasionally, the lead investigator may elect to collect official samples of a food product because of a selected violation of the FD&C Act or for some other reason. When this is done, issue an FDA 482, Notice of Inspection. In these cases, samples should be collected in accordance with procedures outline in IOM Chapter 4.

### 3.2.5.2.11 - REPORTING

Verbal Report - The lead investigator shall report to the site advance agent in person or by telephone.

1. Significant adverse findings should be immediately reported to the site advance agent during the investigation, if resolution of the finding has the potential for disrupting the smooth flow of the food service function.
2. At the conclusion of the investigation, and prior to leaving the location, notify the site advance agent of FDA conclusions and recommendations. One of the following responses would be normal:
  - a. No restrictions recommended. Protectee should be permitted to consume any food or beverage being offered.
  - b. A recommendation that the protectee be advised that one or more specifically named items available should not be selected or consumed.
  - c. In unusual cases, it may be necessary to recommend that the protectee not eat food prepared for the event, or not drink the water provided.

Narrative Report - Following each special investigation conducted for the Secret Service, write a Memo of Investigation for your supervisor's endorsement. The report is for FDA's internal use and should be a chronological accounting beginning with how and when the Secret Service request was received and concluding with recommendations tendered to the Secret Service, and any F/U actions recommended to or planned by participating State/local food protection agencies. The narrative report should include time frames, contact persons, a copy of the menu, a description of the investigational process used, adverse findings, corrective steps taken, the selection and retention of typical meals, and how and why official samples

(if any) were collected and submitted, and a discussion of other matters of significance in your opinion.

Each narrative report must contain:

1. Total time on location.
2. Total time of inspection including, time on location and time necessary for making arrangements in advance, and preparation and submission of required reports. It does not include travel time.
3. Total travel time and mileage.

### 3.2.6 - DEPARTMENT OF JUSTICE

#### 3.2.6.1 - U.S. Attorney

You may be contacted by the U.S. Attorney's office to discuss possible or pending cases or other matters pertinent to FDA. Notify your supervisor of these contacts. You may be accompanied by your supervisor or a compliance officer. If you are contacted by the U.S. Attorney's Office regarding any criminal issues, this is to be referred immediately to the appropriate OCI Office.

During any discussion with the U.S. Attorney, inform him that you are qualified to report the facts of whatever case or item being discussed, but inform him that you are a fact witness only and not qualified as an "expert".

#### 3.2.6.2 - Drug Enforcement Administration (DEA) (Formerly: Bureau of Narcotics)

You should follow the procedures outlined in the Information Disclosure manual if you receive a request to share information with another Federal agency.

#### 3.2.6.3 - Federal Bureau of Investigation (FBI)

The FBI, USDA and FDA are authorized to investigate reported tampering of FDA regulated consumer products under the Federal Anti-Tampering Act (FATA), Title 18, USC, Section 1365. In most cases, FDA's authority for such investigations is also found in the FD&C Act.

USDA and the FBI share enforcement of the FATA with FDA as described below:

1. **FBI Responsibility** - FDA understands that the FBI's primary response in FATA matters will be to investigate particularly those cases that involve a serious threat to human life or if a death has occurred. The FBI will also investigate FATA matters involving threatened tamperings, and actual or threatened tamperings coupled with an extortion demand. The FBI will rely on FDA to determine if tampering with FDA products has occurred.

2. **USDA Responsibility** - The USDA will investigate and interact with the FBI on tampering with products regulated by USDA.

For complete information regarding FBI/FDA actions under FATA, see IOM 8.1.5.9.3.

#### 3.2.6.4 - U.S. Marshals Service

The U.S. Marshals Service (USMS) is the enforcement arm of the federal court. The USMS is primarily responsible for the service of civil process. In other words, when FDA takes an action, such as seizure the U.S. Marshal actually serves the complaint for forfeiture and "arrests" the goods. FDA employees typically accompany the U.S. Marshal to assist in identifying the goods which are to be seized. The USMS is also responsible for ensuring the safe conduct of judicial proceedings and protecting federal judges, jurors and other members of the federal judiciary. District Offices may find it useful to contact the local U.S. Marshals when preparing a situation plan to deal with issues of personal safety while conducting inspections or other operations. See IOM 5.2.1.2.2. and <http://www.usmarshals.gov/>

### 3.2.7 - DEPARTMENT OF LABOR: OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

The MOU with OSHA Concerns Standards for Electronic Product Radiation (225-74-6008).

### 3.2.8 - TREASURY DEPARTMENT

Many different agencies operate under the direction of this department. These include the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau. Agreements and MOUs with the Treasury Department will be discussed below.

#### 3.2.8.1 - Alcohol and Tobacco Tax and Trade Bureau (TTB)

FDA and TTB share jurisdiction over alcoholic beverages. The MOU between FDA and TTB (formerly the Bureau of Alcohol, Tobacco and Firearms (ATF)) delineates the enforcement responsibilities of each agency with respect to alcoholic beverages (MOU 225-88-2000). This MOU, among other things, confirms that TTB will be responsible for testing alcoholic beverages to determine the extent of an adulteration problem and that when FDA learns or is advised that an alcoholic beverage is or may be adulterated, FDA will inform TTB. FDA will also provide laboratory assistance and health hazard evaluations at TTB request. TTB generally has responsibility for alcoholic beverage labeling; however, FDA also has jurisdiction over the labeling of wine with less than 7% alcohol by volume (such as alcoholic ciders and most wine coolers), and beer described in the TTB's

Ruling 2008-3

(<https://www.ttb.gov/images/pdfs/rulings/2008-3.pdf>) as not being a “malt beverage” (also see FDA Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration, (<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm166239.htm>)). Labeling questions for these alcoholic beverages that are under FDA’s jurisdiction should be directed to Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, 240-402-2373.

Based on this MOU (225-88-2000), FDA should refer all complaints involving alcoholic beverages (distilled spirits, wines, and malt beverage products except for labeling issues related to wine with less than 7% alcohol by volume and beer described in the TTB’s Ruling 2008-3 as not being a “malt beverage”) to TTB using the procedure outlined below. When a complaint is received from a consumer, it should be entered into FACTS with the disposition “referred to other Federal agency”. If the complaint is reporting a suspected tampering, it should be referred to the home district and OCI for follow up. In all cases, a copy of the FACTS consumer complaint report should be forwarded directly to the TTB Market Compliance Office with a copy to the FDA liaison officer to facilitate appropriate follow up between the two agencies at the headquarters level.

TTB Market Compliance Office can be reached at 202-453-2251 (Email: [Market.Compliance@ttb.gov](mailto:Market.Compliance@ttb.gov); Fax: 202-453-2873). The FDA Liaison Officer (Office of Food Safety, Center for Food Safety and Applied Nutrition) can be reached at 240-402-1700 (Email: [FDA-TTB-Liaison-Officer@fda.hhs.gov](mailto:FDA-TTB-Liaison-Officer@fda.hhs.gov); Fax: 301-436-2632).

### 3.2.8.2 - Internal Revenue Service (IRS)

MOU with IRS Concerning Legal Actions Taken by FDA Against Alcoholic Beverage Firms for Under filling of Containers (225-71-2006).

The FDA Liaison Office is the Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-605 (240-402-2094).

The ATF Liaison Office is the Chief, Industry Compliance Division (202-927-8100).

### 3.2.9 - DEPARTMENT OF VETERANS AFFAIRS VETERANS ADMINISTRATION (VA)

MOU with the VA are:

1. Concerning Exchange of Medical Device Experience Data (225-75-5011).
2. Concerning Communications and Cooperation Regarding Clinical Research with Investigational New Drugs and Devices, Including Biologicals (225-82-8400).

3. To promote cooperation and coordination between the Food and Drug Administration and the Veterans Health Administration for the purpose of enhancing food safety and sanitation in food operations serving health care facilities of the Department of Veterans Affairs (225-93-2000).

IAGs with the VA are:

1. VA Concerning FDA Responsibility for Quality Assurance for Drugs, Biologicals, Chemicals and Reagents Procured by VA (224-76-8049).
2. VA Regarding FDA Quality Assurance Responsibility for VA Contracts for Medical Devices (224-82-4002).
3. To provide mammography inspections, pursuant to Public Law 102-539 and Public Law 104-262, to Veterans Health Administration facilities.

### 3.2.10 - CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

MOUs with CPSC are:

1. CPSC Concerning CPSC Use of FDA Documents (225-74-8001).
2. CPSC Regarding Jurisdiction with Respect to Food, Food Containers, and Food Related Articles and Equipment (225-76-2003).

### 3.2.11 - ENVIRONMENTAL PROTECTION AGENCY (EPA)

The EPA administers many Acts one of them is the National Environmental Protection Act (NEPA). FDA must be guided by this Act when assisting in voluntary destructions, disposal of laboratory wastes, etc.

Do not condone the wanton pollution of waterways, uncontrolled burning, the creation of a public nuisance or other questionable disposal practices. Note that certain products should not be disposed of in a conventional manner (e.g., sanitary landfill, flushing down the drain, etc.). In particular, certain products that have been banned in the past (chloroform, methapyrilene, hexachlorophene, PCB, etc.), are classified by EPA as hazardous and toxic substances and may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of without prior consultation by the firm with the U.S. Environmental Protection Agency and/or the regulating state authority. Refer to [21 CFR 25](#) and the National Environmental Protection Act for guidance regarding the environmental impact of voluntary destructions.

#### 3.2.11.1 - EPA MOUs

MOUs with:

1. EPA Regarding Matters of Mutual Responsibility Under Federal FD&C Act and Federal Insecticide, Fungicide and Rodenticide Act (225-73-8010).

2. EPA Regarding Potable Water on Interstate Conveyances (225-78-4006).  
The EPA administers a regulatory program in this area, but FDA has the responsibility of notifying the ICC headquarters when problems are found. FDA will, if deemed appropriate include conveyances in their inspection/monitoring schedule. Both agencies will coordinate enforcement efforts, thereby avoiding duplication of efforts.
3. EPA Concerning Control of Drinking Water (225-79-2001).  
FDA has responsibility for water, and substances in water, used in food and for food processing and bottled drinking water.  
FDA will take appropriate regulatory action to control bottled drinking water and water and substances in water, used in food and for food processing.  
The FDA Liaison Office is the Division of Programs and Enforcement Policy, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, HFS-305 (240-402-1488).  
The EPA Liaison Office is the Drinking Water Technologies Branch, Drinking Water Standards Division (202-260-3022).
4. EPA and USDA (FSIS and AMS) re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8400).

New York, NY 10278  
212-264-7662

Charles J. Walters  
EPA Region III  
841 Chestnut Bldg  
Philadelphia, PA  
19106  
215-597-7291  
303-294-1063

Robert E. Safay  
Air & Waste Mgmt Div.  
Region IV  
345 Courtland St.  
Atlanta, GA 30365  
404-347-1847

Louise A. Fabinski  
Emerg. & Remedial Br.  
EPA Region V (M-SHS-6)  
77 W. Jackson Blvd  
Chicago, IL 60604  
312-886-0840

Kansas City KS 66101  
913-551-7692

Glenn J. Tucker  
ATSDR Region VIII (8HWM-FF)  
Waste Management Div.  
Suite 500  
999 18th St.  
Denver, CO 80202

William Q. Nelson  
ATSDR Region IX  
75 Hawthorne St  
Rm 09261  
San Francisco, CA 94105  
415-744-2194

George Thomas  
EPA Region X (MSHW113)  
1200 6th Ave.  
Seattle, WA 98101  
206-553-2113

Some situations where ATSDR guidance is indicated are mentioned below.

In wrecks the physical impact usually causes most damage. Toxic items in the same load, this is illegal, may rupture and add to the contamination. In train wrecks, other railcars loaded with chemicals, oils or other contaminating materials may rupture and contaminate food and drug products in otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Do not overlook the possibility that runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms under FDA jurisdiction.

Chemical spills occurring on land or water can pose a serious threat to the environment and contaminate FDA regulated products both directly and indirectly.

Hazardous waste sites also pose a hazard to the immediate environment, as well as offsite, if runoff contaminates nearby surface waters or if leachate contaminates ground water supplies.

**3.2.12 - AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)**

The ATSDR (formerly CDC Superfund) staff has been designated as the lead agency for the DHHS response to chemical emergencies. The CDC ATSDR Public Health Advisors are located at the EPA Regional Offices. These advisors would not only alert your office of chemical emergencies but would be invaluable in answering questions concerning the severity of the problem and discussing protective measures. Under no circumstances, are FDA employees to enter areas designated as hazardous.

If it is necessary to contact ATSDR employees, their addresses and phone numbers are listed below:

**AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (FORMERLY KNOWN AS SUPERFUND)**

Louise A. House  
EPA Region I  
ATSDR  
EPA Bldg  
60 Westview St.  
Lexington, MA 02173  
617-860-4314

George Pettigrew  
EPA Region VI (6HE)  
1445 Ross Ave.  
Dallas, TX 75202  
214-655-8361

Arthur Black  
EPA Region II  
Rm 3137C  
26 Federal Plaza

Denise Jordan-Izaguirre  
EPA Region VII  
Waste Management Branch  
726 Minnesota Ave

**3.2.13 - FEDERAL TRADE COMMISSION (FTC)**

The MOU with FTC Concerns Exchange of Information (225-71-8003).

**3.2.14 - U.S. NUCLEAR REGULATORY COMMISSION (NRC)**

The U.S. Nuclear Regulatory Commission and the U.S. Department of Health and Human Services, Food and Drug Administration signed a MOU (225-03-4001) on August 26, 1993 (FR Vol. 58, No. 172, 09/08/93, 47300-47303). The purpose of the MOU is to coordinate existing NRC and FDA regulatory programs for medical devices (including utilization facilities used for medical therapy), drugs, and biological products utilizing byproduct, source, or special nuclear material regulated under the Atomic Energy Act of 1954, as amended. These regulatory programs include activities for evaluating and authorizing the manufacture, sale, distribution, licensing, and labeled intended use of such products.

Medical devices affected by this MOU include but are not limited to: in vitro diagnostic kits (radioimmunoassay); utilization facilities licensed to perform medical therapy; and teletherapy and brachytherapy sources, systems, and accessory devices. Biologicals include, but are not limited to, licensed in vitro diagnostic kits (radioimmunoassay), and certain radiolabeled biologics for in-vivo use. Drugs include all those that contain byproduct, source, or special nuclear material.

The organizations in FDA that are responsible for regulating these products are CDRH, CDER, and CBER.

The FDA Liaison Offices are the Center for Devices and Radiological Health, Director, Office of Regulatory Programs(301-796-5895), Center for Drug Evaluation and Research, Director, Office of Compliance, HFD-300 (301-796-3100), and the Center for Biologic Evaluation and Research, Director, Office of Compliance and Biologics Quality, HFM-600 (301-827-6190).

The NRC Liaison Office is the Director, Office of Nuclear Material Safety and Safeguards (301-504-3352).

### 3.2.15 - U.S. POSTAL SERVICE (USPS)

FDA cooperates with postal authorities in areas of mutual concern. If contacted by postal authorities, extend courtesy and cooperation. In any doubtful situation or incidents involving excessive expenditure of time and/or resources, check with your supervisor

#### 3.2.15.1 - Change of Address Information

At times during an investigation or inspection it may become necessary to visit local post offices to obtain new or forwarding addresses of individuals involved. Procedure:

1. Introduce yourself and display your credentials to the local P.O. clerk or official.
2. State the information desired.
3. Present the clerk or official on duty the statement in writing on FDA letterhead using the wording from IOM Exhibit 3-3 which may be reproduced or typed on district letterhead.
4. If you are still refused information or delayed in any manner, contact the nearest U.S. Postal Inspector to handle the matter.

5. At this time there is no charge for providing this information to a Federal Agency. The regulation promulgating a fee has been stayed.

#### 3.2.15.2 - Postal Box Information

At times during an investigation or inspection it will become necessary to obtain the name and address of the holder of a postal box (PO Box).

Procedure:

1. Introduce yourself and display credentials to the local P.O. clerk or official.
2. State the information you desire.
3. Present the clerk or official the statement in writing on FDA letterhead using the wording from IOM Exhibit 3-3 which may be reproduced or typed on district letterhead.
4. At this time there is no charge for providing this information to a Federal Agency. The regulation promulgating a fee has been stayed.
5. If you are still refused the information or are delayed in any manner, contact the nearest U.S. Postal Inspector to handle the matter.

#### 3.2.15.3 - Authority

The authority for providing forwarding address information to government agencies is defined in [39 CFR 265.6\(d\)\(5\)\(i\)](#) which states as follows: (5) Exceptions. Except as otherwise provided in these regulations, names or addresses of postal customers will be furnished only as follows: (i) To a federal, state, or local government agency upon prior written certification that the information is required for the performance of its duties.

Additionally, [39 CFR 265.6\(d\)\(7\)](#) may apply: Address verification. The address of a postal customer will be verified at the request of a federal, state, or local government agency.

### 3.2.16 - FIRM LOCATIONS

Many firms FDA is required to inspect are difficult to locate, including growers, farms, and other types of operations in rural areas. Directions to these firms can be obtained from many sources, including:

1. Visits to Post Offices.
2. If the envelope has a postal meter number and no return address, check with the USPS to determine the name of the firm or holder of that "PB Meter" number.
3. Visits to local health departments.
4. Visits to county extension services.
5. Visits to USDA - Agricultural Stabilization and Conservation Offices of Soil Conservation Service Offices.

Many of these offices have maps of the counties, municipalities, etc. which can be purchased or copied and used with their guidance to find the firms.

After the directions are obtained or the maps copied, copies of the maps with directions can be included in the factory jacket.

### 3.2.17 - FEDERAL FOOD SAFETY COALITION

In August 1999, FDA began an interagency Federal Food Safety Coalition with other federal agencies in an effort to focus on food protection of high-risk populations. The group's objective is to promote the development of effective public health protection systems for food safety within federal programs using the FDA Model Food Code, emphasizing foodborne illness interventions, to reduce the occurrence of the five leading illness risk factors. A formal MOU or partnership has not yet been developed. The agency members are as follows:

1. Dept. of Veterans Affairs, Veterans Health Admin.
2. United States Department of Agriculture, Food and Nutrition Service Child Nutrition Division
3. Dept. of Justice, Bureau of Prisons
4. Dept. of Health and Human Services:
  - a. Head Start Program
  - b. Administration on Aging
  - c. Indian Health Services
  - d. Centers for Medicare and Medicaid Services
  - e. Food and Drug Administration, Center for Food Safety and Applied Nutrition
5. CDC – Vessel Sanitation Program
6. Department of Defense:
  - a. US Air Force
  - b. US Army
  - c. US Coast Guard
  - d. US Navy
7. Department of Interior, National Park Service
8. US Congress, Office of the Attending Physician

## SUBCHAPTER 3.3 - STATE OPERATIONAL AUTHORITY

### 3.3.1 - STATE OPERATIONAL AUTHORITY

Establishment Inspections - All state and local officials have some type of jurisdiction over the food and drug establishments located within their state or local boundaries, regardless of the interstate movement or origin of the products involved. Some states divide the responsibility for food, drugs, etc., among the various agencies within the state. See IOM 3.3.3<sup>1</sup>.

Samples - All state laws provide authority to collect samples of food, drug, and other products within the state.

Embargoes - FDA does not have embargo authority. Some states have embargo and detention authorities, these

authorities are specific within each state. FDA does have administrative detention authority for medical devices and food. Administrative detention for medical devices and food can be used when the Agency has reason to believe that the article is adulterated, misbranded, or presents a threat of serious adverse health consequences to humans or animals. See [FD&C Act section 304\(g\)](#) and [\(h\)](#), IOM 3.2.1.3, 2.2.10, and 2.7.1 for administrative detention information.

Some state laws empower their inspectors to place an immediate embargo on products that are, or are suspected of being, adulterated or misbranded or otherwise in violation of their laws. As a cooperative measure most state agencies will have their inspectors place an embargo at the request of an FDA representative. Do not routinely request such embargo. District assignments may include instructions relative to cooperative embargoes.

In all instances, exercise care in requesting embargoes. In accordance with [Field Management Directive 50 \(FMD 50\)](#), the appropriate state agency should be notified of pending or recommended compliance/enforcement actions within five working days. When a state institutes an embargo at FDA's request, the District must assure that cooperating officials are kept informed of the status of the resulting administrative or legal action. The District must promptly notify state officials when the resulting action is final so that the state can update records and issue required releases for the lot. This helps prevent inordinately long holding times by the state.

Embargoes should not be considered as a mere convenience to the Food and Drug Administration but as an important and effective cooperative measure to be applied only when circumstances indicate such action.

Disaster Operations - Following major disasters, FDA regional directors and District directors will arrange for close cooperation with local and state food and drug officials, Health Departments, the Public Health Service and other agencies engaged in comparable work. When requested to do so, FDA District personnel will assist local and state officials during such emergencies. At such times FDA personnel may be temporarily commissioned by local or state authorities and provided the authority to place embargoes ([See IOM 8.1.5.8.6](#)).

#### 3.3.1.1 - FDA Personnel with State Authority

Certain states have designated selected FDA employees as special representatives or agents of the particular state agency. In these cases, they have furnished the FDA individuals with official state credentials. The FDA representatives given this authority will receive instructions and training, by their District, in the proper exercise of the powers conferred on them and must operate within the guidelines established by their District to monitor this authority. This is particularly important whenever state embargo powers may be used.

### 3.3.1.2 - Joint Inspections

Joint inspections with state or local inspectors are arranged by the District supervisory personnel. Joint inspections are conducted in the same manner as inspections by FDA alone and findings are discussed with the accompanying inspector. The cooperating inspector may wish to take action against the merchandise or the firm under pertinent local or state laws.

### 3.3.1.3 - FDA Commissioned State Personnel

Qualified state regulatory officials may be commissioned under section 702(a)(1)(A) of the FD&C Act to conduct examinations and investigations, which can include conducting inspections, collecting samples, copying and verifying records and carrying out an administrative detention order (following approval by the FDA District Director) under the FD&C Act.

## 3.3.2 - STATE MEMORANDA OF UNDERSTANDING

The FDA has entered into agreements with various state and local agencies covering a variety of issues and work sharing agreements. At the present time not all the states have entered into agreements with FDA. A listing of current MOUs for states, the District of Columbia, and the Commonwealth of Puerto Rico are on [FDA's MOU page](#).

## 3.3.3 - STATE AUTHORITIES AND PHONE CONTACT NUMBERS

This section contains information regarding various state enforcement authorities. Some states operate under state laws patterned after the FD&C Act of 1906 or the current FD&C Act. However, most of the states operate under a "Uniform FD&C Act" which was developed by the Association of Food and Drug Officials (AFDO).

States that have adopted the Uniform FD&C Act as their legal guideline have in most cases adopted the entire act. The food authority in most cases includes among other things the adoption of the food and color additive provisions, pesticide residue amendments, enrichment guidance, etc. The Uniform FD&C Act also includes a provision for automatic adoption of changes in the FD&C Act. Some state legislatures have also included this provision in their laws. Some other provisions of the Uniform Act adopted by state include the new drug provisions, medical device laws, and cosmetic requirements.

Some states have also adopted the Association of American Feed Control Officials (AAFCO) model bill as their legal guideline for feed inspections.

In most cases the contact for "Consumer Protection Issues" would be located in the Office of the State Attorney General

and would usually cover consumer fraud and other consumer protection issues. The State Attorney General's staff usually has mechanisms to deal with health fraud issues not efficiently dealt with by traditional FDA approaches. Contact your District Health Fraud Monitor for guidance in cooperative efforts with the State Attorney General's staff.

A complete listing of the personnel and programs at the state and local level may be found in the FDA Internet Directory of State and Local Officials which was prepared by the Office of Partnerships (HFC-150) at <https://www.fda.gov/ForFederalStateandLocalOfficials/default.htm> or <http://www.afdo.org/>

### 3.3.3.1 - Alabama (AL)

Alabama has adopted the FD&C Act of 1906 and the 1970 AAFCO as their legal guideline. The control agencies are Agriculture and Health. They have not adopted the new drug provisions, the medical device law, nor the automatic adoption provisions.

### 3.3.3.2 - Alaska (AK)

Alaska has adopted the Uniform FD&C Act without the automatic adoption provision and have not adopted either AAFCO feed bill. The controlling agencies are Health, Social Services, and Environmental Conservation. Alaska has adopted the various provisions of the Uniform bill.

### 3.3.3.3 - Arizona (AZ)

Arizona operates under the Uniform FD&C Act and the 1970 AAFCO Feed Bill. The controlling agencies are Health, Pharmacy and the State Chemist. They have not adopted the medical device law, cosmetics law, nor the automatic adoption provisions of the Uniform FD&C Act.

### 3.3.3.4 - Arkansas (AR)

Arkansas operates under the Uniform FD&C Act and the 1970 AAFCO Feed Bill. The agencies in control are Health and the Plant Board. They have not adopted the new drug provisions or the automatic adoption provision.

### 3.3.3.5 - California (CA)

California has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

### 3.3.3.6 - Colorado (CO)

Colorado has adopted the Uniform FD&C Act and the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted either version of the AAFCO Feed Bill.

**3.3.3.7 - Connecticut (CT)**

Connecticut has adopted the FD&C Act, the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Consumer Protection.

**3.3.3.8 - Delaware (DE)**

Delaware has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health, and Pharmacy. They have not adopted the food and color additive amendments, the pesticide residue amendment, enrichment amendment, new drug provisions, medical device law, and the cosmetics law.

**3.3.3.9 - Florida (FL)**

Florida has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

**3.3.3.10 - Georgia (GA)**

Georgia has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the food additive, color additive or pesticide residue amendments.

**3.3.3.11 - Hawaii (HI)**

Hawaii has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health and the Attorney General.

**3.3.3.12 - Idaho (ID)**

Idaho has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill and has not adopted the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health and Pharmacy. They have not adopted the food additive, color additive or pesticide residue amendments of the Act.

**3.3.3.13 - Illinois (IL)**

Illinois has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

**3.3.3.14 - Indiana (IN)**

Indiana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Health and the State Chemist.

**3.3.3.15 - Iowa (IA)**

Iowa has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the FD&C Act. The controlling agencies are Agriculture, Health and Appeals, and Pharmacy.

**3.3.3.16 - Kansas (KS)**

Kansas has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill and has not adopted the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

**3.3.3.17 - Kentucky (KY)**

Kentucky has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Human Resources, Pharmacy, and the University of Kentucky Registration Services.

**3.3.3.18 - Louisiana (LA)**

Louisiana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the provisions of the medical device law.

**3.3.3.19 - Maine (ME)**

Maine has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the food and color additive amendments nor the new drug provisions or the medical device law.

**3.3.3.20 - Maryland (MD)**

Maryland has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

**3.3.3.21 - Massachusetts (MA)**

Massachusetts has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption



provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions of the Act.

### **3.3.3.22 - Michigan (MI)**

Michigan has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce, Licensing and Registration. They have not adopted the enrichment provisions or the cosmetics law.

### **3.3.3.23 - Minnesota (MN)**

Minnesota has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the enrichment provisions, the new drug provisions, the medical device law, nor the cosmetic law.

### **3.3.3.24 - Mississippi (MS)**

Mississippi has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce and the State Chemistry Lab. They have not adopted the food additive, color additive, and pesticide residue amendments, nor the new drug provisions or cosmetic law.

### **3.3.3.25 - Missouri (MO)**

Missouri has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

### **3.3.3.26 - Montana (MT)**

Montana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

### **3.3.3.27 - Nebraska (NE)**

Nebraska has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions nor the medical device and cosmetic laws.

### **3.3.3.28 - Nevada (NV)**

Nevada has adopted the Uniform FD&C Act but not the automatic adoption provisions of the Uniform FD&C Act. They have not adopted either version of the AAFCO Feed Bill. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

### **3.3.3.29 - New Hampshire (NH)**

New Hampshire has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

### **3.3.3.30 - New Jersey (NJ)**

New Jersey has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the pesticide residue amendment.

### **3.3.3.31 - New Mexico (NM)**

New Mexico has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Environment, Health and Pharmacy. They have not adopted the food additive or color additive amendments.

### **3.3.3.32 - New York (NY)**

New York has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Markets, Health, and Pharmacy. They have not adopted the cosmetics law.

### **3.3.3.33 - North Carolina (NC)**

North Carolina has adopted the Uniform FD&C Act and both versions of the AAFCO Feed Bills along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture. They have not adopted the enrichment provisions of the Act.

### **3.3.3.34 - North Dakota (ND)**

North Dakota has adopted the Uniform FD&C Act and neither version of the AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Consolidated Laboratories, Health and Pharmacy.

**3.3.3.35 - Ohio (OH)**

Ohio has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

**3.3.3.36 - Oklahoma (OK)**

Oklahoma has adopted the Uniform FD&C Act but neither version of the AAFCO Feed Bills nor the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the food additive or color additive amendments, the enrichment provisions nor the new drug provisions.

**3.3.3.37 - Oregon (OR)**

Oregon has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the cosmetics law.

**3.3.3.38 - Pennsylvania (PA)**

Pennsylvania has adopted the 1906 FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the food additive, color additive, and pesticide residue amendments nor the enrichment provisions.

**3.3.3.39 - Rhode Island (RI)**

Rhode Island has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Environmental Management and Health.

**3.3.3.40 - South Carolina (SC)**

South Carolina has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

**3.3.3.41 - South Dakota (SD)**

South Dakota has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce and Regulations. They have not adopted the new drug provisions, medical device law, nor the cosmetics law.

**3.3.3.42 - Tennessee (TN)**

Tennessee has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture.

**3.3.3.43 - Texas (TX)**

Texas has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Health and the State Chemist.

**3.3.3.44 - Utah (UT)**

Utah has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions.

**3.3.3.45 - Vermont (VT)**

Vermont has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions.

**3.3.3.46 - Virginia (VA)**

Virginia has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

**3.3.3.47 - Washington (WA)**

Washington has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

**3.3.3.48 - West Virginia (WV)**

West Virginia has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health and Pharmacy. They have not adopted the food additives or color additive amendments, the new drug provisions, the medical device law and the cosmetics law.

**3.3.3.49 - Wisconsin (WI)**

Wisconsin has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption

provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the enrichment provisions, the new drug provisions, the medical device law, and the cosmetics law.

### 3.3.3.50 - Wyoming

Wyoming has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture.

## SUBCHAPTER 3.4 - INTERNATIONAL ARRANGEMENTS

### 3.4.1 - INTERNATIONAL ARRANGEMENTS

The Agency has over the years entered into agreements with foreign governments regarding the quality of foods, drugs, and other products exported to the United States. Refer to FDA's website at <https://www.fda.gov/international-programs/international-arrangements/cooperative-arrangements> for additional information.

### 3.4.2 - MUTUAL RECOGNITION AGREEMENTS

#### 3.4.2.1 - European Community

Changes in FDAMA have required that FDA begin the process of acceptance of mutual recognition agreements relating to the regulation of FDA regulated commodities, facilitate commerce between the US and foreign countries and other activities to reduce the burden of regulation and to harmonize regulatory requirements. See [Section 410 of FDAMA](#). Additional specific information is available at <https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra>.

#### 3.4.2.2 - Food Products

In July 1999, the United States and the EC signed the "AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN COMMUNITY ON SANITARY MEASURES TO PROTECT PUBLIC AND ANIMAL HEALTH IN TRADE IN LIVE ANIMALS AND ANIMAL PRODUCTS". This agreement is very much like a mutual recognition agreement and is based on the equivalence process. It covers a very wide range of human food products, all of animal origin, such as milk and dairy products, seafood, honey, wild game, snails, frog legs and canned pet food. For purposes of this agreement, the EC is considered one "party" and not 15 Member States. Activities to begin assessing equivalence are underway.

## SUBCHAPTER 3.5 - NON-GOVERNMENT AGREEMENTS

The Agency has entered agreements with various non-governmental groups to formulate various programs and guidance See [FDA's Cooperative Agreements page](#).

**3-1 FDA/USDA JURISDICTION**

This table summarizes information concerning jurisdiction overlap for commercial products regulated by either or both FDA and USDA. It does not cover products made for on-site consumption such as pizza parlors, delicatessens, fast food sites, etc.

FDA JURISDICTION	USDA JURISDICTION	
<p>21 USC 392(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals and all members of the deer family including elk (wapiti) and moose)). FDA responsible for all non-specified birds including wild turkeys, wild ducks, and wild geese.</p>	<p>The Federal Meat Inspection Act regulates the inspection of the following amenable species: cattle, sheep, swine, goats, horses, mules or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory Inspection of Ratites and Squab (including emu) announced by USDA/FSIS April 2001</p>	<p>The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&amp;C Act to the extent they are covered by the PPIA. Mandatory Inspection of Ratites and Squab announced by USDA/FSIS April 2001</p> <p>The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose or guinea. Voluntary grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs.)</p>
<p>Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or less than 30% fat, tallow or meat extract, alone or in combination.</p> <p>Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat and poultry meat (limited to less than 2%) in any combination. *</p> <p>Closed-face sandwiches.</p>	<p>Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or 30% or more fat, tallow or meat extract, alone or in combination. *</p> <p>Open-face sandwiches.</p>	<p>Products containing 2% or more cooked poultry; more than 10% cooked poultry skins, giblets, fat and poultry meat in any combination. *</p> <p>Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction.</p>
<p>FDA is responsible for shell eggs and egg containing products that do not meet USDA's definition of "egg product." FDA also has jurisdiction in establishments not covered by USDA; e.g. restaurants, bakeries, cake mix plants, etc.</p> <p>Egg processing plants (egg washing, sorting, packing) are under FDA jurisdiction.</p>		<p>Products that meet USDA's definition of "egg product" are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, eggnog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction.</p>
<p>Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3% red meat), meat flavored spaghetti sauce with mushrooms, (2% meat), pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor</p>	<p>Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie</p>	<p>Chicken sandwich (open face), chicken noodle soup</p> <p>Homogeneous cheese and meat products, e.g., cheese balls with pepperoni, must contain more than 50 percent meat to be amenable to USDA inspection. Cheese products that contain 50 percent or less meat are considered products of the dairy food industry and, thus, are exempt from USDA inspection. When cheese and meat are separate components in a package, the packaged product is amenable,</p>

			provided, it contains 2 percent cooked meat.
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Jurisdiction for products produced under the School Lunch Program, for military use, etc. is determined via the same algorithm although the purchases are made under strict specifications so that the burden of compliance falls on the contractor. Compliance Policy Guide 565.100, 567.200 and 567.300 provide additional examples of jurisdiction. IOM 3.2.1 and 2.7.1 provide more information on our interactions with USDA and Detention Authority.

\* These percentages are based on the amount of meat or poultry product used in the product at formulation.

**HISTORY OF MENU ITEMS**

**DATE** 4/25/03  
**PLACE** Hyatt Hotel  
 St. Louis, MO

MENU ITEM	SUPPLIER	DATE REC'D	PRE-PARED	ADVANCE PREPARED	LOCATION	STEPS IN PROCESS	TEMP OF	TIMES	EMPLOYEE(S) INVOLVED
Egg Rolls (Appetizer)	Independent Foods St. Louis, MO	4/20	yes		freezer	bake	5°-230°F	1600-1730	R. Brown
Ravioli (Appetizer)	ITAL-AMER Foods St. Louis, MO	4/21	yes		freezer	deep fry	5°-300°F	1700 - 1730	B. Black
Cheeses (Appetizer)	Fox Dairy St. Louis, MO	4/24	yes		cooler	slice	40°F	1350 - 1450	C. White
Pate (Appetizer)	Joe' s Butcher Shop E. St. Louis, IL (liver)	4/10		yes 4/10 Chef Welsh	freezer	thaw slice plate	5°-40°F 40°F 40°F	?-1600 1600-1630 1630-1700	K. Green " "
Produce (Salad)	Lombardi' s St. Louis, MO	4/24			cooler	wash plate cool	55°F 75°F 75°-40°F	0730 0845-0945 0945-1730	B. Black & K. Green
Crown Potatoes	"	"			"	slice bake plate	75°F 75°-225°F 200°F	0900-1030 1030-1200 1700-1730	R. Brown & A. Smith
Prime Rib	Joe' s Butcher Shop E. St. Louis, IL	4/24			"	roast slice plate	36°-140°F 135°F 130°F	1500-1800 1800-1830 1930-1900	Chef Welsh C. White Chef Welsh
Wine Chateau St. Juan 2000 Marion Cabernet	Sonoma Valley CA "								

**HISTORY OF MENU ITEMS**

**DATE PLACE**

MENU ITEM	SUPPLIER	DATE REC' D	PRE-PARED	ADVANCE PREPARED	LOCATION	STEPS IN PROCESS	TEMP OF	TIMES	EMPLOYEE(S) INVOLVED



To: Postmaster

Agency Control Number:

Date:

**ADDRESS INFORMATION REQUEST**

Please furnish this agency with the new address, if available, for the following individual or verify whether or not the address given below is one at which mail for this individual is currently being delivered. If the following address is a post office box, please furnish the street address as recorded on the boxholder's application form.

Name:

Last Known Address:

I certify that the address information for this individual is required for the performance of this agency's official duties.

(Signature of Agency Official)

(Title)

**FOR POST OFFICE USE ONLY**

<input type="checkbox"/> MAIL IS DELIVERED TO ADDRESS GIVEN	NEW ADDRESS
<input type="checkbox"/> NOT KNOWN AT ADDRESS GIVEN	_____
<input type="checkbox"/> MOVED, LEFT NO FORWARDING ADDRESS	_____
<input type="checkbox"/> NO SUCH ADDRESS	
<input type="checkbox"/> OTHER (SPECIFY):	BOXHOLDER'S STREET ADDRESS
_____	_____
_____	_____
Agency return address	Postmark/Date Stamp

Under the authority of 39 CFR 265.6(d)(5)(i) and (d)(7)

265.6 Availability of records.

(d) Disclosure of names and addresses of customers. Upon request, the names and addresses of specifically identified [Postal Service](#) customers will be made available only as follows:(5) Exceptions. Except as otherwise provided in these regulations, names or addresses of [Postal Service](#) customers will be furnished only as follows: (i) To a federal, state or local government agency upon prior written certification that the information is required for the performance of its duties. The [Postal Service](#) requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked 'OTHER'. A copy of PS Form 1093 may be provided.

(7) Address verification. The address of a postal customer will be verified at the request of a Federal, State, or local government agency upon written certification that the information is required for the performance of the agency's duties. "Verification" means advising such an agency whether or not its address for a postal customer is one at which mail for that customer is currently being delivered. "Verification" neither means nor implies knowledge on the part of the [Postal Service](#) as to the actual residence of the customer or as to the actual receipt by the customer of mail delivered to that address. The [Postal Service](#) requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked "OTHER".



## INSTRUCTIONS FOR COMPLETING IOM EXHIBIT 3-3

If you have already attempted to locate the individual or firm by sending mail marked on the outside of the envelope "DO NOT FORWARD. ADDRESS CORRECTION REQUESTED", without results, then proceed with this form according to the instructions below.

## INSTRUCTIONS

1. Address the request to the Postmaster at the post office of the last known address.
2. Insert FEI # if known; or assignment or sample number for Agency Control number.
3. On the lines provided, give the name and last known address, including zip code, of the individual or firm. Do not include any other identifying information such as race, date of birth, social security number, etc.
4. The Postal Service provides the service of address verification to Government agencies only. For this reason, the Postal Service requires the signature and title of an agency official to certify that the address information requested is required in the performance of the agency's official duties. The agency official should be if possible, the chief of the office requesting the information. In the interests of efficiency, the signature may be preprinted or rubber-stamped.
5. Type or stamp the agency's return mailing address in the space provided at the bottom of the request. Include your full name and title or the appropriate person's full name and title to whom the form should be returned to. Mail or deliver the request to the Postmaster at the post office of the last known address.

You are not required to submit this request in duplicate or to furnish a return envelope.

# CHAPTER 4 - SAMPLING

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## SUBCHAPTER 4.1 - GENERAL

### 4.1.1 - AUTHORITY

#### 4.1.1.1 - Examinations and Investigations

Collecting samples is a critical part of FDA's regulatory activities. The FD&C Act, Section [702 \[21 U.S.C. 372\(a\)\]](#) gives FDA authority to conduct investigations and collect samples. A Notice of Inspection is not always required for sample collections. If during a sample collection, you begin to conduct an inspection (examining storage conditions, reviewing records for compliance with laws and regulations, etc.), issue an FDA 482 and continue your activities. See IOM 5.1.1 and 5.2.2.

While inspections and investigations may precede sample collection, a sample must ultimately be obtained for a case to proceed, under the law. Proper sample collection is the keystone of effective enforcement action.

FD&C Act - See IOM section 2.2.1 for this information.  
PHS Act - See IOM 2.2.3.7 for this information.

#### 4.1.1.2 - Notice of Inspection

Samples are often collected during the course of an establishment inspection or inspection of a vehicle. See IOM 5.1.1 and IOM 5.2.2.

1. Carriers - Issue an FDA 482 - Notice of Inspection to the driver or agent when it is necessary to inspect vehicles. See IOM 5.2.2.2.
2. Manufacturers, etc. – Issue an FDA 482 - Notice of Inspection when samples are collected from lots in possession of a manufacturer, processor, packer or repacker, whether or not regulatory action is intended toward the articles, the dealer, the manufacturer or the shipper.

#### 4.1.1.3 - Receipt for Sample

Section [704\(c\) of the FD&C Act \[21 U.S.C. 374 \(c\)\]](#) requires issuing a receipt describing any samples obtained during the course of an inspection. The receipt is to be issued to the owner, operator, or agent in charge, upon completion of the inspection and prior to leaving the premises. See IOM 5.2.4 for special situations. See IOM 4.2.5.5 for instructions on completing the form.

#### 4.1.1.4 - Report of Analysis

Section [704\(d\) of the FD&C Act \[21 U.S.C. 374 \(d\)\]](#) requires FDA furnish a report of analysis on any sample of food (including animal food and feed, medicated and non-medicated), collected during an inspection of an establishment where such food is "\*\*\*\* manufactured, processed, or packed \*\*\*, " if the sample is examined for compliance with Section [402\(a\)\(3\) of the FD&C Act \[21 U.S.C. 342 \(a\)\(3\)\]](#). The servicing laboratory is responsible for furnishing the report of analysis. See [FMD 147](#).

## 4.1.2 - VALID SAMPLE

A valid sample is the starting point and keystone for most administrative and legal actions. As evidence, the sample must support the government's charge there is a violation of the law. Also, it must conform to the rules on admissibility of evidence. A properly collected and prepared sample provides:

1. A portion of the lot of goods for laboratory analysis and reserve, a 702(b) of the [FD&C Act \[21 U.S.C. 374 \(b\)\]](#) reserve portion if appropriate, and/or an exhibit demonstrating the violation represented by the lot.
2. A report of your observations of the lot.
3. Labels and labeling, or copies of such, which "accompany" the goods.
4. Documentary evidence of federal jurisdiction over the lot, information about individuals responsible for the violation, where the violation was committed, and similar data.
5. Signed statements from persons who may be called upon as witnesses, if there is a subsequent court action.

## 4.1.3 - RESPONSIBILITY

Collect every sample as if you will be required to testify in court about everything you did concerning each and every event surrounding the sample collection. Mistakes or deficiencies, however trivial they may seem, can fatally damage the government's case. Be objective, accurate, and thorough.

## 4.1.4 - OFFICIAL SAMPLES ([21 CFR 2.10](#))

A sample of a food, drug, or cosmetic is an "Official Sample" if records [see IOM 4.4.7] or other evidence obtained shows the lot from which the sample was collected was:

1. Introduced or delivered for introduction in interstate commerce, or
2. Was in or was received in interstate commerce, or
3. Was manufactured in a territory or the District of Columbia.

A sample of a device, a counterfeit drug, or any object associated with drug counterfeiting, no matter where it is collected, is also an "Official Sample". The statute permits proceeding against these articles, when violative, at any time. See Section [304\(a\)\(2\) of the FD&C Act \[21 U.S.C. 334\(a\)\(2\)\]](#).

Import Samples are Official Samples and require the same integrity as domestic Official Samples. They must be identified with sample number, collection date and collector's handwritten initials. When sample numbers are not available, an entry/line number may be used. Notify the laboratory that a sample is being sent without a sample number and provide identifying information. Update the laboratory as soon as the sample number is available. Interstate documentation is not required; see CPG manual section [110.200](#) and [110.600](#). Import Samples need not be sealed, unless Division policy dictates, as long as the integrity of the sample is maintained.

Normally, [702\(b\) of the FD&C Act \[21 CFR 2.10\(b\)\]](#) portions (hereby referred to as either 702(b) portion or 702(b) reserve portion) are not collected for routine Import Samples. However, in situations where a dispute arises or a potential for regulatory action exists, the 702(b) portions should be collected, and the sample sealed as described in IOM 4.5.4.

#### 4.1.4.1 - Definition - Official Sample

An Official Sample is one taken from a lot for which Federal jurisdiction can be established. If violative, the Official Sample provides a basis for administrative or legal action. Official Samples generally, but not always, consist of a physical portion of the lot sampled. To be useful, an Official Sample must be:

1. Accompanied by records establishing Federal jurisdiction, and identifying the persons having knowledge of the lot's movement and custody of the records. (Evidence of Interstate movement is not required for medical device samples, but, according to policy, is to be obtained when a seizure, injunction, prosecution or civil penalty is contemplated). See IOM 4.4.7.
2. Representative of the lot from which collected.
3. If a physical sample, large enough to permit proper laboratory examination and provide a 702(b) reserve portion when necessary.
4. Handled, identified, and sealed in such a manner as to maintain its integrity as evidence, with a clear record of its chain of custody.

Every physical Official Sample will be fully documented at the time of collection and Collection Reports prepared unless instructed otherwise by the program or assignment.

#### 4.1.4.2 - Documentary Samples

In a "Documentary" (or "DOC") sample, no actual physical sample of the product is taken. A documentary sample is not a sample of records; it is a sample representing a lot of a regulated article (e.g., food, drug, biologic or device). Other elements of an official sample described in 4.1.4 and 4.1.4.1 are required -- see special official sealing instructions below. This official sample consists of the article's labels (or label tracings, photocopies, or photos), accompanying labeling (leaflets, brochures, promotional materials, including Internet websites, etc.) and documentation of interstate movement (freight bills, bills of lading, affidavits, etc. See IOM 4.4.7) Photos of the product, drawings, sketches or schematics, production records, diagrams, invoices or similar items may also be part of the sample. See IOM Exhibits 4-1 and 4-2. As a rule, no FDA 484, receipt for samples is issued during collection of a DOC Sample. See subparagraph 5.2.4.1 for physical evidence exception.

A DOC sample is collected when an actual physical sample is not practical (e.g., very large, expensive, complex, permanently installed devices), in instances where the article is no longer available, or when there is little need for laboratory examination. A single piece of life support

equipment for example, which must remain in emergency service until a replacement is available, may be sampled in this manner.

Another instance where a DOC sample might be collected involves a shipment of product recommended for seizure based on misbranding charges. During availability check, the lot sampled is found to have been distributed; however, a new shipment, identically labeled, is on hand. In this instance, the new shipment may be sampled on a DOC basis since another physical sample and examination is not required. Regulatory action may proceed on the basis of the earlier examination. Thus, only labeling, transportation records, the appropriate dealer affidavits, and an inventory of product on hand need be obtained.

A variation of this procedure involves collecting one or more units and removing (stripping) the original labels/labeling from the product container. It is frequently easier and quicker to collect relatively inexpensive units to field strip than it is to photocopy or photograph all accompanying labels. The sample is handled in exactly the same manner as any other DOC sample, once original labeling has been removed and the remainder of the sample destroyed. A prominent explanation on the C/R alerts reviewers that the original units collected were destroyed after the original labeling was removed. This procedure is not appropriate where complete, intact, labeled units are desired for exhibit purposes, even though there is no intention of analyzing the units obtained.

A documentary sample collected to document GMP deviations, should contain records obtained that document the deviations encountered. You should explain what is being documented in the remarks section of the documents obtained screen in FACTS. Fully describe any record collected as part of the DOC sample and where possible indicate the page of the document that demonstrates the deviation.

When non-digital photos are taken as part of DOC samples, the rolls of exposed film should be sent to established commercial film dealers or color processors for developing. Report the identity of the film processor on the FDA 525. Also see IOM 5.3.4.

See IOM 4.5.2.5 and ORA-wide standard operating procedures for guidance on identifying records associated with a DOC sample. Do not officially seal these records, but list them on the C/R. If any photos are taken as part of the DOC sample, the negatives or electronic media, if any, must be officially sealed per IOM 5.3.4.2 or IOM 5.3.4.3. See IOM Exhibits 4-1 and 4-2 for examples of DOC samples. Attach the documents, photos and negatives along with any other records associated with the sample to the printed FACTS Collection Record. See IOM 4.4.10.5.

Advisory Actions and Administrative Actions are types of actions that do not involve the judicial system. These actions include untitled letters, warning letters, regulatory meetings, suspension of registration, etc. Documentary samples are not required to support advisory or administrative actions.

Records of interstate commerce should be collected and incorporated into the establishment inspection report (EIR) in order to document FDA jurisdiction over products suspected to be in violation. Investigators in training may still be required to prepare documentary samples as directed by their supervisor.

#### 4.1.4.3 - In-Transit Samples

In-Transit samples are those collected from lots held on loading/receiving docks of steamships, truck lines, or other common carriers, or being transported in vehicles. The lot is considered to be in-transit if it meets any of the following characteristics:

1. A Bill of Lading (B/L) or other order to ship a lot interstate has been issued.
2. The owner/shipper or agent acknowledges, preferably by signed affidavit, he has ordered the lot to be shipped interstate.

The owner or operator of the common carrier acknowledges, preferably by signed affidavit, he has an order from the shipper to move the lot interstate.

#### 4.1.4.4 - 301(k) Samples

Section [301\(k\) of the FD&C Act \[21 U.S.C. 331\(k\)\]](#) describes prohibited acts, which can result in one or more separate legal procedures. A sample collected from a lot of food, drug, device or cosmetic which became adulterated or misbranded while held for sale, whether or not the first sale, after shipment in interstate commerce is often referred to as a "301(k) Sample". The term "301(k) Sample" is misleading, but widely used within FDA to describe certain samples collected from lots which become violative after shipment in interstate commerce.

Since some act took place which resulted in the adulteration or misbranding of a previously nonviolative product after shipment in interstate commerce, the "301(k)" documentation is incomplete without identifying the act, establishing when and how it occurred, and the person(s) responsible for causing the violation. This feature, more than any other, distinguishes a "301(k) Sample" from the other Official Samples. When you report the sample collection, the responsible party will always be the dealer. See IOM Exhibits 4-1 and 4-7, "301(k) affidavit."

For example, to document insect adulteration of a finished product, caused by a live insect population in the processing areas of a food manufacturer such as a bakery, you must document receipt of clean raw material and subsequent adulteration caused by the firm's handling or processing of the raw material. Therefore, you would need to show there was an insect infestation at the firm that either did, or may have contaminated the finished product. You would need to collect a sample of the clean incoming flour, and subsamples at points in the system to demonstrate where insect infestations exist in the system. In situations where sampling may disturb static points in the system,

which may result in a higher level of adulteration of the finished product than normal, you should sample in reverse.

301(k) samples can also be used to document adulteration (including noncompliance with GMPs) or misbranding of other regulated commodities, including drugs and biologics. If possible, when collecting a 301(k) sample covering a drug product, you should attempt to document 'adulteration' or 'misbranding' of the active ingredient by the firm's actions. In the case of a biologic (for example, whole blood), which has not moved in interstate commerce, document the interstate receipt of the bag, and the firm's subsequent 'adulteration' or 'misbranding' of the anti-coagulant (considered a drug) in the blood bag.

#### 4.1.4.5 - Induced Sample

An induced sample is an Official Sample ordered or obtained by agency response to some type of advertisement or promotional activity. The sample is procured by mail, telephone, or other means without disclosing any association of the requester or the transaction with FDA. See IOM 4.3.5.4 for additional information.

#### 4.1.4.6 - Undercover Buy

An "undercover buy" is an Official Sample, similar to and obtained in much the same manner as an "induced sample". Undercover buys may be made in person or via a purchase completed either online, or by email, text or phone. Pre-arranged explanations or cover stories are necessary to dispel any suspicions about the requester that may surface in face-to-face, phone or email discussions. "Undercover buys" are frequently used in investigating complaints of illegal activity where the information cannot be substantiated or refuted through more conventional means. "Undercover buys" may also augment existing investigation or inspection efforts and be performed to document violations in firms with a history or pattern of noncompliance.

#### 4.1.4.7 - Post Seizure (P.S.) Sample

A lot under seizure is in the custody of the U. S. Marshal. If either the claimant or the government desires a sample from the seized lot, for any reason, it may be collected only by court order. In most cases, the order will specify how the sample is to be collected, and may provide for each party to collect samples. If the order was obtained by the claimant, permit the claimant's representative to determine how his/her sample collection is made. If the method of collection is improper, make constructive suggestions, but do not argue. Report exactly how the sample was drawn. Unless the claimant objects, mark subsamples collected with "P.S.", your initials and date. "P.S." Samples are Official Samples.

Do not pay for Post Seizure Samples or any samples collected of a lot reconditioned under a Consent Decree. See IOM 4.2.8.1.

### 4.1.4.8 - Domestic Import Sample

To record information on FDA's total coverage of imported products, an additional classification of samples, "Domestic Import" or "DI" was devised. These are Official Samples of foreign products, which have passed through customs and are in domestic commerce. The FDA may have previously taken a sample of the product while in import status, or the product may have been permitted entry without being sampled. If sampled while still in import status, the samples collected are import samples, and not "DI" Samples. However, once the product leaves import status and enters domestic commerce, any sample collected is considered an Official "Domestic Import" (DI) Sample. Note: When collecting DI Samples, especially if a violation is suspected, attempt to determine the port of entry and importer of record. Report this information on the CR. Include the name of the Country of Origin of the product and the Country Code if known.

A sample is classed as Domestic Import (DI), if any of the following situations apply:

1. The label declares the product to be from a foreign country.
2. The label bears the word, "Imported".
3. Records obtained or reviewed reveal the product originated in a foreign country.
4. It is known that the product is not grown or produced in the US; it is packed as a single item with few or no other ingredients added, and it is not manipulated in any major manner, which changes the product or its composition. For example, "Olive Oil" imported in bulk and merely repacked with no added ingredients and no manipulation would be a "DI" sample, while pepper which is processed, ground and packed after entry would not. However, retail packages of ground pepper processed and packaged in a foreign country would be "DI" Samples.
5. Samples of imported raw materials, which are collected before further processing or mixed with other ingredients.

DI samples are significantly different from other official samples in another important respect. Unlike domestic products, where considerable information is readily available on manufacturing and distribution channels, it is frequently difficult to identify the responsible parties for products of foreign origin once they enter domestic commerce. The most practical way is to establish a paper trail of records going back as far as possible in the distribution chain to the actual entry.

Identifying "DI" Samples - When identifying the physical samples, related documents and filling out the seals of Domestic Import samples, preface the sample number with the prefix "DI" in the same manner that other sample type prefixes are used (such as, "DOC", "FS" (See IOM 4.1.5), "PS", etc.)

### 4.1.4.9 - Import Sample

Import samples are physical sample collections of products, which originate from another country, collected while the goods are in import status. Import status ends when Customs has cleared an entry for the shipment. See IOM 4.1.6.1 and chapter 6.

#### 4.1.4.9.1 Special Domestic Import Sample (SDI)

Special Domestic Import samples (SDI) are import samples collected from lines that are released from import status immediately after collection and before sample analysis is complete. This sample type is used primarily for the collection of perishable products and special sampling assignments. This sample type may also be used for other designated sampling situations as directed. See IOM chapter 6.5.7.

### 4.1.4.10 - Additional Sample

This is a physical sample collected from a previously sampled lot of either a domestic or imported product.

1. Additional Import Samples - The sample collected must have the same sample number as the original sample collected.
2. Additional Domestic Sample - The sample collected may have another sample number, but it must be flagged as an "ADD" Sample and the original sample number referenced in the "Related Sample" block on the Collection Record.

### 4.1.4.11 – Reconditioning Sample

Reconditioning Samples - These are taken from lots reconditioned under a Decree or other agreement to bring the lots into compliance with the law. The sample is taken to determine if reconditioning was satisfactorily performed. These samples should be submitted as Official Samples.

### 4.1.4.12 - Audit/Certification Sample

A sample collected to verify analytical results provided by a certificate of analysis or private laboratory analysis that purports to show a product complies with the FD&C Act and/or regulations. This sample type will usually be used with an import sample. See IOM 4.1.4.9.

The [ORA Lab Manual, Volume 3, Section 7](#) provides specific guidance on FDA audit samples. FDA audit samples provide an opportunity for investigators to examine privately sampled regulated commodities for conformance with the associated submitted private lab package. Prior to collecting a FDA audit sample, careful examination of the lot should be conducted for comparison to private lab package evidence (i.e. photographs and documentation). Examples of items to note during examination and comparison of the private lab's packet include:



- Evidence of marked containers distributed throughout the lot indicative of a representative sample.
- Marked cases that are consistent with the submitted lab package.
- Quantity removed for sampling consistent with the lab package.
- Careful attention should also be paid to any indication that the containers selected for sampling by the private sample collector have been staged for sampling. Staging can occur through markings, deliberate damage to labeling, placement within the pallets, etc.

It is important, if evidence is found that a non-conforming private sample was collected, to immediately terminate audit activities/sampling and to report adverse findings to appropriate Compliance staff for evaluation. The Agency will then make decisions on a lot-by-lot, case-by case basis regarding the entries/sampled products submitted for importation.

Audit samples should be recorded under the same PAC codes as surveillance samples and can apply towards the completion of applicable Work Plan and/or Performance goals.

#### 4.1.4.13 - Mail Entry Sample

A mail entry sample is a sample of an imported product that enters the U.S. through the U.S. Mail. See IOM 4.1.4.9.

#### 4.1.5 - FOOD STANDARDS SAMPLE

Food Standards (FS) samples are collected to provide information on which to base Food Standards. Sample integrity is maintained in the same manner as Official Samples.

Note: Samples of standardized foods are not FS Samples.

#### 4.1.6 - INVESTIGATIONAL SAMPLES

These samples, referred to as "INV Samples", need not be collected from lots in interstate commerce or under federal jurisdiction. They are generally collected to document observations, support regulatory actions or provide other information. They may be used as evidence in court, and they must be sealed, and their integrity and chain of custody protected. Examples of INV Samples are:

1. Samples flagged as "Factory Food Samples" or In-Line samples -Raw materials, in-process and unpackaged finished products to demonstrate manufacturing conditions. See IOM 4.3.7.7.3.
2. Exhibits -Filth exhibits and other articles taken for exhibit purposes during inspections to demonstrate e.g., manufacturing conditions, storage conditions and employee practices. Typically, filth exhibits submitted as part of an INV sample are not tied to any specific lot of product but are meant to illustrate the conditions at a firm.

For example, samples flagged as "Inv. Samples of Filth Exhibits" frequently consist of apparent rodent excreta pellets, apparent nesting material, apparent rodent gnawed material, and other evidence of rodent activity. Multiple sub-samples collected along the entire perimeter of a room in a manufacturing facility, food storage area, or warehouse, may be used to demonstrate a rodent infestation. See IOM 4.4.10.1.7.

3. Environmental Samples – See IOM 4.3.7.7.1.

4. Certain Complaint Samples -Injury and illness investigation samples from certain complaints where there is no Federal jurisdiction, or where the alleged violation offers no basis for subsequent regulatory action. Complaint samples from lots for which Federal jurisdiction is clear should be submitted as Official Samples.

When identifying the sample/sub samples and documents related to the sample, and filling out seals, preface the sample number with "INV" in the same manner as other sample prefix types are used (e.g. "DOC", "DI").

Note: Photographs taken to document conditions observed, or sub-samples collected, are included as exhibits to establishment inspection reports. Photographs taken of labeling and records (e.g., B/L, invoice and manufacturing records) that are associated with sample collections are included as attachments to collection reports. See IOM 4.5.2.4, 5.3.3, and 5.3.4.

#### 4.1.6.1 - Non-Regulatory Sample

Samples collected and analyzed by FDA for other federal, state, or local agencies of products over which the FDA has no jurisdiction.

### SUBCHAPTER 4.2 - DEALER RELATIONS

#### 4.2.1 - DEALER DEFINITION AND GOOD WILL

For sample collection purposes, the dealer is the person, firm (which could include the manufacturer), institution or other party, who has possession of a particular lot of goods. The dealer does not have to be a firm or company, which is in the business of buying or selling goods. The dealer might be a housewife in her home, a physician, or a public agency; these dealers obtain products to use but not to sell. The dealer may be a party who does not own the goods, but has possession of them, such as a public storage warehouse or transportation agency.

Rapport with the dealer is important to the success of your objective. All dealers, including hostile ones, should be approached in a friendly manner and treated with fairness, honesty, courtesy and consideration. A dealer may be called as a Government witness in a court case, and a favorable attitude on his/her part is to be sought. Never use strong-arm tactics or deception, but rather be professional and demonstrate diplomacy, tact, and persuasion. Do not make unreasonable demands.

Introduce yourself to the dealer by name, title and organization; present your credentials for examination, and, if appropriate, issue an FDA 482, Notice of Inspection. See IOM 4.1.1.2, 4.2.4, 5.1.1.3 and 5.2.2. Explain the purpose of your visit. Be prepared to answer the dealer's questions and attempt to relieve any apprehensions while at the same time being careful not to reveal any confidential information. Do not disparage the product, its manufacturer, or shipper. Do not reveal the particular violation suspected unless the dealer is responsible, or unless you ask him/her to voluntarily hold the goods. The very fact we are collecting a sample is often reason enough to arouse the dealer's suspicions about the legality of the product.

## 4.2.2 - DEALER OBJECTION TO SAMPLING PROCEDURE

If the dealer objects to your proposed sampling technique, attempt to reach a reasonable compromise on a method that will provide a satisfactory, though perhaps not ideal, sample. Assure the dealer that you will make every effort to restore the lot to its original state, that you are prepared to purchase a whole unit to avoid leaving broken cases, and that the Agency will reimburse him/her for additional labor costs incurred as a result of sampling. See IOM 4.2.8. If a reasonable compromise cannot be reached, proceed as a refusal to permit sampling.

## 4.2.3 - REFUSAL TO PERMIT SAMPLING

Challenges to FDA authority while collecting samples may be encountered by a dealer who, for various reasons including, personal and professional, opposes the activities of the Agency, or of governmental units in general.

Refusals to permit sample collection commonly emerge unless you can identify a section of the law which specifically authorizes it. The suggested approach for dealing with these individuals is to use patient, tactful persuasion, pointing out that the sample is a part of the investigations authorized in Section [702 \[21 U.S.C. 372\(a\)\]](#). If you have not already done so, issue an FDA 482 - Notice of Inspection (except in the case of foreign inspections- see IOM 5.1.3) as soon as it becomes apparent the dealer will continue to object.

Point out and discuss the authorities provided by FD&C Act sections [702\(a\), 702\(b\), 704\(a\), 704\(c\), 704\(d\) \[21 U.S.C. 372\(a\),\(b\) and 374\(a\), \(c\), \(d\)\]](#) and the precedent case mentioned in IOM 2.2.1. If refusal persists, point out the criminal prohibitions of Section [301\(f\) of the FD&C Act \[21 U.S.C. 331\(f\)\]](#).

If samples are still refused, leave the premises and contact your supervisor immediately. Refer to IOM section 5.2.5 and [Compliance Policy Guide manual section 130.100](#) for further discussions on resolving the impasse.

### 4.2.3.1 - Limiting or Preventing Collection of Samples of a Drug

Preventing an authorized representative of the FDA from collecting drug samples may be considered as limiting the inspection. If you have appropriately issued a FDA 482 – Notice of Inspection and the dealer impedes your ability to collect samples, point out and discuss the authority provided by [Section 501\(j\) of the FD&C Act \[21 U.S.C. 351\(j\)\] under Section 707 of the Food and Drug Administration Safety and Innovation Act \(FDASIA\)](#), that potentially deems all drugs manufactured at the facility adulterated in the case of limiting an inspection. In situations where you have begun an inspection, but no FDA 482 is issued (e.g., foreign inspections), document this fact and the limiting activities in your notes based on the authority described above.

If refusal persists, point out that adulteration under section [501\(j\) of the FD&C Act \[21 U.S.C. 351\(j\)\]](#) could lead to further prohibited acts under [301\(a\), \(b\), and \(c\) \[21 U.S.C. 331\(a\), \(b\), \(c\)\]](#).

Also see IOM 2.2.1.4.

## 4.2.4 - NOTICE OF INSPECTION

See IOM 4.1.1.2, 5.1.1.3, 5.1.1.5 and 5.2.2.

Each time you issue an FDA 482, Notice of Inspection, and subsequently collect a sample, issue the appropriate sample receipt (FDA 472 - Carriers Receipt for Samples or FDA 484 -Receipt for Samples).

### 4.2.4.1 - Dealer Responsible for Condition of Lot

An FDA 482 should be issued before collecting samples from firms, carriers, or individuals whom FDA can take regulatory action against for the violative condition of the lot. See IOM 4.1.1.1. When in doubt, issue a Notice of Inspection. If there is no EIR, attach a copy of the FDA 482 to the FACTS Collection Record. See IOM 4.4.10.5.

### 4.2.4.2 - Refusals

See IOM 4.2.3. If a FDA 482 has been issued prior to a sample refusal situation, the copy of the FDA 482 is to accompany the EIR or a memorandum outlining the facts of the refusal if no EIR is prepared.

If you are on a foreign inspection in which a FDA 482 is not issued, reference relevant Compliance Programs and [Chapter 3 of the Guide to International Inspections and Travel Manual](#) for reporting guidance.

### 4.2.4.3 - Carrier In-Transit Sampling

Caution: See IOM 4.3.4 for conditions, which must be met before collecting in-transit samples from common carriers.

When collecting samples from in-transit lots in possession of a commercial carrier, issue the carrier or his agent an

FDA 482. Attach a copy to the copy of the FACTS Collection Record. See IOM 4.4.10.5.

#### 4.2.4.4 - Dealer Requests Notice of Inspection

When inspecting a dealer, and an FDA 482 does not need to be issued, but the dealer requests a Notice of Inspection, issue an FDA 482. Attach a copy to the FACTS Collection Record. See IOM 4.4.10.5.

### 4.2.5 - RECEIPT FOR SAMPLES

Any time you collect a sample after issuing an FDA 482, Notice of Inspection, always issue the appropriate sample receipt FDA 472 - Carriers Receipt for Samples or FDA 484 Receipt for Samples.

Always issue an FDA 484 as a receipt for samples of prescription drugs, including narcotics and controlled substances. See IOM 4.2.5.3, 4.2.5.4, and 5.2.4.

#### 4.2.5.1 - Carriers/In-Transit Lots

Caution: See IOM Exhibit 4-4. Give the original to the carrier or his agent and route a copy to the appropriate fiscal unit for your division. The fiscal clerk will notify the consignee and consignor that a sample has been collected so the owner can, if desired, bill FDA for the sample.

#### 4.2.5.2 - Dealer Requests Receipt

When collecting physical samples of regulated products, not in connection with an EI or where no FDA 482 has been issued, do not routinely issue an FDA 484, Receipt for Samples, except for prescription drugs, narcotics, or controlled substances. See IOM 4.2.5.3 and 4.2.5.4. If any dealer specifically asks for a receipt, prepare and issue an FDA 484 and route a copy with any other records associated with the collection record. See IOM 4.4.10.5.

#### 4.2.5.3 - Narcotic and Controlled Rx Drugs

Regulations of the Drug Enforcement Administration (DEA) impose strict controls and comprehensive record-keeping requirements on persons handling narcotics and controlled substances. As a result, an FDA 484 must be issued for all samples of such drugs collected by FDA.

Each dealer in narcotic and controlled drugs is assigned its own unique DEA registration number. Any time you collect a sample of a narcotic or controlled drug, be sure the Dealer's DEA Registration Number is entered in the appropriate block of the FDA 484. Double-check the number for accuracy. An error may result in possible investigation for drug shortages.

When samples of narcotic or controlled drugs are collected, the complete DEA Registration Number must be entered on the - RECEIPT FOR SAMPLES, given to the person from

whom the samples were collected.

Concise completion of the FDA 484 for samples of narcotic or controlled drugs includes the trade and chemical name, strength, sample size, container size, lot, batch, or control number, manufacturer's name and address, division address and the sample number. See IOM 4.4.10.5. Use of the FDA 484 as a Receipt for Samples of these drugs has the approval of DEA. (See reverse of FDA 484).

#### 4.2.5.4 - Prescription Drugs (Non-Controlled)

Issue an FDA 484, Receipt for Samples, when samples of prescription legend drugs are collected from dealers, individuals, or during inspections. Attach a copy of the FDA 484 to the FACTS Collection Record. See IOM 4.4.10.5.

#### 4.2.5.5 - Preparation of FDA 484

Complete the blocks on the FDA 484 (Exhibit 4-5), Receipt for Samples, as follows:

Block 1 - Enter your Division address and telephone number including area code.

Block 2 - Enter the complete name and official title of the individual to whom you issue the FDA 484.

Block 3 - Enter date on which you finished collecting the sample. If you spent more than one day on the sample collection, enter the date you completed sampling.

Block 4 - Enter the complete Sample Number here. Be sure to include any prefixes such as "DI", "INV", etc.

Block 5 - Enter the firm's legal name.

Block 6 - If the firm is a dealer in narcotics or control drugs, enter their DEA Number here.

Block 7 and 8 - Enter the number, street, city, state, and zip code of firm.

Block 9 - Enter a brief description of the article collected, including the number and size of units collected, product name and any identifying brand and code marks.

Block 10 - Check the appropriate box on the FDA 484.

Block 11 - Enter the amount paid for the sample (even if borrowed, the owner may ask rent for it) and check the appropriate box. If there is no charge (always offer payment except for Post Seizure Samples), enter N/C and leave boxes blank. If, as a last resort, it is necessary for you to use your personal check or credit card and this is acceptable to the person, enter amount and check "Credit Card." box.

NOTE: Older editions of the FDA 484 do not have a "Credit Card." box. If using older editions, write "Credit Card" following the sample amount.

Block 12 - In instances where payment is made for the Sample, whether actually purchased, borrowed or provided at no charge, and there is no Dealer's Affidavit, or any other document executed to show the owner's signature for receipt of payment, obtain the signature of the person receiving payment for the sample.

If Dealer's Affidavit, regular Affidavit or other document is used, the recipient's signature will be on that document, so it is not necessary for him to also sign the FDA 484. In this case insert an applicable statement such as "Dealers Affidavit signed" in this block.

Blocks 13, 14, and 15 - Enter your name, title and signature.

#### 4.2.5.6 - Routing of FDA 484

Original - Give the signed original to the firm, preferably to the individual to whom you gave the FDA 482 and FDA 483. See IOM 4.2.5.3 regarding receipts for narcotics and controlled drug samples.

First Carbon - Accompanies the EIR. If no EIR is involved such as when collecting a sample and the dealer specifically requests a receipt, attach it to the original Collection Record. See IOM 4.2.5.2, 4.2.5.3, and 4.2.5.4.

Second Carbon - This is an extra copy for use as needed. If not filed in the factory file or attached to the C/R or not otherwise needed, it may be destroyed.

If exact copies are used instead of carbon copies, then route one exact copy with the EIR and a second as above.

When numerous subsamples are collected, the second carbon or exact copy may be attached to the original C/R to avoid repetition of the sub descriptions. When used for this purpose, be sure the numbers you assign to the physical subsamples matches those on the FDA 484, and that the subs are adequately described. See IOM Exhibit 4-5. If errors are noted after issuance, handle the same way as instructed under IOM 5.2.3.1.6.1 and IOM 5.2.3.1.6.2.

### 4.2.6 - DEALER IDENTIFICATION OF LOT AND RECORDS

Positive identification of sampled lots and the records covering their sales and shipment are essential to legal proceedings. The dealer's identification of a sampled lot and his identification of the records covering I.S. shipment should be factual and specific. If there is a question about accurate identification of the lot or records, determine all facts and establish identification as clearly as possible. Be alert to any identifying marks, which may later be used on the witness stand for positive identification.

#### 4.2.6.1 - Private Individuals

When collecting Official Samples from private individuals, ask the individual to initial and date the label, wrappings, promotional literature, etc. This will aid in positively identi-

fying the product and related documents in any court proceedings that may develop months, or even years later.

#### 4.2.6.2 - Seriously Ill Individuals

If you collect samples from a person for contemplated regulatory action, and it is obvious the person is seriously ill, you should attempt to locate and obtain a corroborating statement and identification from someone else. This corroborating witness should have personal knowledge of the facts and be available if the principle witness cannot testify in a legal proceeding.

### 4.2.7 - SAMPLING FROM GOVERNMENT AGENCIES

See IOM Subchapter 3.2 for sampling information specific to Other Government Agencies (OGA).

### 4.2.8 - PAYMENT FOR SAMPLES

Payment for all samples, except those collected under authority of a Court Order or Decree, shall be offered to the person from whom the sample(s) were obtained regardless of the amount. See IOM 4.2.8.2.

An exception is import samples. FDA does not pay for Import samples at the time of collection. The importer should bill the Division Office. FDA will not pay for violative import samples. See [21 CFR 1.91](#).

#### 4.2.8.1 - Post Seizure (P.S.) and Reconditioning Samples under Court Order

Do not pay for, or offer payment for, any Post Seizure (P.S.) or other samples including those from reconditioned lots, if collected under authority of a Court Order or Decree. If the dealer insists on payment before permitting sampling, show him/her the Court Order. If he/she still refuses sampling, contact your supervisor immediately for further instructions. You may be instructed to notify the U.S. Attorney.

#### 4.2.8.2 - Determining Sample Cost

If you are collecting samples from firms or representatives of firms who have Federal Supply, Veterans Administration or other contracts with the Federal Government, the cost of the sample should be determined by the scheduled price. Inquire of the firm if they are on contract for the item. If so, pay only the scheduled price.

Some dealers may wish to charge their regular selling price. However, if the cost of the sample seems excessive, try to persuade the dealer into charging a lower price that is more equitable. If asked, inform the dealer that the government considers a fair price to be the dealer's invoice cost plus a nominal charge (usually 10-15%) for freight, handling and storage.

If unable, through tactful discussion, to convince the dealer to lower the sample cost, do not haggle over the price to be paid. If the cost seems exorbitant, check with your supervisor to determine if the sample size can be reduced, or for further instructions. Whenever there is a disagreement over sample cost, ask the dealer to bill the division and report the circumstances in the Collection Remarks field on your FACTS collection record.

If divisions encounter requests for payment for method validation samples (either direct submission by firms to labs or during collection from responsible firms), they should contact the appropriate Office of New Drugs- [CDER](#), or [CVM](#), so that communication may take place with the application sponsor. If product is being collected from commercial distribution not in the control of the sponsor/manufacture, then the division should expect to pay wholesale cost. Expenses for NDA method validation samples should be charged to a PDUFA reimbursable CAN.

#### 4.2.8.3 - Method of Payment

There are two main ways to pay for samples. The sample costs may be billed to the division or cash may be used to pay for the sample. As a last resort, you can use your personal credit card to pay for the sample. Personal funds may be used to pay for samples when an ATM cash withdrawal is unavailable, or when otherwise authorized by division policy. See IOM 4.4.10.3.50 and 4.2.5.5.

##### 4.2.8.3.1 - Costs Billed To Division

Billing sample costs to the division is, in many instances, the most practical method of payment. This is particularly true where substantial costs are involved due to large sample size, expensive samples, when samples are collected from third parties such as carriers and public storage warehouses, or when delivery followed by subsequent billing is the dealer's normal business practice. If available, obtain the dealer's invoice and submit it to the appropriate fiscal unit for your division.

Sampling from public storage warehouses and common carriers incurs costs, which are normally billed because the owner of the product is unavailable. Determine the identity of the owner or his agent and estimate the value of the goods sampled. Arrange with the owner or agent to bill the division.

##### 4.2.8.3.2 - Cash Payment

If you have a government credit card and you need cash to pay for a sample, you are authorized to use your government credit card to withdraw an ATM advance to pay for your sample whether or not you are in travel status. The amount of the withdrawal should be limited to the cost of the sample. You should submit your itemized claim for samples along with the cash withdrawal fee by submitting a local voucher using electronic travel management system. Include the sample number and submit to your fiscal unit for payment. Any documentation should be

provided. Sample costs cannot be charged directly to your government credit card.

#### 4.2.8.4 - Sampling - Labor Charges

Additional labor, use of forklift, or other assistance may be required to move merchandise, skids, pallets, etc., to properly sample and restore the lot. Usually assistance will be available on the premises, or arrangements can be made with management to employ outside professional help.

There is usually little need to discuss payment when requesting nominal use of labor or equipment. However, if there is an indication management expects payment, attempt to reach a clear understanding of the charges before proceeding. If the charges to be incurred appear reasonable, and the cost is minor (about \$25.00 or less), proceed with the work and add the charges to your sample cost. However, if substantial costs are involved, consult with your supervisor before making a commitment to pay.

Where the charges are substantial and have been authorized by your supervisor, arrange for the cost of labor and/or machinery to be billed to the division. Handle these charges separately from the actual cost of the sample. Determine the hourly rate and keep track of time, labor, or machinery actually used. Prepare a short memo outlining the charges and submit it to your division.

#### 4.2.9 - VOLUNTARY EMBARGO

This section deals solely with a "voluntary" hold on regulated products. See IOM 2.7.1 for specific statutory authorities for detaining meat, poultry, egg products, and medical devices.

While there is no specific authority for requesting a voluntary embargo on a lot, voluntary embargoes by a dealer shall be encouraged where the lot sampled is clearly adulterated. By voluntarily holding, the dealer prevents further distribution of suspected violative goods until seizure or other appropriate action can be accomplished.

##### 4.2.9.1 - Perishable Goods

Except in rare instances, it is generally not practical to hold highly perishable items unless the analysis can be completed within 24 hours. You should confer with your supervisor before requesting a voluntary embargo on perishable items.

##### 4.2.9.2 - Obtaining a Voluntary Embargo

When the lot is clearly adulterated, or when instructed to do so by your supervisor, arrange for a voluntary embargo by the dealer. If possible, direct your conversation so that the dealer suggests the embargo. Call the dealer's attention to his/her responsibility under the law, and appeal to his/her sense of public service, integrity, or the health consequences that may be involved.

Always place a time limit on voluntary embargoes using your best estimate of how long it will take to complete the analysis and reach a division decision. Consider such factors as location of the examining lab, difficulty of the analysis required, turnover rate, storage conditions and the perishable nature of the merchandise. Note: Your division's compliance branch can request an extension of the voluntary embargo.

Since the action is voluntary, we cannot compel the dealer to do all the things we might ask him/her to do. While requests for voluntary holds are generally granted, a dealer may act or suggest an alternative approach.

If the dealer indicates a reluctance to voluntarily hold the lot, call his/her attention to Section [301\(a\) of the FD&C Act \[21 U.S.C. 331\(a\)\]](#). If the dealer still refuses, a state embargo may be the next action of choice. See IOM 3.3.1 and consult your supervisor.

If the dealer declines to hold the lot, but proposes returning it to the shipper, the dealer should be warned NOT to return the goods to the shipper and advised FDA does not condone shipping violative goods. Direct his/her attention to Section [301\(a\) of the FD&C Act \[21 U.S.C. 331 \(a\)\]](#).

If the dealer offers to voluntarily denature or destroy the lot in lieu of voluntary embargo, provide or arrange for supervising the denaturing per IOM 2.8.1. If the dealer proposes to recondition the lot, refer him/her to your division compliance branch for approval of his/her method. See IOM Subchapter 2.6 and IOM 2.6.3.

## SUBCHAPTER 4.3 - COLLECTION TECHNIQUE

Sampling operations must be carried out using techniques that ensure the sample is representative of the lot, the sample of the product is in the same condition as it was before sampling, and that the collection technique does not compromise the compliance status of the lot.

### 4.3.1 - RESPONSIBILITY

It is your responsibility to collect your own samples using techniques and methods which will provide the most ideal sample, yet not be objectionable to firm management. This subchapter and the sampling schedules that follow, contain many sampling techniques, but not all. Your training and experience will enable you to become proficient in most sampling operations. However, in new or unusual situations it is your responsibility to use imagination and ingenuity in getting the job done and, if necessary, to consult with your supervisor.

## 4.3.2 - LOT RESTORATION & IDENTIFICATION

### 4.3.2.1 - Restoring Lot(s) Sampled

Restore lots to their original condition. Do not leave partially filled shipping cases, short weight or short volume containers in the lot after sampling. Do not leave the lot in any condition, which might encourage pilferage, or make it unsalable.

When collecting from either full cases or bulk containers, replace sampled units by back filling from a container selected for that purpose. Avoid contaminating the back-filled units. If necessary, correct the contents declaration on the container(s) from which sampled to reflect the actual contents present. Refer to IOM 4.2.2 if the dealer objects to back filling because of company policy, different codes involved, or for other reasons. As a last resort, accede to the dealer's wishes and sample intact units, but record the facts in your regulatory notes and place a brief explanation on the C/R.

Carefully re-close all containers and shipping cases. (Commercially available glues in spray cans or plastic squeeze-type bottles are an effective means of re-gluing containers and cases without defacing with tape or other methods.) Re-cooper or reseal barrels and drums, re-sew bags, etc. If necessary, request use of the dealer's employees in helping to restore the lot or arrange through the dealer to employ outside help. See IOM 4.2.8.4.

### 4.3.2.2 - Identifying Lot(s) Sampled

Identify each container from which units are taken with the date, your initials and the sample number. **NOTE:** For import samples, identify each master container from which units are taken with the following: FDA, division abbreviation, sample date and the lead investigator's initials.

Should the dealer object to your identification procedure, attempt to reach a compromise (e.g., placing the ID in an obscure location, etc.). If the dealer still objects, accede to his wishes, but record the facts in your regulatory notes.

Positive identification of the containers sampled is important if it becomes necessary to resample the lot(s), or if an embargo, seizure, or other action ensues. It also aids the dealer to differentiate between containers that have been opened by FDA as opposed to those opened by pilferage or torn opened by rough handling. It may be necessary to mark more containers than sampled to assure proper identification of the lot. This must be done by using permanent identification (e.g. handwritten ID or by using a rubber stamp).

Many inks will penetrate to the product and act as a contaminant, interfering with the analysis. Do not use markers on sample containers which allow penetration into the product.

Water base markers will run when damp and must be covered with tape. See IOM 4.5.2.3 for identification techniques.

Do not permanently identify articles that are borrowed and will be returned to the dealer.

### 4.3.3 - SAMPLE SIZE

To determine sample size, first consult your assignment. If the assignment doesn't specify the sample size, follow the guidance in the applicable Compliance Program. The IOM SAMPLE SCHEDULE, should be used if the Compliance Program doesn't state the sample size. If none of these furnish the sample size, consult with your supervisor or the laboratory. Collect sufficient sample to allow for the 702(b) portion. See IOM 4.3.3.2 and 4.3.3.3.

#### 4.3.3.1 - Medical Device Samples

The following table represents the devices for which there are sampling instructions in Compliance Policy Guides:

Device	CPG Reference
Clinical Thermometers	See <a href="#">CPG 335.800</a>
Condoms	See <a href="#">CPG 345.100</a>
Surgeons and Patient Exam Gloves	See <a href="#">CPG 335.700</a>

In addition to providing instructions on sample size, these compliance policy guides provide guidance on criteria to determine adulteration and whether or not regulatory action should be recommended. See [WEAC's webpage](#) for additional guidance involving glove sampling.

#### 4.3.3.2 - 702(b) Requirement

When the sample schedule, assignment or other instruction does not specifically provide for the 702(b) portion, collect a sufficient amount to provide this required portion and indicate duplicate availability in the FACTS CR by checking the 702(b) box. You are not required to obtain a 702(b) portion in the following instances exempted by statute or by regulation [21 CFR 2.10\(b\)](#):

1. Devices and tobacco products are not included in the statutory requirement of Section 702(b).
2. The amount available for sampling is less than twice the quantity estimated to be sufficient for analysis, in which case, collect all that is available.
3. The cost of twice the quantity estimated to be sufficient for analysis exceeds \$150.00. If the sample is critical, and the cost exceeds \$150.00, check with your supervisor.
4. The sample cannot by diligent use of practicable preservation techniques available to the Food and Drug Administration be kept in a state in which it could be readily and meaningfully analyzed in the same manner and for the same purposes as the Food and Drug Administration's analysis. If unclear consult with your Supervisor or servicing laboratory to confirm that practicable preservation techniques are not available before relying on this exception.

5. Import samples, collected from a shipment being imported or offered for entry into the United States.
6. The sample is collected from a person named on the label of the article or his agent, and such person is also owner of the article. For example, it is not necessary to obtain a 702(b) portion if the sample is collected from a lot owned by and in the possession of the manufacturer whose name appears on the label.
7. The sample is collected from the owner of the article or his agent, and the article bears no label, or if it bears a label, no person is named thereon.

In the remarks section of the CR, describe the specific circumstances and justification for not collecting the 702(b) portion. The documentation is not needed if the product is a device or tobacco product, or the assignment or compliance guide already states why the 702(b) portion is not needed.

Note: Regardless of the exemptions under [21 CFR 2.10\(b\)](#) listed above, collect the 702(b) portion for filth samples unless your supervisor directs otherwise.

#### 4.3.3.3 - Collecting the 702(b) Portion

Whenever possible, collect separate subsamples in order to provide the firm a portion as required by Section 702(b). Each duplicate subsample should be collected from the same bag, box, case, or container. The total sample should be at least twice the quantity estimated to be sufficient for analysis, including a reserve portion for FDA's laboratory. If unable to collect separate subsamples, assure that the total amount collected for each sample subsample, or the total amount collected from an undivided sample, is at least twice the amount estimated to be sufficient for analysis. See IOM 4.3.7.4 and 4.4.10.3.63.

### 4.3.4 - IN-TRANSIT SAMPLES

The exterior of any domestic package thought to contain an article subject to FDA regulation and in the possession, control, or custody of a common carrier may be examined (photographed, information on the outside copied, etc.) and records of the shipment may be obtained. Such package may not be opened either by an FDA employee or by an employee of the common carrier at the request of an FDA employee except as provided below.

#### 4.3.4.1- Examination without a Warrant

The Office of Chief Counsel has advised FDA employees may, without a warrant, open, examine the contents and/or sample a package which is part of a domestic commercial interstate shipment in the possession, control, or custody of a common carrier only if:

1. The consignor or consignee affirmatively consents to examination and/or sampling of the contents; or
2. The Agency has reliable information the carrier regularly carries FDA regulated articles, and the facility where the sampling is contemplated is subject to FDA inspection.

- Reliable information may come from agency files, the carrier itself, other customers of the carrier, etc. and
3. The Agency has reliable information a particular package sought to be examined is destined for, or received from another state, and contains an FDA regulated article. [Such information may be found on the exterior of the package and/or shipping documents in specific terms. Information may also come from reliable sources, which establish the consignor is in the business of manufacturing and/or shipping FDA regulated articles using a distinctive type of package (shipping container); and the package in question meets such description and shows the consignor to be such firm.]

#### 4.3.4.2 - Examination with a Warrant

Confer with your supervisor on any question concerning the need for a warrant. However, headquarters approval must be obtained because such inspection and sampling may require a search warrant. Contact the Office of Operations (OO) to discuss the matter. They will coordinate as necessary with Office of Enforcement and Import Operations and the Office Chief Counsel and provide further instructions.

If a decision has already been made by the division office to obtain a warrant, follow the procedures outlined in the [Regulatory Procedures Manual, Chapter 6-3](#).

If a common carrier reports a violative article which it discovers under its own package opening procedures, independent of any request by an FDA employee or any standing FDA cooperative program with the carrier, FDA may still need a warrant to examine the material. Unless all the conditions for independent sampling in IOM 4.3.4.1 1 or 2 exist, you must consult with your supervisor, who will arrange for headquarters consultation as outlined above.

Note: Where the identity of an Interstate product is known by virtue of it being visible in bulk or being in labeled containers or packages which are verified as to contents by shipping records, and where such product is under FDA jurisdiction at a given location, it may be sampled according to established IOM procedures.

#### 4.3.4.3 - Resealing Conveyances

If it is necessary to break the commercial seal to enter a railcar or other conveyance, reseal the door with a numbered self-locking "U.S. Food and Drug" metal seal. Record in your regulatory notes (and on C/R if sample taken) the number of the car or conveyance, the identifying number on any car seals removed, and the number of the FDA metal seals applied.

### 4.3.5 - SPECIAL SAMPLING SITUATIONS

There will be situations that arise where the dealer may need to sample product for you due to safety and/or other concerns. After evaluation of the situation and prior to allowing dealer sampling, contact your supervisor for

appropriate guidance and concurrence. If permissible, all dealer sampling must be done with your direct oversight. Note dealer sample collection in your CR.

Do not collect human or animal biological materials (urine, feces, sputum, blood, blood products, organs, tissue etc.) unless arrangements for special handling and special treatment have been made in advance. Most ORA servicing laboratories are not prepared or certified to handle these materials. In addition to guidance for special sampling situations provided below, sampling guidance may also be found in IOM Subchapter 1.5 – Safety under IOM 1.5.3 - Sampling.

Sampling Containers for Lemon Oil or Other essential oils - Plastic or paraffin-coated liners in caps of containers used to hold samples of this type of product are not satisfactory in that the plastic or paraffin is soluble in the oils and interferes with the analysis. Use glass, cork, foil covered, or non-plastic, non-paraffin closures.

Sampling medicinal and other gases - Gases represent a special sampling situation. Please contact your servicing lab to determine an appropriate sampling container and sample size.

#### 4.3.5.1 - Complaints, Counterfeiting / Tampering, Foodborne Disease, Injury Illness

Detailed instructions for investigating and sampling products in connection with consumer complaints, tampering, foodborne outbreaks, injury and adverse reactions, etc. appear in [Chapter 8 of the IOM](#).

Be cognizant of conserving scarce resources when investigating consumer complaints that do not involve injury, illness, or product counterfeiting / tampering. Unnecessary samples waste both operational and administrative resources. Use judgment as to whether or not it is necessary to collect the consumer's portion in situations that do not involve injury, illness, or product tampering. For example, there is little need to collect a physical sample of an insect infested box of cereal from the complainant. Both you and the consumer can readily see it is insect infested. The laboratory would find it insect infested, and the division would merely report the same thing back to the complainant. No practical purpose would be served by either collecting or examining such a sample.

During consumer complaint investigations/follow-up when blood or body fluid contamination is suspected, and when there is no apparent illness or injury, samples should not be collected without first contacting Emergency Operations due to the lack of confidence in the analytical methods and the results associated with certain samples. A decision to collect a sample will be made on a case by case basis, and after consulting with the Office of Regulatory Science, Emergency Operations, and the Office of Medical Products and Tobacco Operations.



### 4.3.5.2 - Recalls

See IOM 7.1 and 7.1.1.7.

### 4.3.5.3 - Natural Disasters

See IOM 8.1.5.8.

### 4.3.5.4 - Induced Samples

If this type sample is desired, your supervisor will provide specific instructions and procedures to be followed. This may involve:

1. Whether to use your correct name or an alias. Caution: if you use an alias, do not use a similar name or a name with initials the same as yours (e.g., Sidney H. Rogers should not use Samuel H. Right). In addition, do not use a division office or resident post as a return address when ordering products or literature.
2. Do not telephone your order in from the office or your home phone because the firm may have "Caller ID" and be able to identify your location by the phone number. For samples induced online, use a non-FDA network computer.
3. Whether to use order blanks contained in the promotional package, advertisement, or promotional activity; or whether false ones will be used.
4. Whether money orders, your credit card numbers, bank checks, or your personal checks should be used for payment. It depends on the situation, but money orders are preferred since these do not involve personal accounts.
5. Where the requested items are to be sent: rented P.O. Box, home address, General Delivery, or other address.
6. How the address and/or your name is to be recorded on the order blank. A code may be used either in your name or address, so any follow-up promotional material sent to that name and address can be keyed to your original order.

When it has been decided to induce a sample and you have discussed the procedures with your supervisor, prepare the order and obtain the money order, or payment document. When all documents for ordering the item(s) are prepared, photocopy all the material, including the addressed envelope, for your record and submit the order.

When the order is received, identify the sample item, all accompanying material such as pamphlets, brochures, etc. (including all wrappings containing any type of printing, identification, numbers, post marks, addresses, etc.), and submit the item and exhibits in the same manner as any other official sample. If payment of the item was by personal check or credit card number, attach a photocopy of the canceled check or credit card receipt if available. You may do this later, after clearance of the check or charge slip. Samples induced online should include a record of the purchase process including point of sale, relevant emails and documentation of where and how the sample was received and collected.

### 4.3.5.5 - Undercover Buy

See IOM 4.1.4.6.

### 4.3.5.6 - Collecting Surveillance Samples on Farms

Specific instructions have been developed for the collection of surveillance samples on farms or from on-farm packinghouses or processors, including pre-notification, interaction with the farm personnel, payment for samples collected on farms and sample size(s). Though these instructions only apply to surveillance samples, they may also be considered for illness investigations or for cause sampling but are not required.

On farm collections should be limited to instances where it is specifically mentioned in an assignment or is preferred by the industry or other sampling venues are not available. When an investigator is planning to collect surveillance samples on a farm, the investigator will call the farm at least 24 hours in advance to notify the farm of FDA's intent to collect samples and share the commodity of interest. There may be instances when responsible farm management will not be available on the planned date and time and the investigator will need to use his/her judgment in negotiating alternate dates as appropriate.

During the pre-notification call, the investigator should also determine an estimate of what the sample(s) will cost if the farm decides to charge for the samples. The investigator will take enough cash to cover the cost of the samples collected and not ask the farm to bill FDA as may be done in other sampling situations.

If the investigator collecting the sample is a PHS Commissioned Officer, the investigator will explain to the farm representative that he/she will be wearing his/her uniform. During this conversation, the officer will describe the uniform he/she will be wearing (e.g., blues, khakis) and also explain why the officer wears the uniform as a Commissioned Officer in the Public Health Service.

When on farm and viewing the inventory of product to be collected, the investigator will determine if the sample size needed will exhaust the farm's supply of the product or may cause the farm to not be able to meet customer needs. If so, consideration should be given to not collecting the sample or if possible modifying the sample collection. If the sample collection will exhaust the entire inventory, the investigator should discuss this with responsible farm management and determine how soon inventory will be restored and if the responsible individual believes the sample collection will impose an economic disadvantage. If the responsible party states that it will cause an economic disadvantage, the investigator should not collect the sample at that time, but rather plan to return at another time when additional inventory will be available for sampling or consider selection of another site for collection.

### 4.3.5.7 - Collecting Feed Samples for BSE Analysis

If your work involves collecting samples for BSE analysis, please review [Compliance Program 7371.009, BSE/Ruminant Feed Ban Inspections](#), specifically Part IV – Analytical, as well as Attachment E of that section for pertinent safety procedures.

Investigators need to be aware of proper safety procedures for collecting, packaging and shipping domestic and imported feed samples. The main objective of safety recommendations is to minimize exposure to feeds and feed dust at the time of sample collection and to minimize future exposure through feed dust on clothing or equipment.

Safety precautions listed should be followed for ALL sample collections for BSE analysis, both import and domestic. Use of these procedures will also minimize exposure risk to other potential pathogens and it is encouraged to follow these procedures whenever any dusty feed samples are collected.

In CP 7371.009, Part IV- Analytical, there are instructions regarding the collection of samples. The CP notes, "**CAUTION:** This material may be dusty and consist of fine particles, especially if the product is in bulk. Exercise appropriate precautions when collecting samples of dusty, loose material. Refer to "[Safety Information for Imported Feeds Assignment - Collection and Analysis](#)".

Minimizing dust exposure can be accomplished as follows:

#### 1. Recommended personal protective equipment (PPE) to be used by personnel collecting feed samples:

- Respiratory protection: minimum half-mask air-purifying respirator (face-sealing) with P100 filters (HEPA)
- Ocular (eye) mucous membrane protection: goggles
- Percutaneous (through skin openings such as cuts, abrasions- unbroken skin poses no known hazard) – waterproof gloves on hands; cover skin lesions, cuts, abrasions with waterproof dressing
- Clothing contamination – disposable coveralls

#### 2. Collection and bagging procedures:

Minimize dust as much as possible when collecting 16 – 1 oz subs and combining them into one sample. Wipe the outside of whirl-pak bag with a water-dampened paper towel in a clean area and place this bag into another whirl-pak bag (**double bag the sample**).

#### 3. Cleanup and PPE removal:

When in a dust-free area, remove the disposable coveralls by turning inside-out, rolling up and placing in a plastic bag for disposal. Wipe shoes with water dampened paper towel. Remove goggles and respirator; wipe outside of goggles and respirator with water-dampened paper towel. Place goggles and respirator in clean carrying bag. Place all wipes in the disposal bag with the disposable coveralls. *Place the bag in a trash receptacle on site if the firm permits or carry out and dispose of properly at your FDA office.*

### 4.3.6 - ASEPTIC SAMPLE

Aseptic sampling is a technique used to prevent contamination by your sampling method. Aseptic sampling involves the use of sterile sampling implements and containers. Your sampling technique is where the lot or sample is contacted only by the sampling implements or the container. Samples collected using aseptic technique, will permit testimony that the bacteriological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the time of the original shipment. Aseptic sampling is critical to not only samples that will undergo microbiological analysis but also samples subject to chemical tests that might be altered by microbial activity. For chemotherapeutics, make sure that shipping conditions ensure that microbial populations remain inactive and do not have the opportunity to degrade the analyte. Whenever possible collect intact, unopened containers. Aseptic sampling is often used in the collection of in-line samples, environmental samples, product samples from bulk containers and collection of unpack-aged product that is being collected for microbial analysis.

Note: Products in 55-gallon drums, or similar large containers, either aseptically filled or heat processed, should not be sampled while the shipment is en route unless the owner accepts responsibility for the portion remaining after sampling. Try to arrange sampling of these products at the consignee (user) so the opened containers can be immediately used or stored under refrigerated conditions. Use ASEPTIC TECHNIQUE when sampling these products.

For more guidance on aseptic technique, you may consult the course *Food Microbiological Control 10: Aseptic Sampling*, which is available to FDA employees through the [ORA U intranet site](#).

#### 4.3.6.1 - General Procedures

If it is necessary to open containers, draw the sample and submit it under conditions, which will prevent multiplication or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling technique. Take steps to minimize exposure of product, sampling equipment, and the interior of sampling containers to the environment.

##### 4.3.6.1.1 - Sterilized Equipment

Use only sterilized equipment and containers. These should be obtained from the servicing laboratory or in an

emergency, at local cooperating health agencies. Pre-sterilized plastic or metal tools should be used. However, if unavailable, the metal tools can be sterilized immediately before use with a propane torch. Permit the tool to cool in the air or inside a sterile container before using. Soaking with 70% alcohol and flaming off is an acceptable method of field sterilization and may be used as a last resort.

If it is necessary to drill, saw, or cut the item being sampled (such as large frozen fish, cheese wheels, frozen fruit, etc.), if at all possible, use stainless steel bits, blades, knives, etc. Wooden handled sampling instruments are particularly susceptible to bacterial contamination, are difficult to sterilize, and should be avoided.

#### 4.3.6.1.2 - CAUTIONS

Be extremely careful when using a propane torch or other flame when sterilizing tools and equipment. Evaluate the conditions pertaining to explosive vapors, dusty air, flame-restricted areas, firm's policy or management's wishes. The use of supportive devices should be considered when torch is not being hand held. Also, be sure all flammable liquids, such as alcohol, in your filth kit are in metal safety cans and not in breakable containers.

If it is necessary to handle the items being sampled, use sterile disposable type gloves (rubber, vinyl, plastic, etc. - surgeon's gloves are good). Use a fresh glove for each sub and submit an unopened pair of gloves as a control. See IOM 4.3.6.5.

#### 4.3.6.1.3 - Opening Sterile Sampling Containers

When opening sterile sampling containers, work rapidly. Open sterile sampling containers only to admit the sample and close it immediately. Do not touch the inside of the sterile container, lip, or lid. (See IOM 4.3.5)

#### 4.3.6.1.4 - Dusty Areas

Do not collect samples in areas where dust or atmospheric conditions may cause contamination of the sample, unless such contamination may be considered a part of the sample.

#### 4.3.6.2 - Sampling Dried Powders

**Cautions** - The proper aseptic sampling of dried milk powder, dried eggs, dried yeast, and similar types of products is difficult because they are generally packed in multilayer poly-lined paper bags. These may be stitched across the entire top, may have filler spouts, or the top of the poly-liner may be closed or sealed with some type of "twists".

The practice of cutting an "X" or "V" or slitting the bag and folding the cut part back to expose the contents for sampling should not be used because it creates a resealing problem; the opening cannot be properly repaired.

The following procedures have been approved by the scientific units in Headquarters and should be used when sampling this type product.

#### 4.3.6.2.1 - Bag And Poly-Liner Stitched Together Across Top Seam

1. Remove as much dust as possible from the seam end by brushing and then wiping with a cloth dampened with alcohol. Note: This does not sterilize the bag as porous paper cannot be sterilized.
2. Remove the seam stitching carefully (and dust cover, if any) and spread the walls of the bag and the poly-liner open enough to permit sampling being careful that no extraneous material such as dust, bits of twine, paper, etc., drops into the product.
3. Carefully scrape off the surface of the product with a sterile device and aseptically draw the sample from the material below.
4. Carefully reclose the bag and re-stitch by hand, or by machine if firm or FDA portable sewing machine is available.

#### 4.3.6.2.2 - Bag Stitched Across Top And Poly-Liner Twist-Closed And Sealed With "Twist" Device - Wire, Plastic, Etc.

1. Brush, alcohol wipe, and remove stitching as described.
2. Remove "twist" seal and carefully open poly-liner using caution that no extraneous material drops into the product.
3. Draw aseptic sample in same manner as in step 3 above.
4. Carefully close the poly-liner with a twisting motion and reseal with "twist" seal arranging it so it will not puncture the poly-liner and re-sew bag as in step 4 above.

#### 4.3.6.2.3 - Bags With Filling Spouts

The filling spout will be located at one side of the top stitching and will either pull out to form a top or side spout.

1. Brush and alcohol wipe the area around the spout and carefully pull it out to reveal the opening. It is better to have the bag on its side while pulling the spout so any dust in the opening falls outside the bag.
2. Carefully spread the sides of the spout apart and aseptically draw the sample. A trier or long handled device is usually better for this type opening because of the limited opening.
3. Carefully close the spout with a firm twisting motion and be sure the opening is closed prior to pushing back into the bag.

#### 4.3.6.3 - Collecting Water Samples

When it is necessary to collect water samples for bacteriological examination, use the following procedures:

1. Use sterile bottles. If dechlorination of sample is necessary, sodium thiosulfate sufficient to provide 100 mg/l should be placed in the clean bottles prior to sterilization. The sodium thiosulfate will prevent the chlorine from acting on the bacteria and assures, when the sample is analyzed, the bacterial load is the same as when collected.
2. Carefully inspect the outside of the faucet from which the sample will be drawn. Do not collect sample from a faucet with leaks around handle.
3. Clean and dry outside of faucet.
4. Let the water run from the fully open faucet for at least 1/2 minute or for 2 or 3 minutes if the faucet is on a long service line.
5. Partially close faucet to permit collecting sample without splashing. Carefully open sample bottle to prevent contamination, as for any other aseptic sampling operation.
6. Fill bottle carefully without splashing and be sure no water from your hands or other objects enters the bottle. Do not over fill but leave a small air bubble at top.
7. Unless otherwise instructed, minimum sample size for bacteriological examination is 100 ml.
8. Pack sample into an insulated shipping container with ice packs to keep sample cool in transit. Do not use wet ice to ship the sample to the lab.
9. Deliver sample to lab promptly. If sample is not examined within 24 hours after collection, the results may be inaccurate.

Note: When documenting specific situations in a plant, you may need to vary this procedure to mimic the actual conditions used by the firm.

#### 4.3.6.4 - Sample Handling

For frozen samples, pre-chill sterile containers before use and keep frozen with dry ice. Use ordinary ice or ice packs for holding and transporting unfrozen samples that require refrigeration. See IOM 4.5.3.5 and 4.5.3.6. Under normal circumstances dried products may be shipped unrefrigerated except in cases where they would be exposed to high temperatures, i.e., above 37.8°C (100°F).

Submit samples subject to rapid spoilage (specimens of foods involved in poisoning cases, etc.) by immediate personal delivery to the bacteriologist where feasible.

#### 4.3.6.5 – Closed Controls

When collecting samples using aseptic technique and the subs are collected using pre-sterilized containers and equipment, collection and submission of unopened, closed controls is required. This includes finished product aseptic samples. See Field Bulletin #30 for more information on environmental samples.

Closed controls should be collected for each lot of control subs used for the sample.

List control subs on your C/R. Control subs should be identified with a different nomenclature than the physical sample, i.e., a, b, c versus 1, 2, 3. Provide control sub lot number(s) and expiration date(s), if applicable.

Examples of various control subs are:

1. Sterile Containers - Where sterile containers are used to collect aseptic samples, submit one unopened container, which was sterilized in the same manner as containers used for sampling.
2. Sterile Disposable Gloves - If sterile disposable gloves are used to handle the product, submit one unopened pair of gloves as a control.
3. Sterile Sampling Equipment - Where pre-sterilized sampling tools are used (e.g., spoons, spatulas, triers, etc.), submit at least one unopened sampling tool as a control.

#### 4.3.7 - ADULTERATION VIOLATIONS

Since adulteration samples are collected to confirm the presence of filth or other deleterious material, they are generally either larger or more selective than samples collected for economic or misbranding purposes.

When widespread evidence of filth or other adulteration is present, 402(a)(4) conditions can be documented by selective sampling. See IOM 4.3.7.3. For adulteration with filth, you will need to field examine (See IOM 4.3.7.1) a number of lots of product to determine the extent of the adulteration and can collect an investigational (INV) sample (See IOM 4.1.6) of filth exhibits and take photographs to document the widespread nature of the evidence. Collect separate sub samples of filth from various areas of the firm to illustrate the extent of adulteration within the firm. Field examine various lots of regulated products and collect official selective samples to document filth or other adulteration. Filth found on the exterior of containers, on pallets containing regulated product, or on the floor adjacent to lots of regulated product you are selectively sampling can be considered subsamples of that official sample. Consult with your supervisor and be guided by the criteria in [Compliance Policy Guide \(CPG\) 580.100 Food Storage and Warehousing - Adulteration - Filth \(Domestic and Import\)](#). The criteria in the Compliance Policy Guide can be used to determine if a particular lot meets the minimum criteria for direct reference seizure. Documenting a number of lots which meet the criteria helps establish the widespread nature of the adulteration.

See IOM section 4.3.7.6 and 4.3.7.7 for instructions on how to selectively sample for microbiological samples, including pathogenic organisms to document adulteration.

When lots appear actionable, determine recent sales from the lot in question. Follow up may be necessary as directed by your supervisor.

#### 4.3.7.1 - Field Examination

Some field examinations are also referred to as bag-by-bag exams or unit by unit exams. When you conduct such

exams take care to describe observations of each unit of product examined, any physical subsamples collected which reflect the violative nature of the lot and exhibits which corroborate your report of observations.

Record in your regulatory notes, subsequently in C/R Collection Remarks field or Continuation Form, or on Analyst Worksheet FDA 431, the results of your unit by unit examination of the lot. Observations should be specific. Report the general storage conditions, the violative condition of the lot, the physical relationship of the violative lot to other lots in the area, how you conducted the examination and how many units you examined. Whenever possible, record quantitative observations.

Report the number and location of live and dead insects, rodent pellets, or other adulteration discovered inside the containers as well as on their exterior surface. Provide graphic measurements of areas of urine/chemical stains on each container and the extent of penetration. Correlate findings of the unit by unit examination with any photographs and physical subsamples collected.

Where the field examination is carefully described and documented, the sample collected from obviously violative lots may be reduced to carefully selected exhibits. The field examination and the report of findings will serve as the analysis.

#### 4.3.7.2 - Random Sampling

The concept of random "blind" sampling is to yield information about the average composition of the lot. It is employed when you have no information or method of determining which units are violative. Usually the violation is concealed and must be found by laboratory methods.

Sample size is usually described in your assignment, IOM Sample Schedule, Compliance Program Guidance Manual, or the applicable schedules. If none of these furnish the sample size, a general rule is to collect samples from the square root of the number of cases or shipping containers but not less than 12 or more than 36 subs in duplicate. If there are less than 12 containers, all should be sampled. Discuss sample size and 702(b) requirements with your supervisor. See IOM 4.3.3.2.

#### 4.3.7.3 - Selective Sampling

In some situations, random sampling is unnecessary or even undesirable. Under these conditions, examine the lot and select the portions which will demonstrate the violative nature of the lot.

In addition to the selective samples collected, exhibits should include diagrams and photographs to demonstrate the violative conditions reported, and which containers were sampled and photographed.

#### 4.3.7.4 - Sample Criteria

The Agency has defined minimum direct reference seizure criteria to assist in assessing filth of individual lots. Criteria for rodent, insect, and bird filth are defined [Compliance Policy Guide \(CPG\) 580.100, Food Storage and Warehousing - Adulteration - Filth \(Domestic and Import\)](#) for human foods, and reiterated in IOM sections 4.3.7.2 - 4.3.7.4. When collecting selective samples of products to show adulteration by filth, be guided by this criteria.

When evidence of rodent, insect, bird, or other animal activity is encountered during an inspection it is your responsibility to assess the evidence you observe and determine and document whether the activity is:

1. Current or old
2. Isolated to one lot (possible [FD&C 402\(a\)\(3\)](#) charges - contain in whole or in part filth or is otherwise unfit for food).
3. Widespread, which requires evidence and documentation to illustrate all of the firm's susceptible products are potentially adulterated because they are being prepared, packed, or held under conditions whereby they may be contaminated. (possible [FD&C 402\(a\)\(4\)](#) charges)

Your assessment and documentation of the evidence observed (diagrams, photos and sample collections) will determine what actions may be required by either the establishment, the Agency, the Court, or all three to correct the problem. The evidence and documentation you collect and develop will be used to show, by a preponderance of evidence, that conditions at the firm have resulted, or could result in adulteration.

Your sample collection should be sufficient to document the extent of the violative conditions and not be limited to this minimum. Even where these minimum prerequisites are not met, you should collect samples as exhibits and evidence, particularly where adulteration under section [402\(a\)\(4\) of the FD&C Act \[21 U.S.C. 342 \(a\)\(4\)\]](#) may be a factor. Your evidence may be used in a subsequent action against the firm, if corrections are not made.

Consult with your supervisor as soon as possible when you find evidence which meets the criteria set forth in [CPG 580.100](#). If you are collecting several samples, the lab should be notified in advance that samples are on their way and should be analyzed expeditiously to facilitate regulatory action. Your supervisor may also want to notify your compliance branch so evaluation of evidence for a possible mass seizure can commence.

#### 4.3.7.4.1 - General

When Selective Sampling consists of an actual sample of a product, however small, as distinguished from bag cuttings, rodent pellets, insects, etc., a 702(b) portion must be obtained. In such cases, collect duplicate subs of the product to provide the 702(b) portion. This 702(b) portion is usually not an exact duplicate of the product collected for

the Selective Sample, but should be collected from the same bag, box, or other container of product sampled. Whether collected from a container or bulk, the 702(b) portion should be taken as close as possible to that portion selectively sampled for analysis. Specify for each sub and duplicate collected, the origin, manner in which taken, and the examination to be made on your C/R. See IOM 4.3.3.3

Submit each portion of bagging or container portion, rodent pellets, material from beneath sampled area, control etc., in separate vial or subsample container.

It's important when collecting a selective sample for adulteration violations that you:

1. Use a coherent numbering/identification system for subsamples to avoid unnecessary confusion for the lab.
2. Provide a detailed listing of individual sub descriptions on the C/R.
3. If possible, provide a copy of any maps, photos or other additional documentation to the laboratory.
4. Be sure to obtain product labeling. Since samples of lots which are sampled selectively are official samples, complete labeling must be collected. See IOM 4.4.9.
5. Note: Whenever a portion of food is collected as part of a selective sample FD &C Act Section 704(d) applies and the CR should be marked as such.

**4.3.7.4.2 - Rodent Contamination**

The minimum direct reference seizure criteria to assist in assessing rodent adulteration of individual lots, as defined in [Compliance Policy Guide \(CPG\) 580.100](#), are summarized as follows:

The storage facility is rodent infested and:

1. Three or more of the bags in the lot are rodent gnawed; or
2. At least five of the bags in the lot bear either rodent urine stains at least 1/4" in diameter, or two or more rodent pellets; or
3. The food in at least one container in the lot contains rodent gnawed material, or rodent excreta or urine.

Whether or not the warehouse is rodent infested; IF:

1. At least three bags bear rodent urine stains of at least 1/4" in diameter which penetrates to the product even though the product cannot be demonstrated to have been contaminated; or:
2. At least two bags are rodent-gnawed and at least five bags bear either rodent urine stains at least 1/4" in diameter, with or without penetration to the product, or two or more rodent pellets; or:
3. The food in at least one bag in the lot contains rodent-gnawed material or rodent excreta or rodent urine, and at least five bags bear either rodent stains at least 1/4" in diameter or two or more rodent pellets.

Additional regulatory guidance concerning rodent adulteration of pet foods can be found in [CPG, 690.600 Rodent Contaminated Pet Foods](#).

**4.3.7.4.2.1 - Examination and Documentation of Rodent Contamination**

Examine the exterior of the containers looking for rodent hairs, urine stains, excreta pellets, gnaw marks, holes, nesting material and live rodents. Make a diagram of the entire lot and note your findings as you examine the individual containers. You will need to include these descriptions on your C/R.

Describe excreta pellets as carefully as possible, Note whether they appear dusty or shiny; soft or hard.

Examine suspected urine stains with ultra-violet light in as near total darkness as possible. A minimum of 15 minutes is normally required for the eyes to become properly adjusted to accurately differentiate between rodent stain fluorescence and normal fluorescence of rice and certain other commodities.

Wet, fresh or continually wetted runs may fluoresce poorly, but the odor of urine will usually be present and should be described on the C/R. Fresh dry urine stains will fluoresce blue-white, while older stains may be more yellowish/white. Rodent hairs will look like blue/white streaks. Look for the typical droplet pattern because rodents commonly urinate while in motion. Report the presence of droplet patterns on your C/R.

Urine stained areas may be photographed under ultra-violet light conditions. Check with your supervisor about the technical aspects of this procedure. Do not mark container surfaces to outline the stained areas when taking either ultra violet or normal photographs. This may contaminate the product by migration through the containers.

A number of things can interfere with the visual identification of urine stains. Many types of bagging and threading materials will fluoresce under U.V. light, however, the characteristic rodent stain fluorescence can be identified by its yellowish color and characteristic pattern. In addition, a number of products exhibit a natural fluorescence. The following products may be difficult to evaluate because of either natural fluorescence or "quenching" of UV rays, even if contaminated. ("Quenching" refers to a covering up or a decrease in the ability of a product to fluoresce.)

<p><b>FOODS</b>                  High Gluten Flour (Natural)                  Nut Meats (Natural)                  Bean Flours (Natural)                  Brans (Natural)                  Pop &amp; Field Corn (Natural)                  Wheat (Natural)                  Starch (Natural)                  Spices (Natural or Quenching)</p>	<p><b>NON-FOOD ITEMS</b>                  Burlap Bags (Quenching)                  Bleached Sacks (Natural-White Glow)                  Lubricants (Oils &amp; Greases) (Natural-Blue/White to yellow/brown glow)                  Pitches &amp; Tars (Natural-Yellow)                  Detergents &amp; Bleaches (Natural-White)                  Sulfide Waste Matter (Natural-Blue/White)</p>
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Note clearly on your C/R if the product or package contains or is directly associated with any of the following:

1. Dried milk products (contain urea).

2. Whole grain wheat (contains urea and allantoin).
3. Animal feeds (urea is usually intentionally added).

#### 4.3.7.4.2.2 - Collecting Exhibits or Subsamples

When sampling lots for rodent contamination, follow the safety precautions in IOM 1.5.5.4. Wear gloves and handle the exhibits with tweezers or forceps. Handle exhibits carefully to prevent loss of microscopic evidence. Where you separate, count, or identify the various elements of an exhibit, (e.g.: sieve and find X number of rodent pellets), maintain the counted portions separate from the other subs. Note on the C/R those subs that were counted, separated, etc.

Collect a representative number of rodent pellets for laboratory confirmation. Place the pellets in a vial or other rigid container to prevent crushing. One of the identifying characteristics the lab looks for is the presence of rodent hairs in the pellets. The more pellets examined increases the possibility of a good identification. However, do not collect all the evidence you see as this would recondition the lot.

Collect portions of urine stains or gnawed holes from containers using small scissors or a sharp knife. Leave a portion of the stain or gnawed hole intact but take a cutting large enough to provide good identification. Usually ½ inch around the stain is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) If possible, take stained cuttings from areas which have not been exposed for extended periods of time to light, in particular, ultraviolet light sources or to intense heat. If you have no alternative or cannot determine the stained areas' history, note the conditions on the C/R. Place cuttings and gnawed holes between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss of hairs or parasites due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as rodent hairs may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting.

Collect a minimal amount of product from under the stained area or hole, preferably just clumped product as a separate subsample. This prevents dilution of the contaminated product with uncontaminated product. Whenever you collect product, regardless of amount, collect a separate subsample to provide a 702(b) portion. See IOM 4.3.7.4.1. and identify per IOM 4.5.2.1.

Collect nesting material with minimal handling. A half cup is enough for analysis. Do not collect any rodents.

**Product Control:** In addition, you need to collect product controls, in duplicate, to provide for the 702(b) portion.

These subsamples should be collected from beneath unstained portions of the container. Collect control samples from 3 different containers.

**Packaging Control:** Collect a portion of unstained container, which does not fluoresce, as a separate subsample for a control. As a general guide, collect the controls from the opposite side of the bag or make the cutting large enough to separate the control area and the stain. Separate the controls from the stains and submit in separate containers. Collect at least 3 container controls for each sample. If the lot consists of different containers or bags of different manufacturers, collect controls to represent each type or manufacturer of the containers.

Submit each portion of bagging or container, pellets, material from beneath sampled area, control, etc., in separate vial or subsample container. Place the subsamples in a dark container, such as a cardboard box to protect them from light and protect the exhibits from being crushed.

#### 4.3.7.4.2.3 - Summary of Sample for Rodent Evidence

The complete official sample will consist of:

1. Subsamples of rodent excreta pellets
2. Subsample of nesting material
3. Subsamples of stained bagging, or portions of the containers, and any adhering pellets.
4. Subsamples of unstained bagging, or portions of the containers, which do not fluoresce, for controls (minimum three required).
5. Subsamples of small portions of the product from directly beneath the stained areas. Do not dilute the contaminated product beneath the stain with the non-contaminated product.
6. Subsamples of small portions of product to serve as 702(b) portions
7. Subsamples of uncontaminated product from beneath the unstained bagging, or other container. These serve as controls and should be collected in duplicate to provide 702(b) portions. Collect control samples from 3 different containers.
8. Subsamples of cuttings from gnawed holes
9. Subsamples of small amounts of product collected from beneath the gnawed holes.
10. Subsamples of small portions of product to serve as 702(b) portions.
11. Product labeling.
12. Interstate documentation.

If conditions warrant, consider collecting an INV sample per IOM 4.1.6. to document widespread rodent activity.

#### 4.3.7.4.3 - Insect Contamination

The criteria from [CPG 580.100](#) below, involving dead insects only, will not be used for action against any food intended to undergo further processing that effectively removes all the dead insects, e.g. processing of cocoa beans.

1. The product contains:

- a. One live insect in each of two or more immediate containers; or, one dead insect in each of three or more immediate containers; or, three live or dead insects in one immediate container; plus
  - b. Similar live or dead insect infestation present on, or in the immediate proximity of, the lot to show a [402\(a\)\(4\) \[21 U.S.C. 342 \(a\)\(4\)\]](#) violation.
2. The product contains one or more live insects in each of three or more immediate containers.
  3. The product contains two or more dead whole insects in at least five of the immediate containers. Note: a situation such as this may follow fumigation of the lot and vacuuming of the exteriors of the bags.
  4. The product is in cloth or burlap bags and two or more live or dead insects are present on at least five of the containers. Note: Some live insects must be present. Product need not be shown to have become contaminated.

#### 4.3.7.4.3.1 - Examination and Documentation of Insect Contamination

Examine the exterior of the containers (especially along seams or creases) looking for insects, larvae, webbing, nesting material, entrance or exit holes, and cast skins. Make a diagram of the entire lot and note your findings as you examine the individual containers. Describe insects or larvae carefully, noting if they are dead or alive. You will need to include these descriptions on your C/R.

#### 4.3.7.4.3.2 - Collecting Exhibits or Subsamples

Collect a representative number of insects for laboratory confirmation. Consider the use of a moistened artist brush to collect subsamples. Place the specimens in a vial or other rigid container to prevent crushing. Collect all forms of insects you see, however do not collect all the evidence from the lot or you might recondition the product. If you collect live insects, be sure to note that on your C/R. However, you should not send live insects to the lab. Freeze the subsamples prior to shipment to ensure they are not alive when you ship them. Note the fact that the subsamples were frozen on the C/R.

Cut portions of bags or containers containing suspected insect entrance or exit holes from containers using small scissors. Usually ½ inch around the holes is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) Place cuttings between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss microscopic evidence due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as insect fragments may adhere to containers

made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting

Collect product from beneath holes which penetrate the packaging as a separate subsample. Whenever you collect product, regardless of amount, collect a separate subsample to provide a 702(b) portion. Note on the subsample itself and on your C/R which subsamples are the 702(b) portions.

#### 4.3.7.4.3.3 - Summary of Sample for Insect Evidence

The complete official sample will consist of:

1. Subsamples of insects, larvae, webbing, etc.
2. Subsamples of portions of the containers with entrance or exit holes.
3. Subsamples of small portions of the product from directly beneath holes.
4. Subsamples of small portions of product serve as 702(b) portions See IOM 4.3.7.4.1.
5. Product labeling.
6. Interstate documentation.

If conditions warrant, consider collecting an INV sample per IOM 4.1.6. to document widespread insect activity.

#### 4.3.7.4.4 - Bird Contamination

Per the criteria from [CPG 580.100](#), if the product is in permeable containers (paper, cloth, burlap, etc.), and

1. The product contains bird excreta in one or more containers, and you feel the insanitary storage conditions will clearly support a [402\(a\)\(4\) \[21 U.S.C. 342 \(a\)\(4\)\]](#) violation.
2. Bird excreta is present on the exteriors of at least five of the containers, and the product contains bird excreta in one.
3. At least 30% of the number of bags examined, but at least five bags, are contaminated with bird excreta; and at least three of the bags bear excreta stains which penetrate to the product, even though the product may not be contaminated.

**Note:** In all instances of bird excreta contamination the excreta must be confirmed by positive test for uric acid.

#### 4.3.7.4.4.1 - Examination and Documentation of Bird Contamination

Examine the exterior of the containers looking for bird excreta. Make a diagram of the entire lot and note your findings as you examine the individual containers. You will need to include these descriptions on your C/R.



#### 4.3.7.4.4.2 - Collecting Exhibits and Subsamples

Remove portions of bird excreta stains from containers using small scissors. Leave a portion of the stain intact but take a cutting large enough to provide good identification. Usually ½ inch around the stain is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) If possible, take stained cuttings from areas which have not been exposed for extended periods of time to light, in particular, ultraviolet light sources or to intense heat. If you have no alternative or cannot determine the stained areas' history, note the conditions on the C/R. Place cuttings between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss of microscopic evidence due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as bird excreta may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting.

Collect a minimal amount of product from under the stained area, preferably just the clumped product as a separate subsample. This prevents dilution of the contaminated product with uncontaminated product. Collect a separate subsample to provide a 702(b) portion (See IOM 4.3.7.4.1).

**Product Control:** In addition, you need to collect product controls, in duplicate, to provide for the 702(b) portion. These subsamples should be collected from beneath unstained portions of the container. Collect control samples from 3 different containers.

Identify the 702(b) subsamples, as such on subsample identification (See IOM 4.5.2.1.) Note on the subsample itself and on your C/R which subsamples are the 702(b) portions.

**Packaging Control:** Collect a portion of unstained container as a separate subsample for a control. As a general guide, collect the controls from the opposite side of the bag or make the cutting large enough to separate the control area and the stain. Separate the controls from the stains and submit in separate containers. Collect at least 3 container controls for each sample. If the lot consists of different containers or bags of different manufacturers, collect controls to represent each type or manufacturer of the containers.

#### 4.3.7.4.4.3 - Summary of Sample for Bird Evidence

The complete official sample will consist of:

1. Subsamples of stained bagging, or portions of the containers.

2. Subsamples of unstained bagging, or portions of the containers for controls (minimum three required).
3. Subsamples of small portions of the product from directly beneath the stained areas. Do not dilute the contaminated product beneath the stain with the non-contaminated product.
4. Subsamples of small portions of product to serve as 702(b) portions.
5. Subsamples of uncontaminated product from beneath the unstained bagging, or other container. These serve as controls and should be collected in duplicate to provide 702(b) portions. Collect control samples from 3 different containers. Submit each portion of bagging or container portion, pellets, material from beneath sampled area, control, etc., in separate vial or subsample container.
6. Product labeling.
7. Interstate documentation.

#### 4.3.7.4.5 - Chemical Contamination

Collect samples from lots suspected of dry chemical contamination in much the same manner as described for rodent urine. After collecting a sample of the contents from immediately beneath the suspected area, collect residues from the surface of the bag or container. In the case of infiltration of loosely woven bags, shake or tumble the bag over a large sheet of clean paper to collect the siftings as a sample.

#### 4.3.7.4.6 - Mold Contamination

The USDA/FGIS has approved a number of commercial screening tests for detecting aflatoxin contaminated corn. However, these tests usually require a chemical extraction process and are therefore not amenable to FDA field examination procedures.

The black light test (also referred to as the Bright Greenish-Yellow Fluorescence (BGYF) test) is a presumptive test used to screen and identify corn lots that should be tested further for aflatoxins. The test is based on BGYF observed under long wave (366 nm) ultraviolet (UV) light produced by the molds *Aspergillus parasiticus* and *A. flavus* on "living" corn (i.e. corn that has been stored less than 3 months). The growth of these fungi may result in aflatoxin production. Aflatoxins per se do not produce BGYF under long wave UV light. It is thought the BGYF is produced by the reaction of kojic acid formed by the fungi and a peroxidase enzyme from living corn. Corn that has been in storage for a lengthy period of time (3 months or more) may give false positive BGYF. Therefore, determine how long the corn being sampled has been in storage. If it has been in storage over three months, do not use the following field screening procedure.

Essential steps for this black light procedure are:

1. A 10 lb. sample representative of the corn lot must be obtained by probing, or by continuously sampling a grain stream.

2. Examine using a 366 nm UV light (portable black-lights meet this criteria).
3. Wear goggles or use a viewer that screens out UV light. Shine the light on the corn sample which has been spread in a single layer on a flat surface in a darkened room.
4. Use a 2 lb. portion, and carefully observe the entire corn surface one kernel at a time. Examine the entire sample using this procedure.
5. Count all BGYF glowers (kernels or particles that "glow" bright greenish-yellow). Compare the BGYF color with a fluorescent standard, if one is available. Remember normal corn, if it fluoresces, will fluoresce a bluish white.
6. If four (4) or more BGYF particles are detected in the 10 lb screening sample, collect a sample for laboratory analysis.

### 4.3.7.5 - Abnormal Containers

See IOM SAMPLE SCHEDULE CHART 2 - Sampling Schedule for Canned and Acidified Foods for listing can defects.

### 4.3.7.6 - Microbiological Samples

During inspections of firms producing products susceptible to microbial contamination (e.g., peanut butter, dried milk, dairy products, frozen ready-to-eat seafood, crème filled goods, breaded items, prepared salads, etc.), sampling may be warranted, based on observations or as directed in the Work Plan, Compliance Program, or assignment. Proof of adulteration with fecal organisms, elevated levels of non-pathogenic microorganisms, or presence of pathogenic microorganisms must be established. Follow instructions under IOM 4.3.7.7 when collecting microbiological samples to document manufacturing conditions conducive to adulteration.

#### 4.3.7.6.1 – Collection Of Samples For Molds

Mold Samples - During inspections of manufacturers such as canneries, bottling plants, milling operations, etc., it may be necessary to collect scrapings or swabs of slime or other material to verify the presence of mold. The sample should represent the conditions observed at the time of collection and consist of sufficient material to confirm and identify mold growth on the equipment. If possible, take photographs and obtain scrapings or bits of suspect material. Describe the area scraped or swabbed, e.g., material was scraped or swabbed from a 2" x 12" area.

Suspected filth, collected from ceilings, walls, and equipment, for mold examination must be kept moist by placing it in a container with a small amount of a 3-4% formalin solution. Large amounts of slime may be placed in a wide mouth glass jar with either a 1% formaldehyde solution or a 3-4% formalin. Note: Formalin is normally sold as a standard stock solution of 37%. To obtain the required 3-4% formalin solution, mix 10 ml of the 37% stock solution with

90 ml of distilled water. This will yield the appropriate strength solution necessary to fix the mold.

Although formaldehyde or formalin are the preservatives of choice you may preserve the subs in either a 50% alcohol solution or in acetic acid (full strength vinegar) if formaldehyde or formalin are not readily available.

Note that formaldehyde/formalin is a common sensitizing agent that can trigger an allergic reaction in normal tissue after single or repeated exposures. It is also classified as a known human carcinogen (cancer-causing substance) by the International Agency for Research on Cancer and as a probable human carcinogen by the U.S. Environmental Protection Agency (EPA). Investigators must understand the hazardous properties of formaldehyde/formalin so that control measures can be taken to minimize exposure.

The above instructions apply to the collection of raw material, in-line and finished product samples for mold. However, in-line and finished product subs such as doughs, etc., which may be harmed by the formaldehyde, may be frozen. Check with your laboratory for its recommendation regarding preserving mold samples.

### 4.3.7.7 – Collection of Environmental and Product Samples for Food Susceptible to Contamination with Pathogenic Microorganisms

Sampling for products susceptible to microbial contamination and the environment in which they are produced may help identify the presence of pathogenic microorganisms before they can cause illness. With the recent increase in foodborne outbreaks and inspections identifying links between outbreaks and environmental (including non-food contact surface) contamination, there will be an increased focus on routine environmental sampling during inspections. Conduct environmental surface sampling as directed by the work plan, compliance program or assignment, or based on inspectional observations. If you are unsure of the circumstances under which to perform environmental sampling, consult with your supervisor. Also see IOM 5.4.7.2 for inspectional guidance for firms producing products susceptible to contamination with pathogenic microorganisms.

Collection of environmental and product samples for microbiological testing requires a thorough understanding of critical factors associated with the production of the specific product being inspected. To prove the establishment is being operated in an insanitary manner it is necessary to show the manufacturing operation or conditions at the facility are likely to, or have contributed to the bacterial load of the product. When feasible, inspections should cover equipment condition before a day's production begins and the clean-up at the end of the day's production. For environmental *Salmonella* sampling, it is preferable to sample before the plant conducts a wet cleaning operation.

Environmental sampling should include sponges or swabs of food contact surfaces (particularly for *Listeria*

*monocytogenes*) and non-food contact surfaces (particularly for *Salmonella* serotypes), based on observations, or as directed. Environmental monitoring supplies should be brought into the firm using precautions to prevent the transfer of foreign material into the processing area.

In-line sampling should be conducted based on observations or as directed. Collect finished product only after consultation with CFSAN, HFS 605 Division of Enforcement, or as directed in the compliance program or assignment.

When conducting environmental sampling or product sampling for microbiological testing, whenever applicable, an investigator/ microbiologist team approach should be used. For environmental sampling, a third person is recommended to assist with collection and/or recording of information.

#### 4.3.7.7.1 - Environmental Sampling

CFSAN has developed guidance on the specific locations within a firm to collect environmental samples to increase the likelihood of detecting *Listeria monocytogenes* and *Salmonella*. See IOM Exhibit 4-20 and 4-21 and FIELD BULLETIN #30 – FOOD PROGRAM AREA INSTRUCTIONS FOR ENVIRONMENTAL SAMPLING for guidance on environmental sampling/locations for these microorganisms. In addition, please view the training video in Field Bulletin #30, “Environmental Sampling in Food Manufacturing FD148” which provides technical and procedural information on environmental sampling.

In most cases, it is preferable during discussion with the firm not to mention FDA's intent to collect environmental samples until immediately before sampling begins. Advance notice/pre-announcement of environmental swabbing may possibly provide the firm with the opportunity for unscheduled sanitation activities. Any such actions by the firm could potentially inhibit microbial recovery and compromise environmental sample(s).

During the initial phases of the inspection, the Investigator should conduct a walkthrough assessment observing and mapping operations, including the location of equipment, flow of the product, foot traffic of employees, forklift/mule traffic patterns, segregation of raw material versus finished products, and consider sampling areas where food is exposed and being processed, particularly post-treatment/pasteurization.

The “Zone Concept” identifies and prioritizes processing areas from highest risk and closest to the product to lowest risk and farthest from the product for potential contamination and harboring growth and niches for targeted pathogen and therefore should be implemented upon conducting environmental sampling as follows:

- Zone 1: Refers to all direct food contact surfaces such as slicers, mixers, conveyors, utensils, racks, work tables, etc. For inspections focusing on the presence of *Salmonellae*, such as firms producing peanut products and other dry product environments, food contact surfaces are normally not sampled unless specifically requested in the assignment or CP. In contrast, for inspections focusing on detection of *Listeria monocytogenes*, such as firms producing seafood or cheese products in a wet environment sampling of food contact surfaces is essential.
- Zone 2: Encompasses the areas directly adjacent to food contact surfaces (Zone 1). For investigations focusing on *Salmonellae*, this is the area where environmental contamination is most likely to directly affect safety of the product. In a small production room, Zone 2 encompasses all non-food contact surfaces in the processing area, such as the exterior of equipment, framework, food carts, equipment housing, gears, ventilation and air handling equipment, and floors. In a much larger room (e.g. 20,000 square feet) Zone 2 is the area in the immediate vicinity of food contact surfaces, such as around the exposed product in which you could envision a pathway to product contamination either through the actions of man or machine.
- Zone 3: The area immediately surrounding Zone 2. Zone 3 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 2 via actions of humans or movement of machinery. Examples of Zone 3 areas include corridors and doorways leading into food production areas or areas in a large production room that are further away from food handling equipment than typical zone 2 areas. Walls, phones, forklifts and “mules”, even if physically located in Zone 2, should be considered Zone 3 due to a decreased likelihood of cross-contamination.
- Zone 4: The area immediately surrounding Zone 3, generally considered a remote area. Zone 4 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 3 via the actions of humans or machinery. Examples of Zone 4 areas include an employee locker room if not immediately adjacent to food production rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

Every effort should be made to conduct *Listeria* sampling when the facility has been in production for **at least four hours and before any wet cleaning is performed**. In instances with smaller firms that have short production periods, swabbing should be conducted during the mid to tail end of their production schedule.

In most cases, subsamples for *Salmonella* will be collected from the Zones 2 – 4 (see below), concentrating primarily on Zone 2. Samples should be collected from the equipment itself, particularly equipment mounting and support structures. When targeting *Listeria*, swabs will be collected primarily from Zones 1 and 2. Perform most of the sampling for *Listeria* in, on, and around food contact equipment, focusing on areas where food is exposed and being processed, particularly post-treatment/pasteurization.

A large majority of the environmental samples collected should be taken from Zones 1 (when directed and depending on the organism in question) and 2, and to a lesser degree Zone 3 areas. Very few, if any, environmental samples should be taken from Zone 4 areas.

Swab subsample numbers for each organism are as follows:

- For *Salmonella* environmental swabbing, collect at least 100 swabs/subs and ideally 300 or more subs
- For *Listeria* environmental swabbing, collect at least 50 swabs/subs and ideally 100 or more subs.

Document the possible link between the source of an environmental sample and contamination of the food product using both written descriptions and photographs. Describe the location of the sample in relation to areas where food is exposed and any mechanical or human activities you observe that might cause an organism to be spread beyond this niche environment. The division's response to a positive swab will depend on the proximity of the sample location to the processing line and the likelihood of cross-contamination between the swabbed surface and food or food contact surfaces.

On occasion, firms may opt to collect their own swabs in conjunction with your sample. If this occurs, request the firm to provide their results when available.

#### 4.3.7.7.2 - Environmental Sampling Equipment and Instructions For Large

### and Small Area Environmental Surface Sampling

These instructions should be followed in order to ensure standardization of FDA environmental sample technique across divisions.

For environmental sampling, the broth or buffer serves two purposes: 1) to neutralize sanitizer that may be on surfaces that you are sampling, and 2) to provide nutritional requirements for the organisms of interest to survive the transport to the laboratory.

Day and Engley (D/E) neutralizing broth or buffer (the terms broth or buffer are used interchangeably for this product) has been shown to be effective as a neutralizing agent against the widest range of sanitizing agents that may be in use by a firm and, per Office of Regulatory Science (ORS), is the one to be used for general purpose environmental sampling.

For large area environmental sampling, hand held sponges or sponges on a stick should be used. The sponges on a stick reduce manual contact with the sponge during the sampling procedure and are good for accessing tight spaces. Dacron tip swabs are recommended for small area environmental sampling (approximately 10cm x10 cm, or 4 x 4 inches).

#### Sampling Equipment:

If sources cannot be located for sponges or swabs pre-hydrated with D/E Neutralizing buffer or broth, use unhydrated sponges and swabs along with single use tubes of D/E neutralizing broth. Do not add additional D/E buffer or broth to other types of hydrated sponges and swabs that contain either a neutralizing broth or an enrichment broth. Addition of D/E broth to these may dilute the concentrations of both components to the extent they will not be effective.

Hand held sponges or sponge on a stick pre-hydrated with D/E neutralizing broth if available, dry hand-held sponges or sponge on a stick, swabs pre-hydrated with D/E neutralizing broth, dry swab in swab tube with screw on cap or single use tubes of D/E Broth are recommended.

If you need sourcing information for equipment please contact the [Division of Domestic Human and Animal Food Operations \(DDHAFO\)](#) at (301) 796-0360.

Other general sampling supplies you will need for environmental sampling:

- Sterile gloves (size 7 and 9 to include latex free styles)
- Hand sanitizers (wash and sanitize hands often during sampling)
- Cooling medium for samples
- Boxes or coolers
- Labels to ID samples
- Permanent marker
- Flashlight

Sterile metal spatulas (small) or other sterile implement to scrape debris out of cracks

It is important to use sponges or sponges on a stick for the large majority of samples since you can sample and “scrub” a larger area with a sponge compared to a swab. Swabs are only appropriate for areas that are inaccessible to sponges.

#### Sampling Method:

For large area environmental sampling, hand-held sponges or sponges on a stick should be used. The sponges on a stick reduce manual contact with the sponge during the sampling procedure and are good for accessing tight spaces. Dacron tip swabs are recommended for small area environmental sampling (approximately 10cm x10cm, or 4 x 4 inches) and for cracks and crevices.

#### Gloves:

For collection of environmental samples in Zones 2 - 4 and for firms targeted as part of *routine surveillance* inspections only, it is not necessary to change gloves between each sub provided that the CSO or analyst remains in the same zone and the integrity of the gloves is not compromised during the course of collecting the sub, (i.e. glove rips, or if it is brushed against a lab coat, etc.) For example, if 50 swabs are collected in Zone 2, the CSO or analyst would not need to change gloves between each of these subs until moving to another zone, another distinct processing room or area, or if the condition of the gloves warrants changing. However, gloves should be sanitized between each sub by applying a 70% solution of ethyl alcohol (preferred) or 70% isopropyl alcohol. It is expected that collection of a large number of subs in one area would necessitate several changes of gloves.

For swabs collected in Zone 1 and during “for-cause” inspections (such as those conducted in response to a current or previous outbreak, or an emergency), continue to follow the established policy and change gloves between each sub as described in the Environmental Sampling training video.

#### Sampling of Dry Surfaces:

Using a felt-tip black permanent marker, label the sterile bag containing the sponge with appropriate sample information.

1. Wash and sanitize your hands to the mid-forearm. Use clean disposable paper towels for drying your hands.

2. From the outside of the sponge bag manipulate the handle toward one side. Pull off the top of the whirl-pak bag holding the Sponge-stick along the perforation. Using the tabs on both sides of the wired band, pull gently to open the bag. Do not remove the Sponge-stick.

3. Pour into the Sponge-stick bag 9-10 ml or sufficient volume of DE neutralizing broth on the side away from the

handle to hydrate the sponge (do not get broth on the handle). Be careful not to touch the opening of the broth container to any non-sterile surface before or during this transfer.

4. Massage the sponge through the outside of the bag to facilitate absorption. From the outside of the bag, push the Sponge-stick to the upper portion of the bag. While pushing the sponge-stick up from the bottom of the bag, squeeze excess D/E broth from the sponge back into the bag. The sponge should be moist but not dripping wet.

5. Using aseptic technique unwrap and place a sterile glove upon the hand you will use for swabbing. Do not touch any non-sterile surface (i.e. clothes, skin, counter tops, etc.) with the outside surface of the sterile glove. The other hand can be left ungloved for manipulation of non-sterile surfaces and materials if preferred.

6. Remove the Sponge-stick from the bag using your gloved hand. Using even and firm pressure push the sponge in one direction across the desired area of the environmental surface 10 times vertically, then 10 times horizontally. If visible soil or residue is present, sample the surface by vigorously rubbing the sponge over the designated area until the soil or residue is removed. Sampling of large flat surfaces (i.e. floor, table tops, and conveyor belts) should cover areas as referenced above, depending if the area is unclean, or has been cleaned and sanitized. It may be necessary to wet the sponge with additional neutralizing broth when sampling large and/or porous areas. Try to use only enough buffer to keep the sponge gliding smoothly over the surface. If there is excess buffer, squeeze it back into the whirl pack bag and continue until you have sampled the entire sampling site.

7. After sampling, return the sponge to original Whirl-Pak bag with any excess buffer, snap off the handle in accordance with the product instructions that accompany the Sponge-stick, and submit as a subsample.

8. Remove the used sterile glove and discard.

9. Squeeze as much air out of the bag as possible. Roll the top of the bag over several times until it is folded all the way down to the sponge. Fold in the tabs to lock the fold in place. Place the sponge bag inside another empty Whirl-Pak or equivalent bag and seal as before. Both bags must be tight enough to provide both a leak proof seal and minimal airspace during shipment of the moistened sponge.

10. As soon as possible, place the double-bagged sponge inside an insulated cooler, with pre-frozen gel packs to keep the samples cold, but not frozen, and transport/ship the sample to the servicing lab for analysis so it is received by the lab within 24 hours of collection.

#### Sampling of Wet Surfaces:

Sample using aseptic techniques with a dry Sponge-stick following the general instructions above for removing the Sponge-stick from the bag, and for swabbing. After sampling, return the Sponge-stick to the original sterile

Sponge-stick bag and using aseptic techniques add 10 ml of D/E neutralizing broth to the bag. Proceed as instructed in #5-10, above.

Small Area Environmental surface sampling procedure (approximately 10cm x10cm, or 4 x4 inches):

Swabs are suitable for sampling only very small areas that cannot be accessed any other way. For example, the swab can be used to sample the material in a hole in the floor such as might be encountered when a piece of floor mounted equipment is removed from an area and the floor has not been repaired to fill the bolt holes. Swabs may also be useful for sampling floor cracks or the inside of tubular equipment mounts.

#### Sampling of Dry Surfaces:

Collect samples using aseptic techniques with the swab pre-hydrated with D/E Neutralizing Solution. Using even and firm pressure, swab in one direction across the desired surface 10 times vertically, then 10 times horizontally, then 10 times diagonally. If visible soil or residue is present, sample the surface by vigorously rubbing the swab over the designated area until the soil or residue is removed. Return the swab to its vial, place in a Whirl-Pak bag, and as soon as possible place inside an insulated cooler with pre-frozen gel pack for transport/shipment to the laboratory.

Dust and debris scrapings may also be collected using a sterile implement from facilities producing dry products such as nuts and powders. A minimum of 5 to 10 grams should be collected with 100 grams being optimum. When sampling mops or brooms, swabbing with a sterile sponge pre-hydrated with D/E Neutralizing solution is an efficient method although mop strands and broom bristles may also be clipped and submitted.

#### Sampling of Wet Surfaces:

Collect sample using aseptic technique using the dry swab in the same manner as noted above. After swabbing, using aseptic technique add D/E neutralizing solution to the swab and transport to laboratory as noted above.

Collect debris on equipment and from floor defects, joints and gaps. Debris can be scraped out using a sterile implement, such as a small metal spatula. A minimum of 5 to 10 grams should be collected, with 100 grams being optimum.

#### Closed Controls:

For environmental samples only, collect one closed control for each distinct lot of sterile equipment used and submit with the final collection of subs on the last day of sampling.

#### Open Controls:

Open controls are not to be submitted for environmental sample collections.

#### Sample Numbering:

Often multiple days are required to collect an appropriate number of environmental swabs. If an environmental surface sample is collected on multiple days during an

inspection, use a new sample number for each day, e.g., sample no. 100000 (first day) and sample no. 100001 (second day). The subs should be numbered sequentially, e.g., subs. 1-100 (first day) and subs 101-175 (second day). Link the sample numbers to the assignment for tracking purposes. Environmental swab subs should be numerical, i.e. 1, 2, 3, etc.; control subs should be alphabetic, i.e. a, b, c, etc.

Product codes have been created to allow for the tracking of environmental samples by commodity; Drugs and Foods/Feeds. When entering data into the FACTS systems for environmental samples, the collector of the sample will select the correct Sample Basis and enter the correct product code based upon the commodity.

All environmental samples, including swabs, soil, water, and animal scat, are to be identified as Investigational (INV). Use the following environmental sampling product codes: 52Y[ ] [ ] 07 for Farm Environmental Swabs/Samples; 52Y[ ] [ ] 08 for Process/Manufacturing Environmental Swabs/Samples; 52Y[ ] [ ] \*\* for Animal Carcass Rinse/Swabs, where \*\*= 01 (Beef), 02 (Chicken), 03 (Lamb), 04 (Pork), 05 Turkey), 06 (Other Animal Swabs); [52Y\[ \] \[ \] 09 for Postharvest Water \(for Agriculture use\);](#) [52Y\[ \] \[ \] 10 for Preharvest Water \(for Agriculture use\);](#) and [52Y\[ \] \[ \] 11 for Spent Sprout Irrigation Water \(use for testing\).](#)

For Drug Environmental Swabs/Samples use product code 66Y[ ] [ ] 07. Do NOT use the product code of the covered product for environmental samples.

### **4.3.7.7.3 – In-Line Sampling/Factory Food Sample**

In-line sampling should be conducted as directed or based on inspectional observations.

Each in-line subsample will consist of approximately 114 g (4 oz), in duplicate (702(b) portion), if that amount is available (Also see IOM 4.3.3.2 - 702(b) Requirement). All in-line samples must be collected aseptically.

Sampling Areas (this is not a comprehensive listing of areas to collect in-line samples, since each firm will be different, depending on processing/packaging techniques and the finished product produced:

"Raw" ingredients used in the manufacturing of finished foods (including those conveyed by bulk tankers) should be considered for sampling to determine the effect of subsequent processing on bacterial content. Of particular concern are raw materials which can support microbial growth, are not normally cooked or prepared in a manner lethal to pathogenic microorganisms (such as dairy, soy, corn or sugar syrup-based products), and adequate controls to ensure the safety of the finished product are not in effect. Since the major portion of some finished food products are not homogeneously contaminated, it may be

necessary to collect multiple subsamples of the raw material(s) to establish a reliable microbial base line.

Obtain sequential subsamples with the view of bracketing each step of the processing operation, in particular those steps suspected as routes of product contamination. A series of in-line samples should be collected during the first part of a shift, and a duplicate series during the latter part.

If products or components are heated (e.g., blanched, boiled, etc.) take subsamples immediately before and immediately after heating, before possible insanitary equipment and processing delays contribute to bacterial increases. Particular attention should be given to determine routes of cross-contamination from the raw product to the "heated" product, especially if this heating step is critical to the destruction of pathogenic organisms.

If a product is capable of supporting microbial growth and is not being handled expeditiously, sample before and after this particular processing step.

Take time and temperature measurements of cooking, freezing and cooling procedures. Sample when appropriate to demonstrate possible microbial growth. Large masses of ingredients may cool or warm slowly enough to permit microbial growth.

Improperly cleaned equipment may contaminate the product with bacteria. This may result in either a uniform or a spotty increase in bacterial numbers. If possible, scrapings of questionable material should be in sufficient quantity to be easily weighed and quantitatively diluted, if collected for analysis.

#### 4.3.7.7.4 - Finished Product Sampling

Collect finished product as directed in the compliance program, assignment or by your supervisor. Collect product from production on the day of the inspection and from the previous day's run. Sampling multiple lots should be considered depending on the type of product and process used. The subsamples should consist of ten (10) retail size containers at least 114g (4 oz) each, in duplicate (702(b) portion).

If the finished product is also to be analyzed for Salmonella, collect samples in accordance with instructions in the IOM. See *Salmonella* Sampling Plan, Schedule Chart 1.

#### 4.3.7.7.5 - Reporting Environmental Sampling Results On The FDA 483

Environmental sampling in the foods program has had increasing focus in assignments issued to the Field. FDA/ORR, with the concurrence of and in conjunction with Office of Chief Counsel (OCC) and the ACRA, has outlined criteria in order to implement a consistent policy for the reporting of positive environmental sample results on the FDA 483 as applicable to the foods program only. Current policy, going forward, is to report significant positive

environmental sample results, from swabs collected at food firms, on the FDA 483, if the results are known prior to the conclusion/closeout of the inspection. In addition, divisions are not being asked to unnecessarily extend inspections to include these results. Reasoning behind the implementation of this policy includes:

- Informing the firm of positive results where food products are concerned
- Eliciting firm feedback in response to positive results
- The opportunity to provide relevant information to both regulators and the public when released under FOIA thereby potentially uncovering and linking other investigational information that can aid in the determination of root contamination cause(s)
- The responsibility to document positive environment sample results as significant observations that can contribute to potentially unsafe conditions as they pertain to the Public's health.

Positive environmental sampling results should be noted on the FDA 483 when the following conditions are met:

- Related to a current or future foods program inspection/investigation
  - Inspection has not been closed (Note: it is not requested that the period of inspection be extended for the purpose of receiving analysis results)
  - Positive sample finding(s) is/are a significant observation, i.e. a route of contamination from the environment to the product is clearly demonstrated, such as, for example, positive sample result(s) in Zones 1 and/or 2 for Listeria or positive sample result(s) in Zone 2 and/or 3 for Salmonella
- Findings in Zone 3 (Listeria) and Zone 4 for either pathogen should not be reported on the 483 as they are normally not considered significant, except in combination with positive findings in Zones 1 or 2, when these would further strengthen regulatory action.

#### 4.3.7.8 - Samples for Viral Analysis

Sample instructions will be issued by the appropriate Center on a case by case basis.

### 4.3.8 - ECONOMIC VIOLATIONS

#### 4.3.8.1 - Net Weight

Field weighing for net weight is primarily to determine the likelihood of short weight units. The laboratory will confirm both tare and net weights.

Use a Gurley, Troemner, or equivalent balance. Check the accuracy of the balance before and after use. If this equipment is not available, or the units exceed their capacities, use commercial scales. If possible, have the commercial scales checked in your presence by the local Sealer of Weights and Measures. If this is not possible, report the name, type of scale, style and capacity, minimum

graduations, apparent sensitivity, and date of last sealing and by whom.

#### 4.3.8.1.1 - Tare Determination

Whenever possible, determine a minimum of six tares selected at random. If empty containers are readily available, or if tares vary widely (e.g.; glass jars), determine at least 12 tares.

#### 4.3.8.1.2 - Field Examination

Weigh 48 units, if that number is available, selected at random from the square root of the number of cases in the lot with a minimum of 6 and a maximum of 12. Where units are selected from the production line, do so in representative manner. Report the code weighed and if short weight, the quantity in the code. Unless otherwise instructed, do not weigh leaking containers. Identify each unit with the corresponding sub number on the Field Weight Sheet (FDA 485).

Submit the units indicated by the asterisks on the FDA 485 plus twelve additional weighed units for reserve if the average net is below that declared on the label.

#### 4.3.8.1.3 - Field Weight Sheet

Record weights on Form FDA 485, Field Weight Sheet. See IOM Exhibit 4-6. Submit Field Weight Sheet with the printed FACTS Collection Record.

Individual Captions:

Block 1 Date - Enter the date weighed.

Block 2 Sample No.- Enter the sample number of the C/R.

Block 3 Product - Enter the specific name of the product, i.e., macaroni in cellophane, butter in aluminum wrappers, olive oil in glass, etc. Quote significant portions of the label including the declared net weight.

Block 4 Type of Balance - Enter the type of balance used i.e., Gurley, Troemner, etc. If balance used is not FDA equipment, give style, capacity, minimum graduations, etc.

Block 5 Responsible Firm and Address - Enter the name and address of the firm most likely responsible for the short weight violation.

Block 6 Address Where Weighed - Enter the name and address or location where weighed.

Block 7 Warehouse - Enter the type of warehouse where product is stored, i.e., cold storage, truck dock, production line, etc. Enter the temperature and estimate the humidity where possible.

Block 8 No. Of - Enter the number of cases, and number and size of units per case in the lot. Enter the number of cases from which subs were weighed and the number of

subs weighed from each case. If the units are collected from a production line, estimate the number of units produced of the code weighed.

Block 9 Gross Weight - Arbitrarily assign and record the shipping case number from which each sub was weighed. Number each unit submitted to correspond with the sub number on the Field Weight Sheet. Record weights to second decimal place.

Block 10 Preliminary Tare - Determine and record tare weights as provided in IOM 4.3.8.1.1. Obtain the preliminary average tare by totaling preliminary tares and dividing by the number of tares weighed.

Block 11 Weighing Results - Determine the average gross weight by totaling gross weights and dividing by the number weighed; enter preliminary average tare from caption 10 in block 11b; determine average net weight by subtracting block 11b from 11a; enter the declared net weight as stated on the package weighed; determine the shortage by subtracting block 11c from 11d.

Block 12 Preliminary % Short - Enter the preliminary percent short, which is determined by dividing e by d.

Block 13 Remarks - Record any observations on the condition of the lot or storage facilities which might affect net weights, (faulty machine sealing of packages, extreme high temperature, extended length of storage, etc.)

Block 14 Division - Enter the name of the collecting division.

Block 15 Employee Signature – Sign the form.

Block 16 Employee Title – Enter your title.

#### 4.3.8.2 - Volume Determination

Field determination of volume is a screening procedure to determine the likelihood of short volume units in the lot. The laboratory will confirm both tare and net volume.

##### 4.3.8.2.1 - Free Flowing Liquids

The approximate volume of small containers of free flowing liquids may be obtained by direct measurement. Standardized graduated cylinders calibrated to "contain" a given volume can be obtained from the laboratory. Use the smallest graduate that will hold the volume to be measured. Under no circumstances use a graduate to measure a volume less than 25% of the maximum capacity of the graduate. Proceed as follows:

1. Select 8 units at random; one from each of 8 cases or otherwise representative of the lot.
2. Empty contents into calibrated graduate holding the container in a nearly vertical position but tipping so that the bottom of the container will drain. Allow to drain one minute after stream breaks into drops. Obtain an anti-foaming agent from the laboratory if beer or other product likely to foam are measured.
3. Hold the graduate vertically with the surface of the liquid level with the eye. Place a shade of some dark material



immediately below the meniscus and read volume from the lowest point of the meniscus. A convenient device for this purpose is a collar-shaped section of thick black rubber tubing cut open at one side and of such size as to clasp the graduate firmly.

4. If no units containing less than declared volume are found, no further determinations are required.
5. If one or more units containing less than declared volume are found, measure 4 additional units selected as above.
6. If the total of twelve determinations contains only one short volume unit, be guided by the significance of the average shortage as related to the individual program guideline.
7. If the total of twelve determinations contains more than one short volume unit, an Official Sample of 48 units should be collected regardless of the average shortage figure.

#### 4.3.8.2.2 - Viscous Liquids

Direct measurement of viscous liquids or large containers is not practical. Field weigh 48 units as specified in IOM 4.3.8.1.3.

#### 4.3.8.3 - Labeling

See "[Industry Resources on the Changes to the Nutrition Facts Label](#)" for guidance. See CFSAN's [Office of Dietary Supplement Programs](#) and [Office of Nutrition and Food Labeling](#) websites as well as [FDA.gov](#) for the most up-to-date information regarding claims in labeling.

Also, see [CPGM 7321.005](#) to determine enforcement priorities for food labeling violations, including those related to the [Food Allergen Labeling and Consumer Protection Act \(FALCPA\)](#).

### 4.3.9 - ORGANOLEPTIC EXAMINATIONS

Examination of many products may be conducted on the spot without fixed laboratory equipment. These examinations vary from simple visual observations for gross filth, such as rodent pellets in wheat, to the detection of odors of decomposition in seafood. Organoleptic examinations for regulatory purposes shall be made only by those individuals qualified by training or experience to conduct such examinations.

If it is necessary to collect physical subsamples for organoleptic examination and they are collected from bulk, the subs must be packed in glass jars to prevent the product from picking up foreign odors.

Review your Compliance Program Guidance Manual and IOM 4.3.7.1 and 6.3.1 for field examination techniques which may be applicable to specific products or industry.

### 4.3.9.1 - Whole-Bag Screening

When making filth examination by screening shelled peanuts, dried bean, peas and similar products, packed in large containers (i.e., 50-125 lb. bags) use the portable folding whole-bag screens available in your division.

Conduct the examination in a well-lighted area. Set up screen and adjust height to permit opening the bags directly onto the high side of the screen. Place another bag or container on the screen's low side to catch the screened product.

Place a sheet of clean butcher or similar paper in screen body to catch screenings and insert screen wire over paper.

Open stitches of bag being examined to permit approximately ten to twenty-pound portions to enter onto high side of screen. Gradually work the product across the sieve to the low side and into the receiving container. Do not push large quantities rapidly across screen because insects, eggs, stones, excreta pellets, etc., will be carried along with the product and will not sift through the sieve openings.

Examine the screening from each bag and subjectively report live or dead insects, rodent excreta pellets, or other obvious filth. Submit screenings as separate subs if actionable.

## SUBCHAPTER 4.4 - DOCUMENTATION & CR

### 4.4.1 - AUTHORITY

[Section 703 of the FD&C Act \[21 U.S.C. 373\]](#) describes FDA's authority to access and copy records of interstate shipment.

### 4.4.2 - OBJECTIVE

For FDA to initiate formal legal action, interstate jurisdiction must be established. Most often, this is done by documenting interstate movement of a product by copying records ("getting the records") of a shipment represented by an Official Sample. However, on occasion, jurisdiction can be fixed on a limited list of articles, e.g., counterfeit drugs, medical devices, oleomargarine, through other means.

### 4.4.3 - POLICY

Judicial Actions are defined as those actions that involve the judicial system. Judicial actions include seizures, injunctions, warrants, and prosecutions. Interstate commerce must be documented, and proper evidence attached to appropriate collection reports to support a judicial action. For Administrative Actions, such as Citation or Suspension of Registration, follow the same procedure as with Judicial Actions.

Advisory Actions are defined as actions that do not include the judicial system. The actions may include those such as untitled or warning letters, regulatory meetings, etc.

Fully document every physical Official Sample at the time of collection unless instructed otherwise by the program or assignment. The type of interstate records (transportation records, freight bill, waybill, bills of lading, etc.) to be collected are outlined in IOM 4.4.7. The evidence required depends upon the violation and the type of judicial action proposed.

Documentary samples (see IOM 4.1.4.2) - not required to support administrative and/or advisory actions such as untitled letters, warning letters, suspension of registration, regulatory meetings, etc. There is usually no need to prepare a documentary sample in these cases, however, records of interstate commerce should be collected and incorporated into the establishment inspection report in order to document FDA jurisdiction over products suspected to be in violation. Additionally, an affidavit (see IOM 4.4.8) identifying the product(s) of concern, labeling, invoices, statement regarding interstate commerce and key evidence of violations may be prepared for signature by the appropriate party and attached to the inspection report in support of administrative and/or advisory actions. Documentary sample(s) are required for judicial actions such as seizure and injunction. In situations where potential further FDA judicial action is anticipated after an administrative and/or advisory action has been taken (i.e., seizure of products after suspension of registration) documentary samples should always be prepared.

#### 4.4.3.1 - Collection Records

Sample Collections are recorded in the Field Accomplishments and Compliance Tracking System (FACTS). Individuals who may be assigned to collect samples should routinely obtain in advance, a supply of FACTS sample numbers, to be used by the collector to identify samples in the field, prior to accessing FACTS to prepare a sample collection record.

#### 4.4.4 - RESPONSIBILITY

Document samples in accordance with procedures in this Subchapter being certain the copies of records obtained cover the product sampled.

Do not remove the dealer's only copy of records. Whenever possible, scan, photograph or photocopy, if duplicates are not available. Reproductions should be reviewed to ensure all relevant information is readable. Records should not be accepted by email from outside USFDA.

It is possible to enhance the clarity of photocopies from poor originals (e.g., second or third carbon copies, copies in blue ink, etc.) by overlaying the "original" document with one or two clear yellow plastic sheets. These clear yellow plastic sheets are available at most stationery stores.

If the above procedure does not enhance the copied document, pen and ink additions should be made. Records copied on FDA forms must be accurate and legible.

If you are documenting a shipper violation at a dealer, it is your responsibility to show the storage conditions did not contribute to the violation. Obtain an affidavit describing handling of the goods after receipt, and any other information which supports the violation.

In cases where the product does not move Interstate but is formulated from I.S. raw materials, government jurisdiction may be established by documenting the I.S. nature of the major raw materials. This is done by linking copies of records for the I.S. raw material with the production of the final product, by affidavit from a knowledgeable and responsible firm official. See IOM Exhibit 4-7.

Note: In the case of imported products which have been released to commerce, documentation of the sample should also include the port of entry and the importer of record to facilitate investigation by the home division if necessary.

#### 4.4.5 - SAMPLE RECORDS IDENTIFICATION

Identify copies of all records obtained and attached to the collection report (except FDA forms) with the sample number (including the prefix if appropriate), collection date, and collector's handwritten name or initials (the person who signs the collection report, See IOM 4.5.2.5. If a document is more than one page in length, it must be numbered or attached in a manner that will allow further reviewers to determine if any pages are missing. See IOM 5.11.4.3.20.

If the firm maintains their records on film or electronically, see IOM 5.3.8.3.3, 5.3.8.3.1 and 5.3.8.3.2.

#### 4.4.6 - EVIDENCE REQUIRED

When documenting violative situations, consider whether you have established FDA's jurisdiction, documented interstate commerce, shown a violation, and determined responsibility for the violation. The contemplated legal action determines the extent of documentation. A preponderance of evidence is required to prevail in a civil action, such as a contested seizure, as opposed to a criminal prosecution, which requires evidence establishing guilt beyond a reasonable doubt.

##### 4.4.6.1 - Seizure

For a seizure action, FDA must establish jurisdiction over the product, show its interstate movement and document a violation.

Obtain copies of any document proving the article was introduced into or in interstate commerce or held for sale after shipment in interstate commerce. Collect copies of the best records available, without extensive search or travel. See [Section 304\(a\)\(1\) of the FD&C Act \[21 U.S.C. 334\]](#).

### 4.4.6.2 - Injunction or Criminal Prosecution

The proof required depends on the violation of [Section 301 of the FD&C Act \[21 U.S.C. 331\]](#).

#### 4.4.6.2.1 - Introduction Into Interstate Commerce

Proof is required showing introduction into interstate commerce on or about a certain day by a specific person of a specific consignment of the article. In addition, delivery for introduction into I.S. requires proof the seller had knowledge the purchaser intended to introduce the article into interstate commerce. See [Section 301\(a\) or \(d\) of the FD&C Act \[21 U.S.C. 331 \(a\) or \(d\)\]](#).

#### 4.4.6.2.2 - Adulteration Or Misbranding In Interstate Commerce

Proof is required showing that a specific consignment was in interstate commerce and was rendered violative by a specific person on or about a certain date while therein. See [Section 301\(b\) of the FD&C Act \[21 U.S.C. 331 \(b\)\]](#).

#### 4.4.6.2.3 - Receipt In Interstate Commerce

Proof is required showing receipt of a violative consignment in interstate commerce on or about a certain date, along with evidence to show specific delivery thereafter by a specific person. It is essential to show the violative condition of the shipment was known to the consignee before the delivery or proffered delivery. Whether it was sold or given away is immaterial. See [Section 301\(c\) of the FD&C Act \[21 U.S.C. 331 \(c\)\]](#).

#### 4.4.6.2.4 - Manufacture Within A Territory

Proof is required of manufacture within any territory by a specific person on or about a certain date. See [Section 301\(g\) of the FD&C Act \[21 U.S.C. 331 \(g\)\]](#).

#### 4.4.6.2.5 - False Guaranty

Proof of the giving on or about a certain date of a specific guaranty and proof of its falsity; usually a specific sale (and delivery) on or about a definite date to the holder of the guaranty. Interstate commerce is not required, except evidence the consignee normally engages in some interstate business. See [Section 301\(h\) of the FD&C Act \[21 U.S.C. 331\(h\)\]](#) and 21 CFR [7.13](#), [201.150](#) and [701.9](#).

#### 4.4.6.2.6 - Dealer Violation

Proof of interstate origin of the article, and proof of a specific manipulation which adulterates or misbrands the article, on or about a certain date by a specific person. See [FD&C Act 301\(k\) \[21 U.S.C. 331 \(k\)\]](#).

### 4.4.6.3 - Complaint or Injury Samples

Generally, samples collected from complainants during investigation of injuries or foodborne out-breaks are investigational in nature and not documented. However, if the nature of the contamination or adulteration is such that regulatory action may be warranted, the interstate nature of the sample should be documented. Affidavits from the consumer, retailer, and wholesaler should be obtained.

At times, even though you may not be able to obtain physical portions of the involved item, a Documentary Sample can be collected by photographing the container, contents, labels, codes, etc., and obtaining necessary affidavits and interstate records. See IOM 4.1.6 for sample criteria on complaint samples.

During investigations of alleged tampering incidents, complainants must be advised of the provisions of the [Federal Anti-Tampering Act \(FATA\)](#). A general discussion of the FATA, its provisions for investigation, filing of false reports, and tampering can be useful and informative to those individuals.

Prior to concluding your interview of the complainant, obtain a signed affidavit attesting to the circumstances of the complaint. See [IOM 8.1.5.7](#).

### 4.4.7 - DOCUMENTING INTERSTATE SHIPMENTS

The minimum set of records ordinarily submitted with a sample will consist of a copy of the invoice covering the sale of the lot to the dealer, the transportation record showing interstate commerce, and an affidavit signed by the dealer, which identifies both the lot sampled and the applicable records. See IOM 4.4.5 and 4.4.7.

Documentation obtained at a location other than the dealer where the sample was collected should be the subject of a memorandum to accompany the collection report.

#### 4.4.7.1 - Sales Records

An invoice does not establish interstate commerce and thus federal jurisdiction. It does not prove actual movement. However, it may provide information as to the value of the goods, carrier, date of shipment, etc. and bear a Food and Drug type guarantee. Collect copies of the invoice to show the owner's intent to sell the product and tie other records to the sample. If the invoice covers numerous items, copy entries covering items sampled and indicate omissions by asterisks. Copy the invoice on the FDA 1662. See IOM Exhibit 4-8. If the invoice bears a Food and Drug guarantee, copy the guarantee on the back of the FDA 1662. Other records which may be substituted in the absence of an invoice are copies of purchase orders, receiving records, canceled checks, correspondence, etc.

Invoices covering in-transit shipments usually are not available. Document any available transportation record

that establishes the lot to be in interstate commerce. Be sure to name the shipper and consignee if known. Where positive identification of a shipment cannot be made by personal observation, obtain a statement from the carrier's agent identifying the shipment sampled as having been delivered by the consignor on a certain day for delivery to the consignee. Include in this statement reference to the particular transportation record covering the shipment. The transportation record will generally be available after the shipment is delivered.

Where the sample is taken from a vehicle or dock as the vehicle is loaded, and there are no unusual circumstances which must be explained in a regular affidavit, use the FDA 1664b, Affidavit (In-Transit Sampling).

See IOM Exhibit 4-3.

#### 4.4.7.2 - Transportation Records for Common Carrier Shipments

[Section 703 of the FD&C Act \[21 USC 373\]](#) provides for mandatory access to and copying of all records showing interstate movement of commodities subject to the Act. This is provided the request is in writing, and the records are in the possession of common carriers, or persons receiving or holding such commodities.

[Section 704\(a\) of the FD&C Act \[21 USC 374\(a\)\]](#) provides mandatory access, upon presenting your credentials and issuing a written notice of inspection, to documents covering the interstate movement of, non-prescription drugs for human use, prescription drugs and restricted devices. The authority applies to inspection of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs for human use, or restricted devices are manufactured, processed, packed or held.

**Note:** At times, you may have only the name of the carrier (trucking company), with no address or phone number. If you are unable to locate the trucking company, contact the local office of the [U.S. Department of Transportation \(DOT\) Federal Motor Carrier Safety Administration \(FMCSA\)](#). If you furnish this office the name of the trucking company, they will be able to provide the address and phone number. Division DIBs have the phone numbers of local offices of the FMCSA as part of a MOU between DOT and FDA; information can be found as well as on the [FMCSA field office contact information website](#).

##### 4.4.7.2.1 - Refusal To Permit Access To Records In Possession Of Common Carriers

Refusal to permit access to and copying of all records showing interstate movement of articles subject to FDA jurisdiction is unlawful provided the request for such permission is issued in writing. You cannot state that the law requires the records be furnished to FDA unless you also explain it is required only after a written request is issued.

If refused, after providing a written request, politely explain the law requires the records to be furnished. You are more likely to get the records through courteous persuasion and tact than through stressing the force of law.

##### 4.4.7.2.2 - Written Request For Records

If a carrier, consignee, or any other person refuses to supply I.S. records, and it is apparent he will not do so without a written request, report the facts to your supervisor. Do not routinely issue a written request for I.S. records since evidence so obtained may not be used in the criminal prosecution of the person from whom obtained.

If the request is being made of a carrier who has no responsibility for the violation, issue a written request only after approval by Division Management. When authorized by your supervisor to issue a written request, prepare a statement, using the following guidance, or as otherwise directed by your supervisor:

"Pursuant to Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) permission is hereby requested for access to and copying of all records showing quantity, shipper, and consignee, showing movement in interstate commerce and/ or the holding after interstate movement of\_\_\_\_\_."

Clearly identify the specific lots which are the subject of the request, the firm and the individual to whom the request is given.

##### 4.4.7.2.3 - Bill Of Lading

The shipper who delivers the goods to the carrier for shipment, prepares The Bill of Lading. It is an order for the carrier to move the goods. When the carrier's agent signs the Bill of Lading he acknowledges receipt for the shipment. The carrier's office in city of origin of shipment maintains a copy of the Bill of Lading. Information normally included is the name and address of shipper, name and address of consignee, date of shipment, name of carrier, vehicle number, and a description of the goods. Copy Bill of Lading on Section II of the FDA 1662. See IOM Exhibit 4-8. Create a memo to link the carrier's (e.g., UPS, FedEx, etc.) tracking number document to the actual shipment and delivery documentation and attach to the DOC sample CR with a memo explaining how the records were obtained.

##### 4.4.7.2.4 - Freight Bill

This record is prepared by the transportation company for the purpose of collecting freight charges. It includes the same information found on the Bill of Lading, plus additional data about the carrier's handling of the shipment and cost involved. Railroads prepare Freight Bills at their destination offices, where copies can be made. Steamship and airlines combine the Bill of Lading and Freight Bill into one form. Copies are filed at both origin and destination offices of these carriers. Truck lines prepare Freight Bills at the origin office and both origin and destination offices should have copies. The dealer should have a Freight Bill if he received the goods directly in interstate commerce.

Copy Freight Bills on Section II of the FDA 1662. Enter the type of shipping record in block 21. Section I and II may be executed together on one sheet. If only one section is used, leave the other section blank, and submit the entire page. (See IOM 4.4.7.2.4 and 4.4.7.3 for information on documenting carrier shipment records in CR.)

#### 4.4.7.2.5 - Waybill

The transportation company uses the Waybill in its own operations, and it accompanies the shipment during transit. Copies are not given to the shipper or consignee but can be obtained from the carrier. Other transportation records are generally more readily available than Waybills. Air Freight Waybill numbers are designed so that the originating line and point of origin are encoded in the Waybill number itself. Each airline has a numerical code description, indicated by the first two digits of the number. The three letters, which next follow indicate the point of origin. For example, Waybill No. 01LGA, designates American Airlines (01) as the carrier, and La Guardia Field (LGA) as the point of origin. Most airline offices have a copy of "Official Air Freight Transmittal Manual", which lists the codes. Other express shipping companies, such as Federal Express, and United Parcel Service have their own codes.

#### 4.4.7.3 - Mail or Parcel Service Shipments.

Always attempt to collect the original wrappings showing cancellation of origin office and address sticker. Record the facts obtained from the dealer on the FDA 463, Affidavit (Parcel Post/Service). See IOM Exhibit 4-9. Before the individual signs the statement he should be asked to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit.

To obtain documentation for USPS shipments, ask the dealer where the sample is being collected, to use the shipment label reference number to print the shipping documents from <https://www.usps.com>. If the article was shipped with Express Mail®, point-by-point tracking details are available. To obtain documentation for parcel service (e.g., UPS and Federal Express) shipments, ask the dealer to use the "tracking number" to print the shipping documents from the parcel service's web-site. Prepare form FDA 463a.

If the shipment is not recent, the dealers may not have access to the records through their accounts. In this case, a visit must be made to a major parcel service/ parcel post office to obtain documentation. See IOM 4.4.7.2.2 and 4.4.7.2.3.

#### 4.4.7.4 - Shipment by Privately-Owned Conveyance

Obtain on the FDA 463a, Affidavit, a dealer's statement setting forth the facts, including the date and manner of receipt. The affidavit by the dealer may not be evidence,

since the dealer lacks personal knowledge of the point of origin. Ascertain the name and home address of the driver of the conveyance, vehicle license number, the name and address of the driver's employer or the owner of the conveyance and the driver's license number. Obtain an Affidavit, from the driver setting forth the facts of the shipment. See IOM Exhibit 4-10.

#### 4.4.7.5 - In-Transit Sampling Affidavit

See IOM 4.1.4.3 and 4.3.4.3 for definition and sampling procedures. When obtaining samples from in-transit lots, if it is a straightforward uncomplicated sample requiring no unusual explanations, use the FDA 1664b, Affidavit (In-Transit Sampling). See IOM Exhibit 4-3. Otherwise, use the regular Affidavit, FDA 463a.

### 4.4.8 - AFFIDAVITS

Statements on various affidavit forms may be obtained from persons who have dealt somehow with the goods sampled, know material facts relating to the movement of the goods, and/or to events affecting their condition. Such facts, recorded in writing and signed by the person who can testify in court to those facts, can be used either to establish federal jurisdiction or fix the responsibility for a violation. The statement may identify documents proving I.S. movement of goods sampled; it may name the person who could testify to the identity of the goods sampled, and it may certify the sample collected is from the lot of goods covered by the records. See IOM 5.10.7 for additional requirements for Bioresearch Monitoring affidavits.

#### 4.4.8.1 - General Considerations for all Affidavits

You should have the affiant read the statement and make necessary corrections before signing the affidavit. Mistakes, corrected and initialed by the affiant are an indication he/she has read and understood the statement. A handwritten statement by the affiant, declaring he/she read and understood the statement is a valuable tool to counter the possibility the affiant might later claim ignorance of what was signed.

Before the individual signs the statement, ask him/her to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. See IOM Exhibit 4-11.

You should only sign the affidavit in the presence of and immediately after the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at \*\*\*\*" Subscribed, in this context means to attest by signing. Thus, your signature is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. If you provide a copy of the affidavit to the affiant, you should keep

the original affidavit since the original is an official FDA document.

In cases where the affiant does not speak English, prepare the affidavit on form FDA 463a in the affiant's native language. If necessary, enlist the assistance of a translator. Having a qualified translator present is necessary to explain the statement and assist in discussion. The affiant will only sign the version in their native language, as that would be the one the affiant can attest to. After the affiant signs the affidavit that was written in their native language, you will sign the native language version as the affiant has sworn this statement to you.

A second affidavit should be created to translate the statement into English, with the translator as the affiant. This affidavit includes the translator's qualifications and the English translation of the statement. The translator will swear the translation of the native language affidavit is accurate. After the translator signs the second affidavit, the FDA employee will sign. The translator and witness to the second affidavit should not be the same individual. The translator's signature is placed following the written English translation and their credentials are written in the narrative section of the affidavit. The second affidavit should be appended to the original.

#### 4.4.8.2 - Refusal to Sign the Affidavit

Prepare the statement as described above even if it is apparent the affiant will refuse to sign the affidavit. Have the affiant read the affidavit. If they decline, read it to them. Request the affiant correct and initial any errors in his/her own handwriting. Ask the affiant if the statement is true and correct. Ask him/her to write at the bottom of the statement "I have read this statement and it is true, but I am not signing it because..." in his/her own handwriting.

If the affiant still does not sign the affidavit, you should write a statement noting the refusal situation. Write this near the bottom and within the body of the affidavit. Include the actual situation, such as, you recorded the above facts as the affiant revealed them, the affiant read or refused to read the statement and avowed the statement to be true, and the affiant's reason for refusing to sign (e.g., "upon advice of corporate counsel", "per corporate policy", etc.). Sign and date this statement in the body of the document; only sign in the signature block if the affiant signs the affidavit. Once the refusal is documented on the affidavit, it is not necessary to include any additional narrative under the "Refusals" heading of the EIR.

#### 4.4.8.3 - Confidential Informants

You should take special precautions when obtaining an affidavit from a confidential informant. The affiant may be reluctant to sign a statement, which reveals his or her identity. See IOM 5.2.9 for guidance on interviewing confidential informants.

#### 4.4.8.4 - Affidavit (Dealer/Warehouseman)

The Affidavit (Dealer/Warehouseman), FDA 1664, is used to document the dealer or warehouseman identification of the lot and related records. See IOM Exhibit 4-12.

Fill in all blanks on the form as applicable. There are sufficient blanks for listing up to three invoices and up to three shipping records covering the lot in question. Any unused blanks should be lined out and strike out the words or letters in parentheses which are not applicable.

Be certain the dealer knows what he is signing. Before the individual signs the statement, he/she should be asked to affirm the affidavit is true and accurate.

You should only sign the affidavit AFTER the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at \*\*\*\*" Subscribed, in this context means to attest by signing. Thus, your signature is attesting to the fact the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. Also see IOM 4.4.8.5 for conditions not amenable to use of the FDA 1664.

#### 4.4.8.5 - Affidavit (FDA 463a)

Unusual sampling situations may present circumstances that do not lend themselves to presentation on the FDA 1664 or 1664b. In these situations, record the facts on an FDA 463a, Affidavit.

There is no prescribed format for composing the statement. However, you should positively identify the affiant by name, title, and address at the beginning of the statement and show why he/she is qualified to make the statement. The facts should be arranged in an order roughly paralleling that of the FDA 1664. The most manageable narrative describes the events and circumstances chronologically. Whatever format is used, the recorded facts must be intelligible to the reader unfamiliar with the transaction. See IOM Exhibit 4-7, 4-10, 4-11, and 4-13.

Ascertain all the facts and record those which are material, relevant, and to which the affiant can affirm.

Narrate the facts in the words of the affiant, using the first-person singular. Do not use stilted terms such as, "that" as in the expression "that I am the president of..." If the statement is long and complex, break it down into logical paragraphs.

Have the affiant read the statement and make necessary corrections before signing the affidavit. Mistakes that have been corrected and initialed affiant are an indication he/she has read and understood the statement. A handwritten statement by the affiant declaring he/she read and understood the statement is a tool to counter the possibility the affiant might later claim ignorance of what was signed.

Before the individual signs the statement, he/she should be asked to affirm the affidavit is true and accurate. A

statement to that effect can also be added at the conclusion of the affidavit. Only sign in the signature block if the affiant signs the affidavit. See IOM Exhibit 4-11.

You should only sign the affidavit AFTER the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at \*\*\*\*" Subscribed, in this context means to attest by signing. Thus, your signature is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. You and the affiant should sign all pages of a multi-page affidavit.

#### 4.4.8.6 - Affidavit (Jobber)

Form FDA 1664a is used to document movement of goods from a jobber to a dealer. See IOM Exhibit 4-14. Complete all blanks as applicable. There are sufficient blanks to list up to three invoices and three shipping records. Line out any unused blanks and strike out all words and letters in parentheses, which are not applicable.

Be sure the jobber knows what he/she is signing. Before the individual signs, he/she should be asked to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. Only sign in the signature block if the affiant signs the affidavit. See IOM Exhibit 4-11.

You should only sign the affidavit AFTER the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at \*\*\*\*" Subscribed, in this context means to attest by signing. Thus, your signature is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. The dealer may be provided a copy of an affidavit if he/she requests it.

### 4.4.9 - LABELS AND LABELING

No sample documentation is complete without copies of the label and labeling. No special effort is needed to obtain copies of the label when it is on the individual units collected. However, the goods may be accompanied by labeling which is not affixed to the product. In this case, you must obtain **clear and complete** copies of all labeling. Although your sample assignment may not specifically request the collection of accompanying labeling, determine if such labeling exists, and if it is present, collect it.

Collect copies of all labeling as directed by your assignment or Compliance Program (CP), when you are collecting labeling specifically to document labeling violations; otherwise, one copy is sufficient for routine review. The CP may require the collection of additional copies so that various offices can review the labeling simultaneously. Be sure to review the CP to ensure you collect enough original copies of labeling. Scan or mount as appropriate, individual

copies of labeling so they can be reviewed by various individuals located in separate offices. If the labeling design prohibits effective scanning, multiple copies of the labeling may be necessary. Do not collect the actual labeling if only one copy is available. To do so may remove the offending literature and thus correct the misbranding or you may misbrand the product yourself, by removing legally mandated information. Photographs or other copies must be made in this case.

#### 4.4.9.1 - Labels & Accompanying Labeling

These are defined as:

1. Label - A display of written, printed, or graphic matter upon the immediate container of an article.
2. Labeling - All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article. Labeling includes such material as circulars, booklets, placards, displays, window streamers, books, article reprints, websites, etc., that supplement or explain a product and /or are part of an integrated distribution system for the product. If the labeling and the product are in functional proximity at a point of sale, provide diagrams or photographs of this relationship. If the labeling and the product are found at a manufacturer or distributor, document the role that the labeling will play in the distribution of the product (e.g. to whom will it be sent and when).

Dealer Identification - Request the dealer (Note: a manufacturer may be considered a dealer if the product being sampled is located at the manufacturer) identify collected copies of accompanying labeling with his initials and the date. This will identify these copies of labeling if they are introduced in court later. Prepare a dealer's affidavit on the FDA 463a, covering the relationship of the labeling to the goods. This affidavit should include the following information.

1. Description of Labeling - Describe briefly each piece of literature by name of identifiable quote, i.e., Leaflet, "Do You Have Tired Blood" or Window Streamer, "Amazing New Tranquilizer". State the quantity of such labeling on hand.
2. Location of Labeling - Report the location of each different piece of literature and how much of each is at that location.
3. Method of Distribution - Determine how the labeling is made available to the public. Describe how it is displayed such as: for voluntary pick-up; mailed to prospective customers; distributed without being displayed, etc.
4. Source of Labeling - Describe whether the labeling was sent to the dealer by the shipper of the goods or if the dealer prepared the labeling himself or if it originated from another source. It is important to document this point to fix responsibility in the event the agency wishes to pursue action against that individual. It is not necessary to determine or fix responsibility in order to seize the goods. Document the shipment of the labeling if a source other than the dealer supplied the labeling.

5. Instructions to Dealer - The manufacturer or shipper often provide sales promotion instructions to the dealer. Obtain copies of such instructions if available.

#### 4.4.9.2 - Bulk Shipments

Do not remove the label from bulk containers such as drums, barrels, and large bags, if this results in misbranding the article. Remove and submit an identical label from an empty container if available. Photograph or trace the label if none other is available.

Note: Besides using tracing paper, it is possible to trace a label on a piece of plastic, similar to a document protector, using either a ball point pen or stylus. If it is difficult to read, filling in the tracing with a marker, may highlight the tracing.

#### 4.4.9.3 - Unlabeled or Partially Labeled Lot

The regulations provide for controlled shipment in IS commerce of unlabeled goods. It is a violation to ship unlabeled goods unless:

1. The shipper operates the establishment where the article is to be processed, labeled or repacked, or
2. If the shipper is not the operator of the establishment, he must first obtain from the owner a written agreement signed by the operator. The agreement must contain the post office addresses of both parties and describe the specifications and the processing, labeling, or repacking procedures, in sufficient detail to insure that the article will not be adulterated or misbranded within the meaning of the Act, upon completion of the processing, labeling or repacking.

Determine if there is a labeling agreement and obtain copies of pertinent correspondence. [21 CFR 101.100](#), [201.150](#), and [701.9](#).

##### 4.4.9.3.1 - Documentation

Collect both un-labeled and re-labeled units or specimens of the label to be affixed. Collect specimens of any shipping case labels and any labeling which accompanied the original shipment.

Obtain evidence showing how the lot was labeled at the time of receipt; how the misbranding occurred, and who was responsible. Use photographs and diagrams if necessary to portray the present condition of the lot. If any of the lot has been resold, collect documentary evidence of the resale.

#### 4.4.10 - REPORTING SAMPLE COLLECTIONS

See IOM 1.1 English language requirement. For each sample collected prepare a FACTS Sample Collection Record. Remember the collection report is the basis for

most administrative and regulatory actions. The data entered into specific fields of the report are intended to provide information for the compliance officer to prepare documents for legal proceedings. While there may be more than one right way to describe the specific circumstances you are documenting, it is important to keep in mind the subsequent readers of your collection report. See IOM Exhibits 4-1, 4-2, 4-15, and 4-16 for examples. Sample collection data may be entered either from an FDA office or from a remote location in the field using a laptop computer and modem. If change is needed to the data in the FACTS Firms table relating to the sample collection, e.g., the firm's name or address has changed; you (the collector) should notify your division's OEI coordinator, so the information can be updated in the FACTS firm table.

After collection data is entered into the FACTS system, you (the collector) must check the record for accuracy and completeness, send it to a supervisor for review, if appropriate, and then sign it electronically. The original data will be stored and permanently associated with this record. Any future changes to the FACTS database reference tables, such as the firm files, employee name, data codes, etc., will not alter the original data in the electronically-signed sample collection record.

Only the collector has editing privileges for the signed original sample collection record. You may modify the original record but must electronically sign each revision. All modifications of the original record are permanently retained as part of the original record. A permanent electronic record trail is created, capturing and retaining every change to original and subsequent records. If retrieval of the sample collection data is needed, the original record and all changes to the original record can be retrieved. See IOM 5.10.7 for additional information for Bioresearch Monitoring sample collections.

#### 4.4.10.1 - Flag

The following situations require an entry in the Sample Flags screen in FACTS. See IOM Exhibit 4-15.

##### 4.4.10.1.1 - 301(K) Sample

"301(k) Sample" - See IOM 4.1.4.4.

##### 4.4.10.1.2 - Complaint Sample

Use this flag for any sample collected from a complainant during follow-up investigation.

##### 4.4.10.1.3 - Dealer Voluntarily Holding

This flag alerts the reviewer the lot is being voluntarily held. Enter how long in the Flag Remarks field. This information will be important for the compliance officer to know when preparing a seizure or other regulatory action. This information needs to be entered as soon as the CR is created, in order for the laboratory to adequately prioritize sample analysis and provide a timely notification to the firm.



#### 4.4.10.1.4 - Exhibit Sample

When sample is to be used exclusively for court exhibit without analysis.

#### 4.4.10.1.5 - Factory Food Sample

Flag as "Factory Food Sample" when sample(s) of any item, used in the production of any food product, are taken during the EI. See IOM 4.1.6.

#### 4.4.10.1.6 - Fumigated

Enter name of fumigant in Flag Remarks field.

#### 4.4.10.1.7 - Inv. Samples Of Filth Exhibits

Enter the product code of the filth exhibits in the Product Code field of the FACTS Sample Collection Screen. **Note the product code for exhibits consists of the Industry Code followed by "YY-99" or "Y--99" as below.**

Example: Filth Exhibits of gnawings, pellets, wood splinters, etc.

In a food plant = 52YY-99  
 52 = Misc. food related items  
 Y = Exhibits  
 Y = Sub class - None  
 - = Dash  
 99 = Evidence exhibits n.e.c.

In a drug plant = 66Y--99  
 66 = Misc. drug related  
 Y = Exhibits  
 - = Dash  
 - = Dash  
 99 = Evidence exhibits n.e.c.

Other industries: Handled in same manner using applicable industry code(s).

#### 4.4.10.1.8 - Pesticide Sample

After flagging a pesticide sample, the basis for sampling must be entered in the Flag Remarks field as either "Pesticide Compliance" or "Pesticide Surveillance". Additionally, the name of the county and state, or country where grown must be entered in the appropriate fields in the Collection Record.

**Pesticide Episode** - An "episode" is defined as a violative pesticide (or other chemical contaminant) finding and all samples collected in follow-up to that finding. All samples must be associated with one responsible firm (grower, pesticide applicator, etc.) and one specific time period (e.g. growing season). The following examples are provided for clarification of this definition:

1. Samples of cantaloupes from Mexico reveal violative residues. Any destination point samples or subsequent compliance samples from the same shipper or grower

would along with the original sample be considered an episode.

2. Grower Jones has violative residues of chlorothalonil on collards for which there is no tolerance. Field samples, I.S. samples, and packing shed, or warehouse samples of these collards would all be part of the same episode.
3. Grower Jones also has violative residues of omethoate on kohlrabi about two months later. This is a separate episode.
4. Along with the omethoate on kohlrabi, Grower Jones has violative residues of omethoate on beets. Normally this would be considered a separate episode from the previous episode. However, if information were available showing that both residues resulted from the same application of the pesticide or the residues were closely related in some other way, the beets might be considered as part of the kohlrabi episode.
5. Grower Smith has violative residues of disulfon and permethrin on kale. This would be considered as one episode because only one commodity is involved.

Note: The detention without physical examination procedures provide for recommending detention based on a single violative pesticide finding. See [RPM Chapter 9-6](#). Under these procedures we may anticipate that the number of compliance samples collected in follow-up to a violative finding may diminish appreciably and, in most cases, will be limited to occasional audit samples. These samples should also be linked to the sample number (episode number) of the original violative sample that prompted the automatic detention. This episode number will be indicated in the applicable Import Alert.

The Episode Number will be the sample number of the first violative sample collected in a series of samples and is used to identify the other related samples within an episode. The division must assure that the Episode Number is used within the division and any other divisions which follow-up to the original violative sample. This number must appear in the Episode Number field of the FACTS CR.

#### 4.4.10.1.9 - Reconditioned

When collected in connection with a reconditioning operation in accordance with a court order.

#### 4.4.10.1.10 - Sampled In Transit

Use when the sample is collected from a carrier or while in transit. Indicate this flag in the Collection Remarks field. See IOM 4.1.4.3 and 4.3.4.

#### 4.4.10.1.11 - Split Sample

Use this flag when a sample is divided between two or more laboratories.

#### 4.4.10.1.12 - Survey Sample

Use this flag for any sample collected under a Compliance Program, which directs samples be collected as part of a survey, or if an assignment to collect the sample(s) indicates the sample(s) are "Survey" sample(s). Use this flag

for any sample collected under the Drug Surveillance Program (CPGM 7356.008); enter the survey number in the flag remarks section.

#### 4.4.10.1.13 - Under State Embargo

This flag alerts the compliance officer that the lot is being held under state embargo. Enter how long in the Flag Remarks field.

### 4.4.10.2 - Type Identification

When applicable, using the list of values, choose one of the following to complete the Sample Type field in FACTS. Identify any documents associated with the sample, and the sample itself, with the corresponding prefix, if noted followed by the FACTS sample number.

#### 4.4.10.2.1 - Additional (ADD)

To identify a physical sample collected from a previously sampled lot. Do not report or document as an "ADD Sample" those instances when only additional records or documentation are obtained for the sample.

#### 4.4.10.2.2 - Audit/Certification

To identify a physical sample collected to verify analytical results provided by a certificate of analysis or private laboratory analysis that purports to show the product complies with the Food, Drug and Cosmetic Act.

#### 4.4.10.2.3 - Documentary (DOC)

To identify an official sample comprised of documents and photographs, collected without a physical portion. Do not use this designation to identify a physical sample for which you wish to delay analysis. See IOM 4.1.4.2 and Exhibits 4-1 and 4-2.

#### 4.4.10.2.4 - Domestic Import (DI)

To identify samples collected of foreign products, which have passed through Customs and entered domestic commerce. The country of origin must be reported on the C/R. See IOM 4.1.4.8.

#### 4.4.10.2.5 - Food Standards (FS)

To identify samples collected to provide information on which to base Food Standards. See IOM 4.1.5.

#### 4.4.10.2.6 - Investigational (INV)

To identify samples collected to document observations and/or where interstate commerce does not exist or is not necessary. See IOM 4.1.6.

#### 4.4.10.2.7 - Mail Entry

To identify a sample of an imported product that entered the United States through the U.S. Mail.

#### 4.4.10.2.8 - Non-Regulatory

To identify a sample collected and analyzed by FDA for other federal, state or local agencies of products over which FDA has no jurisdiction.

#### 4.4.10.2.9 - Official

To identify a sample which is representative of a lot of any product covered by the Food, Drug and Cosmetic Act for which interstate commerce can be documented.

#### 4.4.10.2.10 - Post Seizure (PS)

To identify samples collected pursuant to a court order from a lot under seizure. See IOM 4.1.4.7.

#### 4.4.10.2.11 - Regulatory

A sample collected or analyzed by non-FDA personnel, including samples submitted by industry.

### 4.4.10.3 - Preparation

The collection record (C/R) is the starting point and the basic reference for all actions and considerations based on the sample. It contains or bears direct reference to every important point about the sample and the lot from which it was collected. See IOM Exhibits 4-1, 4-2, 4-15, and 4-16 for examples.

Individual Fields - Complete the individual fields on the FACTS Sample Collection Screen as indicated. The following fields must be completed to save the sample information; Sample Class; Sampling Division; Collector; Collection Date; Sample Basis; Sample Type; FIS Sample Number; Sample Description; Product Code; Product Description; Resp. Firm Type; Resp. Firm FEI Number; PAC; Sample Origin; and CR and Records Sent To. The fields described below are listed in alphabetical order to facilitate locating the instructions. Please note, when a collection report is generated, the field names may change on the report.

Any information that needs to be included regarding the sample and that cannot be documented via FACTS, should be documented on the C/R Continuation Sheet, FDA 464a. For example, pictorial descriptions of a field exam for a filth sample; or a description of relative documents and what they demonstrate regarding the subject lot of a documentary sample; etc.

#### 4.4.10.3.1 - Accomplishment Hours

Enter the accomplishment data for every sample collected, by clicking on the "clock" icon at the FACTS task bar. In the

Accomplishment hours screen, enter the PAC by selecting from the list of values and type in the number of hours spent collecting the sample. Also enter all PACs that were entered in the Collections PACs field on page 2 of the collection record. If another person is involved in the collection, add their time by clicking on the "Add" button. See IOM exhibit 4-16 page 2.

#### 4.4.10.3.2 - Analytical Assignment

After saving a collection record, the system will prompt you for analytical assignment data. Enter lab analysis data (PAC and PAF) for your sample. The analytical PAC and PAF (Problem Area Flag) may be different from the collection PAC and PAF. Enter split sample data on separate lines. For DOC samples leave this field blank. Do not enter any data in this form if the sample is being delivered to a non-FACTS lab.

#### 4.4.10.3.3 - Brand Name

Enter the Brand Name of the product. This is found on the labeling of the product. It is important to identify the product completely so the compliance officer can communicate accurate information to the court and the U.S. Marshal in the event of a seizure.

#### 4.4.10.3.4 - Carrier Name

Enter name of the transportation company who transported the goods in interstate commerce if known at the time of preparation of the CR. You may need to obtain this later to fully document interstate commerce. In the case of a 301(k) sample, this is the transportation company who moved the component you are documenting across state lines. For a 301(a) sample documenting the shipment of a violative product in interstate commerce, enter the name of the carrier utilized by the manufacturer or distributor to carry the goods across state lines.

#### 4.4.10.3.5 - Collection Date

Enter the date using the format - mm/dd/yyyy. **Note: the default date is today's date. Be careful not to use the default date if the sample was not collected on the date the CR is created. Only one date can be entered; if the sample collection was accomplished over several days, use one date. Be consistent. This date should be used to identify the physical sample and any records attached to the CR. This field is critical; be certain to verify the date.**

#### 4.4.10.3.6 - Collection Method

Describe how you collected the sample and which subs are the 702(b) portion. Relate the number and size of the sampled units and subsamples to show how each was taken, e.g., "Two cans of product randomly collected from each of 12 previously unopened cases selected at random." Note any special sampling techniques used, e.g.: "Subs collected using aseptic technique and placed in

sterile glass jars or whirl-packs" or "Subs 1-10 consist of approx. 1# of product. Subsamples 1-10 collected from bulk storage Bin #1 composited in unused, brown, paper bag." Completely describe the collection method of each sub of selective samples with multiple subsamples, including your observations of the conditions, e.g.: "Two live insects collected from seam of bag #2. Live insects were observed exiting bag and two were collected upon exit." You will normally need to use a continuation sheet to describe collection of all subsamples and your description of the lot "bag-by-bag" examination. See IOM 4.5.2.1 regarding sub identification.

#### 4.4.10.3.7 - Collection PACs

Enter the Program Assignment Code (PAC), which is most correct, from the list of values. If the PAC on your assignment is not listed, discuss with your supervisor or FACTS Lead User.

#### 4.4.10.3.8 - Collection Reason

Enter the complete reason for collection giving the suspected violation, compliance program guidance manual, and analysis desired. Identify any inter-division, regional, headquarters initiated, assignment document(s) in sufficient detail so the document can be located, if necessary. If the sample was collected during an inspection to document violations found, state that and indicate the date of inspection. See IOM exhibits 4-1 and 4-16.

#### 4.4.10.3.9 - Collection Remarks

Enter any remarks you feel are necessary. Describe any special circumstances. If a 704(d) [21 U.S.C. 374(d)] letter is indicated, include the name, title, E-mail address (if available) and the telephone/fax number of the most responsible person at the firm to which the letter should be addressed. If a 702(b) sample is not collected, describe the specific circumstance and justification for not collecting the 702(b) portion unless it is a device or tobacco product, or the assignment or guide already states why a 702(b) portion is not needed. If the sample is an in-transit sample, state the sample was collected in-transit, from whom sampled (e.g. driver and carrier firm), and where sampled. If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field. You may use a "CR Continuation Sheet", FDA 464a if you need more space.

Note: Confirmation of firm Email address and inclusion in collection remarks is integral in order to provide results in an efficient and timely manner. According to [Field Management Directive \(FMD\) 147](#), if the firm has agreed to hold products pending FDA results or if the analytical results are laboratory classification 3, the Laboratory Director or their designee shall email the results of analysis to the collecting division's established email account for receipt of analytical results.

**4.4.10.3.10 - Collector**

Your name should appear here by default.

**4.4.10.3.11 - Collector's Id On Package/Document**

As the Sample Collector, quote your identification placed on the packages, labels, etc., e.g., "55563 12/5/05 SAR". Samples are to be quoted with the information in the order shown in the example without additional symbols, words, or characters. See IOM 4.5.2.3. When multiple units are collected, all or at least a portion should be labeled as subsamples. Subsample numbers need to be included on the C/R and in the EIR. You may include the sub numbers used in this block outside of the quotes, e.g., "55563 12/5/05 SAR" subs 1-30.

**4.4.10.3.12 - Collector's Id On Seal**

Quote your identification used on the Official Seal applied to the sample, e.g., "235812/5/05 Sylvia H. Rogers, Investigator". See IOM 4.5.4.1 and exhibit 4-17. If you use the FDA metal seal, enter the words "Metal Seal" followed by the seal identification and number, e.g., "U.S. Food and Drug 233", entering the actual number of the seal used. Samples need to be kept under lock or in your possession, until sealed. The Collection Remarks field needs to describe any discrepancy between the date sealed and the date collected. Normally, the sample should be sealed on the same day as collected. **Note: Include your title when quoting the seal.**

**4.4.10.3.13 - Consumer Complaint Number**

If the sample relates to a consumer complaint, enter the complaint number. This will allow your CR to be linked to the complaint and viewed by the Consumer Complaint Coordinator and other Division and Center personnel.

**4.4.10.3.14 - Country Of Origin**

Select the Country of Origin, if known. This field is of particular need when the sample is a Domestic Import Sample.

**4.4.10.3.15 - County**

Select the County where the sample was collected (or grown if appropriate, i.e. a pesticide sample of an agricultural product.) This field is not needed for many samples. Use for pesticide samples to aid in later communication with State officials in the event of a violative result.

**4.4.10.3.16 - CR & Records Sent To**

Enter the division which is most likely to initiate any regulatory action. This field requires some thought on the part of the collector and communication with the

supervisor. For a 301(k) sample, where the dealer is responsible, this is the division where the sample was collected. Do not assume the address on the label is the location where follow-up to a violative sample will be initiated. Do not send the records to another division unless you know it is the division of the actual responsible firm. Field survey samples will be filed by the collecting division.

**When a Non-FACTs affiliation is selected, provide the reason in the remarks section.**

**4.4.10.3.17 - CRX/DEA Schedule**

Choose the appropriate schedule from the list of values, if applicable.

**4.4.10.3.18 - Dairy Permit Number**

Enter if applicable. If you are collecting samples from a dairy, obtain this number from the firm.

**4.4.10.3.19 - Date Collected**

See Collection Date IOM 4.4.10.3.5.

**4.4.10.3.20 - Date Shipped**

Enter date in the format, mm/dd/yyyy. This is the date of interstate shipment. Obtain it from the documentation you collected to document interstate movement of the product. Identify the document you used to determine this date in the "Documents Obtained" section.

**4.4.10.3.21 - Documents Obtained**

Click on the "Documents Obtained" button to enter Document Type, Document Number, Document Date and Remarks for any records collected to support a violation or show interstate movement of the product sampled. Enter an identifying number and date for invoices, freight bills, bills of lading, etc. Include the name and title of person signing any affidavits in the Remarks field. Be sure to describe the reason each document attached to the collection record was obtained. For example, when referring to a bill of lading, indicate that it was collected to document the interstate movement of the product. Also indicate which documents were collected to document specific violations encountered during inspections. State the number of pages for each document if it contains more than one page and refer the reader to the appropriate section/page of the document which shows the deviation you are documenting. Indicate the number of photographs attached. Depending on the sample and what you are trying to document, you may use the document number to record the actual number of the document (i.e., invoice number or bill of lading number) or to order the documents attached. You should order your documents in a manner that allows easy review (be guided by your supervisor or Compliance Branch). This section may also be used to list C/R attachments including FDA generated forms. See IOM exhibit 4-1.

#### 4.4.10.3.22 - Episode Number

Enter an episode number if applicable. See IOM 4.4.10.1.8.

#### 4.4.10.3.23 - Estimated Value

Enter the estimated wholesale value of the lot remaining after sampling. Obtain this information from invoice or other records. (This is not the value to be used for seizure bond purposes; however, it may be used by the division to evaluate whether seizure is an appropriate action.) Estimate value if you have no documentary reference. For DOC samples (see Exhibits 4-1 and 4-2), indicate the estimated value of the lot. If the DOC sample is collected to document a lot that has already been shipped, estimate the value, or obtain a figure from your documentation, which represents what was shipped. Many times, a DOC sample is collected merely to establish interstate commerce, in those situations, the value of the goods that traveled, or will travel, in interstate commerce is what is needed.

#### 4.4.10.3.24 - FEI Number

The FEI number is a 10-digit unique identifier, which is used to identify firms associated with FDA regulated products. Use the Build button to query the database and find an FEI for firms associated with your sample. If one does not exist, FACTS will assign one to the firm. Take care in entering search criteria to avoid creating unnecessary FEI numbers. **You must enter an FEI for a dealer on every CR, unless you check the box indicating the dealer is a consumer.**

#### 4.4.10.3.25 - Firm Name

This will be filled in by FACTS when you select an FEI.

#### 4.4.10.3.26 - Firm Type

Using the list of values, select one of the following for each FEI entered, with respect to the product sampled:

##### 4.4.10.3.26.1 - Dealer

This is always the firm from which the sample was collected. **There must be a dealer entered on every CR, unless you check the box indicating the dealer is a consumer. Note: this is not the same as the establishment type of the firm identified by the FEI. There are circumstances where you may identify the same firm as the dealer and another establishment type, such as when collecting a plant in-line sample.**

**Note: If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field.** When the sample is an in-transit sample (see IOM 4.1.4.3), enter the consignee of the lot as the dealer and state in **collection remarks** the sample was collected in-transit, from whom sampled (e.g. driver and carrier firm), and where sampled.

#### 4.4.10.3.26.2 - Grower

Select "Grower" if the FEI identifies a producer of a raw agricultural commodity.

#### 4.4.10.3.26.3 - Harvester

Use "Harvester" for an FEI identifying the harvester of the product sampled.

#### 4.4.10.3.26.4 - Ingredient Supplier

"Ingredient Supplier" should be used to identify a firm which supplied a raw material or component. For example, when documenting a 301(k) [21 U.S.C. 331(k)] situation.

#### 4.4.10.3.26.5 - Manufacturer

Use "Manufacturer" with an FEI, which identifies the manufacturer of the product sampled. **Note: this may be the same as the dealer when a product is sampled at a manufacturer. In that case, you can enter the FEI twice and identify it as both the manufacturer and the dealer.**

#### 4.4.10.3.26.6 - Shipper

The shipper is the firm responsible for causing the interstate movement of the product.

#### 4.4.10.3.27 - FIS Sample Number

Enter the last two digits of the fiscal year. The remainder of the number will be assigned by FACTS. Note: FIS sample numbers will no longer be required when the FIS is turned off.

#### 4.4.10.3.28 - Food Canning Establishment

Enter "Food Canning Establishment" if applicable.

#### 4.4.10.3.29 - Hours

See Accomplishment Hours in IOM 4.4.10.3.1.

#### 4.4.10.3.30 - How Prepared

Explain how the sample was prepared prior to submission to the laboratory; how you identified some or all the units; and how you wrapped and sealed the sample. Note any special preparation methods such as fumigation, frozen, kept under refrigeration, etc., and the form in which the sample was delivered to the laboratory, e.g. in paper bags, original container, etc. If coolants or dry ice were used, indicate so here. It is important to be specific as to how you protected the integrity of the sample and the chain of custody, e.g., "Subs identified as noted (describe how 702(b) portion was prepared/handled- see IOM 4.5.2.1), placed in unused, brown paper bag; bag taped shut and FDA seal completed (as noted) and applied, bag identified as noted in pen/ink. FDA 525 attached to sealed bag,

placed in brown, cardboard box and prepared for shipment, then delivered to division security guard desk for UPS pick-up”.

#### 4.4.10.3.31 - Lot Size

Enter the amount of goods on hand before sampling as determined by your inventory of the lot. Include the number of shipping cases and the size of the components, e.g., 75 (48/12 oz.) cases, 250/100 lb. burlap bags, 4/100,000 tab drums, 24 cases containing 48/12/3 oz. tins. If accompanying literature is involved, describe and state the amount on hand. For DOC samples (see Exhibit 4-1 and 4-2), also indicate the lot size, e.g. "one x-ray machine" or "50000 syringes and 1000 promotional brochures."

#### 4.4.10.3.32 - Manufacturing Codes

Click on the "Manufacturing Codes" button to enter and identify all codes, lot numbers, batch control codes, etc., and how they are displayed on labels, containers and shipping containers. Enclose the code in quotes, e.g. "code". For example, code embossed on can cover, "87657888" or code applied in ink on side of container, "0987878". Also indicate the manufacturing codes used on products for which a DOC sample was collected, for example, "serial number "ABC" stamped on metal plate." See IOM Exhibit 4-2.

Enter any expiration dates in the Exp. Date field.

#### 4.4.10.3.33 - Method of Collection

See Collection Method in IOM 4.4.10.3.6.

#### 4.4.10.3.34 - National Drug Code (NDC)

Enter if applicable

#### 4.4.10.3.35 - Orig CR & Records To

See CR and Records Sent To in IOM 4.4.10.3.16.

#### 4.4.10.3.36 - Payment Method

Select one of the following from the from the list of values: "Billed"; "Borrowed"; "Cash"; "Credit Card"; "No Charge"; "Voucher". The "Credit Card" option means you used your personal credit card as a last resort.

#### 4.4.10.3.37 - Permit Number

See Dairy Permit Number in IOM 4.4.10.3.18.

#### 4.4.10.3.38 - Product Code

Enter the 7-digit product code. Use the [Product Code Builder](#) for guidance. When 301(k) samples are collected, the full product code of the finished product must be entered. See IOM exhibit 4-1. See IOM 4.4.10.1.7 for product codes for filth or evidence exhibits. Special product

code considerations include environmental samples. See environmental sample identification instructions under IOM 4.3.7.7.2.

#### 4.4.10.3.39 - Product Description

Enter a complete description of the product including the common or usual name and the product packaging/container system. For example, aspirin tablets packed in clear, non-flexible plastic bottle with white screw on top with yellow stick-on label and black printing. Bottles packed in white, paperboard boxes with black printing. Paperboard boxes packed in brown cardboard boxes with black printing. If you need additional space, continue the description in remarks. See IOM exhibit 4-1.

#### 4.4.10.3.40 - Product Label

Quote pertinent portions of the label such as brand name, generic name, quantity of contents, name and address of manufacturer or distributor, code, etc. In the case of drugs, quote the potency, active ingredients and indicate whether Rx or non-Rx. Quote sufficiently from accompanying literature to identify. In the case of a Documentary Sample, sufficiently describe the article to identify what is sampled.

**NOTE:** When the product sampled is packaged in a container, shipping case or similar container, quote the pertinent labeling from the container.

When quoting from a label, or labeling, use exact spelling, capitalization, punctuation, arrangement, etc., as found on the original label(ing). Use asterisks to indicate any omissions.

#### 4.4.10.3.41 - Product Name

Product Name field is completed by FACTS when you select the product code.

#### 4.4.10.3.42 - Reason For Collection

See Collection Reason in IOM 4.4.10.3.8.

#### 4.4.10.3.43 - Recall Number

If the sample was collected as part of a recall investigation where the recall number is already known, enter the recall number.

#### 4.4.10.3.44 - Receipt Issued

Select "FDA472", "FDA484", or "None" from the list of values.

#### 4.4.10.3.45 - Receipt Type

See Receipt Issued in IOM 4.4.10.3.44.

#### 4.4.10.3.46 - Related Samples

This field is used to identify a sample number to which other sample information can be linked. When you collect more than one sample from a single shipment or there is more than one sample relating to a possible regulatory action, designate one sample as the "lead" sample. Enter that sample number in this field of the collection record for each related sample. Other related sample numbers should be listed in the Collection Remarks field.

#### 4.4.10.3.47 - Resp. Firm Type

Choose the appropriate type from the list of values for the firm most likely to be responsible for a violation. For a 301(k) [21 U.S.C. 331(k)] sample the responsible firm should be "Dealer". You should only enter one firm with the firm type you designate as the responsible firm type.

#### 4.4.10.3.48 - Sample Basis

Select from the two choices on the list of values.

"Compliance" means the sample was collected on a selective basis as the result of an inspection, complaint or other evidence of a problem with the product. "Surveillance" means the sample was collected on an objective basis where there is no inspectional or other evidence of a problem with the product.

Please note official samples can be either compliance or surveillance, and INV samples can also be either. See IOM Exhibit 4-16 for more information.

#### 4.4.10.3.49 - Sample Class

Make a selection from the following list of values: "Collaborative Study"; "Criminal Investigation"; "Division Use Sample"; "Normal Everyday Sample"; "Petition Validation"; "Quality Assurance"; "State Partnership"; "Total Diet".

#### 4.4.10.3.50 - Sample Cost

Enter the cost of the sample. If no charge, enter 0. If, as a last resort, you use your personal credit card to pay for the sample, enter the amount paid in this field and select "Credit. Card" in the Payment Method field. If you are unable to determine the cost of the sample and the firm states they will bill you later, enter the estimated cost in this field and state that it is an estimate in the Collection Remarks field.

#### 4.4.10.3.51 - Sample Delivered Date

Enter the date on which the sample was delivered to the laboratory or for shipment. For DOC samples, you must leave this field blank. If you make an entry, you must enter a laboratory.

#### 4.4.10.3.52 - Sample Delivered To

Enter to whom you delivered the physical sample. If delivered to your own sample custodian under seal, show delivery to servicing laboratory or sample custodian. If delivered to an analyst, report e.g., "In person to Analyst Richard R. Doe." If you shipped the sample, enter the name of the carrier to whom the sample was delivered. Enter the carrier shipment tracking number. If the sample is shipped by air, enter the air waybill number. If shipment is by parcel post, give the location of the post office, e.g., "P.P., Austin, TX." For a DOC sample, this field may be left blank. If the sample is being sent to a non-FACTS laboratory, enter the laboratory here.

#### 4.4.10.3.53 - Sample Description

Briefly describe what the sample consists of, i.e., three unopened, 200 tablet bottles; 20 lb case of iceberg lettuce; or documentary sample consisting of records, literature and photographs, etc.

#### 4.4.10.3.54 - Sample Flags

Click on the "Sample Flags" button to choose an appropriate flag using the list of values. See IOM 4.4.10.1 and exhibit 4-15.

#### 4.4.10.3.55 - Sample Number

Select a pre-assigned sample number, using the list of values button, or the system will enter a sample number when the record is saved.

#### 4.4.10.3.56 - Sample Origin

Choose "Domestic" or "Domestic/Import" from the list of values.

#### 4.4.10.3.57 - Sample Sent To

Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the [ORS Sample Distribution site](#). See IOM 4.4.10.5. If you are splitting the sample among multiple laboratories for various analyses, enter each laboratory separately. Generally, in that case you will have more than one PAC code. If, because of your assignment, you are aware the sample should be forwarded to a second laboratory after the first analysis is complete, include that information in the Collection Remarks field. However, you should only enter a laboratory in this field if you are sending the sample there, not if the laboratory will be expected to forward it. For a DOC sample, leave this blank. If the sample is to be sent to a non-FACTS lab, leave this field blank, enter the lab in the Sample Delivered To field, print a copy of the collection record and enclose it in the FDA 525 attached to the sample.

#### 4.4.10.3.58 - Sample Type

Make a selection from the list of values. You can enter only one value. If more than one type applies, choose one and indicate the other in remarks. If the sample is a domestic import, be sure to enter "DI", so that you can enter the foreign manufacturer. See IOM 4.4.10.2.4.

#### 4.4.10.3.59 – Sampling Organization

Make a selection from the list of values. This is the division that actually collects the sample.

#### 4.4.10.3.60 - State

Select the State where the sample was collected. This field is optional for many samples. Always use it for pesticide samples.

#### 4.4.10.3.61 - Status

This field is pre-filled by the system as "In-Progress". Select "Ready for Review", from the list of values, when you are ready to send the record to your supervisor for review, if you are required to do so. After supervisory review, if appropriate, change the status to "Complete". This will cause the electronic signature form to be activated.

#### 4.4.10.3.62 - Storage Requirements

Select from the following list of values: Ambient; Frozen; Refrigerated, Dry Ice, Fresh, Uncontrolled and Flashpoint.

- D=Dry Ice – used to indicate the product is cooled using dry ice (frozen CO<sub>2</sub>)
- H=Fresh – used to indicate the product is an unprocessed or raw agricultural commodity and stored accordingly
- U=Uncontrolled – used to indicate product is stored under conditions in which the temperature is not controlled (this would be considered a non-temperature regulated warehouse/facility, conveyance not under temperature control, etc.)
- P=Flashpoint – used to designate the flashpoint of a flammable substance (Identify the flash point in °F or °C in the 'Remarks' section)

#### 4.4.10.3.63 - 702(b) Portion Collected

Check this box if the sample you collected contains a 702(b) Portion of any food, drug or cosmetic to be held by FDA for release to the owner or person named on the label for their own analysis. This includes samples where 1) the sample schedule already accounts for the 702(b), 2) you collected in duplicate and separated the duplicate out and 3) you collected in duplicate and did not separate the duplicate out. If you did not separate the 702(b) portion, note this in the remarks so the laboratory can separate the 702(b) portion. If no 702(b) portion was collected, do not

check this box and provide reason for non-collection in the Collection Remarks section (4.4.10.3.9).

#### 4.4.10.3.64 - 704(d) Sample

Check this box if the sample is collected during an inspection (e.g., a FDA 482 has been issued) of a food manufacturer, processor or packer, and the firm is entitled to a copy of the analytical results. See [FMD 147](#). Include in Collection Remarks name, title, E-mail address (if available) and telephone/fax number of the most responsible person at the firm. See also IOM 4.1.1.4 and 4.4.10.3.9.

#### 4.4.10.4 –Lab Servicing Table (LST) Dashboard

The National Sample Distributor (NSD), implemented in October 2007, has been phased out completely with the implementation of Program Alignment.

Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the [ORS Sample Distribution site](#). The LST Dashboard is an interactive tool showing respective sample capacities by PAF and servicing lab. The LST Dashboard can be used to identify all servicing labs with current available capacity for a selected PAF. Special notes or instructions are also included on the LST Dashboard, which may include directions pertaining to diversions and/or suspensions.

The Lab Servicing Table (LST) will continue to be updated as a reference. The LST Dashboard is a supplement to the LST.

When completing a sample collection, the Lab Selection screen will include a "Lab Reference" button which links to the LST Dashboard. After referring to the LST Dashboard to identify a lab with available capacity, select the appropriate servicing lab via the listed laboratory values.

#### 4.4.10.4.1 – Other Information

[The Office of Regulatory Science intranet website](#) maintains current documents related to the Laboratory PAF managers Contact List and the Division Compliance Contacts. Questions on sample analyses, assignments, laboratory capability, or otherwise can be directed to the Office of Regulatory Science contacts listed at that site.

Additional information on sample collections/laboratories, including assignments, SCOPE and contacts, can be found at

Field Guidance-

<http://inside.fda.gov:9003/ProgramsInitiatives/FieldOperations/FieldGuidance/default.htm>

Field Programs-

<http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/default.htm>



Also reference 4.5.5.2 - Routing of Samples.

### 4.4.10.5 - Routing

Anyone who has user access to the FACTS system has access to the electronic records contained therein, including sample collection records. Individuals requiring sample collection data can query the system and retrieve data, based on the query parameters. In those cases where an individual needs to receive immediate notification of a sample collection, the collector may communicate the sample number via E-mail, telephone, or another means to a user, and the user may then query the system and obtain the desired data. It is not always necessary to print paper copies of FACTS sample collection records for those who have access to FACTS.

Routing Records Accompanying Sample Collection Record - Forward Collection Record from FACTS and original records through your supervisor to the division office compliance branch most likely to take regulatory action.

When a sample is to be billed, route a copy of the FDA 484, if issued, annotated with the FACTS sample number to the appropriate fiscal unit for your division. If possible at the time of collection, provide the FACTS sample number to the firm and request that this number be placed on the billing invoice. If no sample number is available, ask the firm to identify the bill with your name as the collector to help the fiscal unit match the bill to the sample record in FACTS. The fiscal unit will have access to the sample collection record in FACTS to obtain detailed sample information.

## SUBCHAPTER 4.5 - SAMPLING: PREPARATION, HANDLING, SHIPPING

### 4.5.1 - OBJECTIVE

The preparation, handling, and shipping of samples is your responsibility, and must be carried out in a manner which assures the sample's integrity and supports testimony that the sample examined was the same sample you collected from the documented shipment.

As few persons as possible should handle the sample to reduce the likelihood of compromising sample integrity. In order to maintain "chain of custody", it is important that properly packaged and identified samples be opened only by the sample custodian(s). See [ORA Lab Manual, Volume II, Section 5.8](#) for information about relinquishing samples.

### 4.5.2 - IDENTIFYING MARKS

#### 4.5.2.1 - Subsamples

Identify a representative number of subsamples (subs) with the sample number (including prefix, if appropriate), collection date and your handwritten initials. If individual sub identity must be maintained, assign and mark each sub with a separate Arabic numeral. In some comprehensive

inspections or investigations it may be important to correlate the manufacturing control code with the sub number.

When a variety of articles are included under one sample number, fully identify each sub and describe them on the C/R. Factory exhibits should be fully identified and, where appropriate, correlated with inspectional observations, manufacturing procedures, and/or routes of contamination. See IOM 4.2.5.6 for using the FDA 484 - Receipt for Samples as a memo to accompany C/R to describe subs collected.

When multiple subs are taken from cases, bales, boxes, etc. in the lot, Arabic numerals and letters in combination may be used for identification. For example: if two cans are taken from each case in the lot, the cans may be marked as subs 1a, 1b, 2a, 2b, etc. to identify the subs as coming from case #1, case #2, etc. If the second can or container taken from each case is the 702(b) [21 U.S.C. 372(b)] portion, it is desirable that all duplicate portions be sealed separately from the FDA portion. This fact should be so noted on the cases and C/R.

If multiple subsamples are to be collected, it may be advantageous to place identifying information such as sub number, sample number, and collection date on peel-off labels, tape, etc. in advance of sampling to save valuable time. Your initials must be in your own handwriting.

Do not place peel-off labels directly on cans for ACD samples collected for cause as these can interfere with the analysis.

#### 4.5.2.2 - Borrowed Samples

Although most samples are purchased, some may be borrowed, non-destructively examined, and returned to the owner. These samples must be handled carefully to avoid defacing or damaging the product.

Identify borrowed samples so the identification can be removed with no damage to the product, i.e. a sticker label that can be peeled off.

#### 4.5.2.3 - Identification Techniques

Mark a representative number of subsamples with the sample number, collection date and your handwritten initials. Similarly identify any outer packaging, labels or circulars. If more than one person is involved in collecting the sample, the person preparing and signing the C/R initials the subs. Reinsert circulars removed from packages. See IOM 4.3.2.2 for procedures on identifying lots from which sampled.

Transparent tape such as Scotch Magic Transparent tape accepts ball point ink and may be used on glossy items such as glass, plastic, tin, etc. Glass, such as bottles, vials and ampoules, may be identified by using a very fine pointed felt or nylon marking pen and covering the identification with transparent tape for protection.

Do not use tape on very small containers such as ampoules, which must be snapped or broken to remove the contents for analysis. Tape wrapped around the container may interfere with assay.

Do not use permanent type markers when identifying subs in absorbent containers if the ink may penetrate into the product thus contaminating the sample.

Diamond or carbide tipped stylus pencils may be used to mark tin, glass, etc. Do not use diamond or carbide tipped stylus to mark products in glass under pressure (i.e., carbonated beverages).

#### 4.5.2.4 - Photographs

Unless they are part of a DOC Sample, photographs are exhibits, to an EIR, report of investigation, or complaint. They are not samples. Photos taken during inspections and investigations are not described on a C/R, but are submitted as exhibits with the EIR. Photographs related to DOC Samples, e.g., labeling, records, and product, are identified with the sample number, collection date, and handwritten initials on the border or backside. See IOM 4.4.5 Attach the photos to the FACTS Collection Record.

In describing photographs, do not mark the face of the print. Narrative descriptions may be placed on the mounting paper next to the print or, if explanatory graphics are required, use a plastic overlay. See IOM 5.3.4.2.3 for negative identification and submission procedures and IOM 5.3.4.3 for digital photos.

IMPORTS: See IOM 6.2.8– Photographs: Identification and Storage.

#### 4.5.2.5 - Records - Accompanying Literature and Exhibits

Identify all copies of sample records, accompanying literature, and attached documents with the sample number (including prefix, if applicable), collection date and your handwritten initials as described in IOM 4.5.2.1. If an attached document is more than one page in length, it must be numbered or attached in a manner that will always allow further reviewers to determine if any pages are missing.

### 4.5.3 - SAMPLE HANDLING

All samples must be handled, packaged, and shipped to prevent compromising the identity or integrity of the sample. Samples must be packed with shock absorbing materials to protect against breakage of containers or damage to Official Seals. Frozen samples must remain frozen; perishable products may be frozen, if freezing doesn't interfere with the planned analysis, products requiring refrigeration (e.g., fresh crabmeat for bacteriological analysis) should be shipped in ice. Use your experience and knowledge (and that of your supervisor, if necessary) to determine the most appropriate packing and shipping method.

#### 4.5.3.1 - Fumigation

See IOM 1.5.3.1 for safety precautions.

General - As soon as possible, freeze any sample containing, or suspected to contain live insects, as long as freezing will not change or damage the product or break the container. If freezing is inappropriate to maintaining the integrity of the sample, fumigation may be carried out using air tight containers (such as a mason-type jar with inner ring, or a polypropylene container with air tight lid), with sufficient fumigant to kill the insect infestation. Contact your servicing laboratory for alternative fumigants.

Moth crystals, containing paradichlorobenzene (PDB), is an alternative fumigant. Do not use mothballs or moth flakes containing naphtha or naphthalene. Do not use moth crystals in or near plastics, particularly Styrofoam/polystyrenes as crazing or melting may occur. Other alternative fumigants include: liquid household ammonia or ethyl acetate, either of which can be used to dampen a cotton ball and placed in an appropriate container; or cut small portions of commercial pesticide strips.

##### 4.5.3.1.1 - FUMIGATION SAFETY PRECAUTIONS

Follow safety precautions when fumigating samples. **Contact your local servicing laboratory or MSDS for the appropriate protective gear and handling of fumigants.** Guidance is as follows:

1. Carry all alcohols, fumigants, and other hazardous liquids in approved safety containers.
2. When fumigants or preservatives are used, limit your exposure to these chemicals. Minimize transfer and exposure time. Avoid getting chemicals on hands or clothing. DO NOT MIX CHEMICALS.
3. Insure [DOT regulations](#) and [guidance](#) and [International Air Transport Association \(IATA\) guidelines](#) are followed when mailing or shipping samples containing fumigant or preservative. Exceptions for small quantities are listed in [49 CFR 173.4](#).
4. The sample identification data on your packaging, the FDA-525 and C/R, must always identify the fumigant and method of fumigation, and/or preservative used.
5. Material Safety Data Sheets (MSDS) for each chemical fumigant or preservative used must be available at each duty site and enclosed with the shipped sample. Read and follow all instructions and precautions listed on the MSDS.

##### 4.5.3.1.2 - Procedures For Fumigation

Place a small amount of fumigant, in an airtight container. Separate the fumigant from the sample with a piece of paper, paper napkin, or unscented facial tissue. Put specimen or product into container and seal tightly. Do not re-open container unless absolutely necessary. If possible, use a glass container with a lined screw lid. A mason-type jar with inner ring is also acceptable.

### 4.5.3.1.3 - Exceptions To Fumigation

When submitting samples or exhibits to show live infestation, do not fumigate. Consult with your supervisor or your servicing laboratory PRIOR to sending or bringing a live infestation into the laboratory to permit preparation for proper handling and storage. Do not fumigate sample when submitting samples for pesticide residue analysis.

### 4.5.3.1.4 - Preservation Liquids

Insects may be killed and preserved in 70% ethyl alcohol or a 1:1 mixture of 70% ethyl alcohol and glycerin (may be labeled glycerol). These chemicals can be obtained from your servicing laboratory. Do not collect rodents or animal tissues unless specifically instructed. Insure all vials or bottles of preservation liquids are tightly sealed to avoid leakage. Identification labels may be placed in containers, but must be written in India ink or 2H pencil only. Keep all preservation liquids away from excessive heat or open flame.

Identify preservative used on FDA 525, C/R, and on sample container. Enclose a copy of the MSDS with the shipped sample. Follow DOT and IATA guidelines when shipping or mailing samples with preservatives as stated under fumigants.

### 4.5.3.2 - Labeling

Samples collected for label review only should be officially sealed in clear plastic bags. This will permit cursory review and, if necessary, photocopying of the container label and reduce the need to break the seal each time the label is examined.

### 4.5.3.3 - Samples for Pathological Examination

Tissue samples are not routinely collected for microscopic or pathological examination. Authorization must be obtained from the appropriate Center before collecting samples of this material.

When assigned to collect tissue samples, unless directed otherwise by the program, the assignment, or your supervisor, cut the tissue into 1/4 inch pieces and preserve in 10% buffered formalin, or in other suitable preservatives as directed. Do not freeze the sample since frozen tissue is not suitable for pathological studies.

### 4.5.3.4 - Small Sample Items

Samples in small vials, bottles, boxes and similar type containers may be placed inside the FDA 525 envelope after identification. When the envelope is used as the sample package, place the official seal across the glued flap and the blank face of the form.

If the sample container (vial, bottle, etc.) is officially sealed, it may be placed in the same FDA 525 together with copies of the assignment.

### 4.5.3.5 - Frozen Samples

Containers - Pre-chill sterile containers before collecting frozen samples. Transfer liquids in glass to expandable containers before freezing. If the liquid must be frozen in glass, leave sufficient headspace to allow expansion. If freezer facilities are not available or if the sample is to be shipped, pack with dry ice in insulated containers.

Dry ice and insulated containers may be obtained from ice cream or dry ice dealers, and economical polystyrene (Styrofoam) containers are available at most variety stores. However, while Styrofoam containers have excellent insulating qualities, they will not withstand shipping abuse unless protected by sturdy outer cartons.

Note: If your division desires the return of Styrofoam freezer chests or ice packs used in shipping samples, note this fact on the C/R and FDA 525.

Dry Ice - Caution: Dry ice is potentially dangerous and requires caution in handling and shipping. Do not handle with unprotected hands; transport in your car without adequate ventilation; or place inside tightly closed metal, plastic, or similar type containers that do not breathe. If it is necessary to use this type container, adequately vent to prevent pressure build up. Do not use glass containers for packaging or storing dry ice. (Note: Failure to adequately vent a container containing dry ice may cause a dangerous pressure build up, resulting in serious risks to sample integrity and personal safety for those handling the container).

Note: If a sample is to be analyzed for ammonia contamination, it must not be shipped frozen in dry ice. Use other methods of freezing, if frozen shipment is necessary.

#### 4.5.3.5.1 - Shipping Frozen Samples

If using a U.S. Government Bill of Lading, it is important to give a full and accurate description of the sample for rate purposes. If more than one commodity is in the shipment, describe and enter each separately.

In all packages where dry ice is used, distribute the dry ice equally on all sides of the sample package using pieces as large as possible. Be sure the container is insulated on all six sides and tape all edges securely to assist in insulating the carton. Do not place dry ice inside officially sealed packages.

Freezing by dry ice is not effective for more than forty-eight hours. For overnight shipments, use at least one pound of dry ice per pound of sample. Increase the amount for longer hauls or unusually warm weather. (Note: When samples are in plastic type containers, the dry ice must be wrapped in paper to prevent direct contact with the plastic. The extreme cold generated by the dry ice may cause plastic to become brittle and rupture.)

Shipments made via FedEx Corporation, Priority 1, Purolator, Airborne or by other fast air express carriers, will be delivered to consignees early the next business day. Tests have shown the following amounts of dry ice will be adequate when this method is used:

For samples already in frozen state: five to ten pounds of dry ice depending on sample size is normally sufficient. For samples requiring only to be refrigerated: A minimum of ten pounds of dry ice is sufficient.

According to current policy and practices for shipping dry ice with respect to CFR 49, the International Air Transport Association (IATA) regulations and the UPS Dangerous Goods Agreement:

For non-medical, non-hazardous U.S. domestic air packages with 2.5 kg (5.5 pounds) or less of dry ice, mark the outer carton with (prominently and visibly in 1" block letters):

- "Dry Ice" or "Carbon Dioxide, Solid"
- If dry ice, then also "DRY ICE; 9; UN1845."
- A general description of the non-hazardous contents (e.g. food, meat)
- The amount of the dry ice contained in the package at the time of packaging or a statement that there is 2.5 kg [5.5 pounds] or less in the package
- Use the dedicated Dry Ice Label (available from the carrier, for an example see IOM Exhibit 4-19.) Complete the bottom portion of the sticker and note the amount of dry ice in kilograms.

For non-medical U.S. domestic packages with greater than 2.5 kg (5.5 pounds) of dry ice:

- Indicate in Campus Ship that you will be shipping dry ice, or attach Hazardous Materials shipping papers available from the carrier (\$5 per package dry ice fee applies)
- The package must be prominently and visibly marked, in 1" block letters, as containing "Dry Ice" or "Carbon Dioxide, Solid", UN1845 (See: IOM Exhibit 4-19).
- A label identifying dry ice contents is available from the carrier, for an example see IOM Exhibit 4-19
- The net weight of dry ice at the time of packaging must be indicated on the shipping papers and can also be marked on the outer package (prominently and visibly marked in 1" block letters)
- UPS Dangerous Goods Agreement required (Note: A UPS Dangerous Goods Agreement, available from the shipper, is required to be filled out and provided to the shipper at time of shipment).

Note: The dry ice may freeze the edges of the product, so if it is imperative no part of the sample becomes frozen, use coolants other than dry ice. Mark the FDA 525 that dry ice was used.

See IOM 4.5.5.8.6 when shipping sample packages containing hazardous or toxic items by air.

#### 4.5.3.5.2 - Control

To prove the shipment did not thaw in transit, place a jar or leak-proof plastic bag of chipped ice in the shipment adjacent to the sample package, but not within the officially sealed package.

#### 4.5.3.6 - Refrigerated (Not Frozen) Samples

Maintain refrigerated (not frozen) samples in a refrigerator at 4.4°C (40°F) or below. Use either wet ice or some type of "Ice Pak", "Liquid Ice", "Sno-Gel", "Kool-It", or similar products to maintain the required temperature range.

Place Ice Paks, etc., in sealed plastic bags to protect samples from possible contamination should the container break, the ice melt, or the refrigerant penetrate the sample. Use insulated shipping containers for shipping samples to the laboratory.

#### 4.5.3.6.1 - Control

If it is necessary to show the sample temperature did not go above the desired or specified temperature, you can use one of several methods, such as including a pre-chilled, shaken down, maximum reading thermometer or commercially available indicators. Take care to place the thermometer outside of the sealed sample package and attempt to place in an area anticipated to be likely to reach the highest temperature. Describe the method used on your C/R.

#### 4.5.4 - OFFICIAL SEALS

Domestic samples, regardless of type, shall be sealed with form FDA 415a, Official Seal, or, in some situations with the FDA "Metal Seal". See IOM 4.5.4.6 for use of metal seals. See also IOM 4.1.4.2.

Note: With the approval of your supervisor and laboratory, it is not necessary to affix an official seal to a sample that will be in the sample collector's continuous personal custody until it is submitted personally to an analyst. This procedure should be reserved for emergencies and high priority situations. The sample should be submitted the same day it is collected with the subs properly identified. The C/R must state you personally delivered the sample to "Analyst \_\_\_\_\_" or other appropriate staff member.

Make every effort to prepare and submit your samples on the date collected so the C/R, sub identification, and the final official seal bear the same date, and thus enhance

sample integrity. However, if you cannot finish the sample preparation on the same day collected, you must explain in the C/R Collection Remarks field what steps you took to protect the integrity of the sample, e.g., officially sealed and locked in supply cabinet, locked in safe, etc.

Never place more than one sample in the same officially sealed package.

Official seals may be used up to five years beyond the expiration date indicated by the manufacturer of the seal. Field offices should periodically monitor their official seal inventory and discard or destroy any official seals that are more than 5 years beyond the expiration date indicated by the manufacturer of the seal.

#### 4.5.4.1 - Preparation

Inscribe FDA 415a, official seal, with the division office name, sample number (with the appropriate prefix), the date applied, your signature, printed name and title. See IOM Exhibit 4-17. The seal must bear only one signature. If more than one person is involved in collecting the sample, the person preparing and signing the collection record must sign the seal.

#### 4.5.4.2 - Application

Seal the sample package so that it cannot be opened at any point without evidence of tampering. If the surface of the sample container is of such construction or condition that the FDA-415a, official seal, will not adhere (e.g., waxed container, frosted over, sweating, etc.), wrap or place sample in a container to which the official seal will hold. See IOM 4.5.4.6.

To ensure the sample package cannot be opened at any point without evidence of tampering, wrap clear packing tape around the package that the seal is adhered to and across at least two sides of the official seal. The clear packing tape should not cover any text on the official seal.

When using the self-adhering seals, the surface on which the seal is to be placed must be clean and dry. The seal must be rubbed when affixed to generate heat and help it bond.

#### 4.5.4.3 - Sealing Method

There are many acceptable methods of officially sealing samples. Because of the wide variety of shapes and sizes of samples, and the ingenuity you may have to apply to package and packaging situations, explicit methodology will not be detailed here. If you are unsure of a sealing method, consult your supervisor.

#### 4.5.4.4 - Protecting the Official Seal

Protect the sealed surface by wrapping the package securely with heavy wrapping paper for mailing or shipment. If your officially sealed package is not further wrapped for

shipping and the tape(s) and official seal are thus exposed, you must protect the Official Seal from damage during shipment by:

1. Covering the official seal with a sheet of heavy wrapping paper or heavy clear plastic (e.g. from a document protector) of sufficient size to cover the surface of the official seal.
2. Tape the protective paper or heavy clear plastic securely around the edges so it cannot come loose and expose the official seal. Do not paste or glue the paper or plastic to the face of the official seal since this will obliterate the official seal when removed.
3. When you protect the official seal by heavy paper, write "FDA Seal Underneath", or similar wording across the protective paper. This alerts the receiving custodian the official seal is underneath, and to take care when removing the protective paper. If you cover and protect the seal with heavy clear plastic, the sample custodian will be able to copy the necessary information off the seal without removing the protective cover.

#### 4.5.4.5 - Broken Official Seals

Reseal the sample whenever you break the official seal. Each seal used on the sample will be submitted with the records associated with the collection record, properly initialed and dated, to provide a continuous history.

There is only one class of seal: an "official seal". Anytime a sample is sealed with the FDA 415a, or with the FDA Metal Seal, the item is "officially sealed". An officially sealed sample must sometimes be reopened to prepare it for submission to the laboratory, or for some other legitimate reason. In that situation, the original seal must show the date it was broken. When the sample is ready to be resealed the new seal must show the date it is applied. This procedure must be followed each time the official seal on a sample is broken. Each seal will show the history of the date it was applied and broken. See instructions in Exhibit 4-17. Indicate in the collection remarks field of the FACTS C/R the fact that the seal was broken and reapplied and attach the broken seal to the FACTS C/R. This provides an unbroken, documented chain of custody.

#### 4.5.4.6 - Metal Seals

Where it is impossible to use the paper official seal, the numbered self-locking "U.S. Food and Drug" metal seal may be used. This seal is effective for use on wooden crates, drums, baskets, etc., where the FDA 415a cannot be used. Record the number of the metal seal used on the CR. See IOM 4.3.4.3 for instructions on the use of the metal seal to reseal railroad cars or conveyances. When a supply of these seals is needed by your division, contact the [Division of Domestic Human and Animal Food Operations \(DDHAFO\)](#) at (301) 796-0360.

#### 4.5.4.7 - Sealing Non-Sample Items

Although the primary purpose of the official seal is for sealing samples, there are times when the official seal may

be used to officially seal items other than samples. The FDA metal seal is often used to seal rail cars or vehicles as indicated in IOM 4.3.4.3.

When directed by your supervisor, you may use an official seal to seal questionable or suspicious bioresearch records encountered during an inspection or investigation to prevent tampering or to preserve their integrity. As explained in the applicable compliance program, the procedure must have the approval of the bioresearch monitoring staff (HFC-230) prior to implementation.

**4.5.5 - SAMPLE SHIPMENT**

When you cannot personally deliver a sample to the examining laboratory, ship it by the most economical means commensurate with the need for rapid handling. See IOM 4.5.5.2 and 4.5.5.6 for special information on shipments to FDA Headquarters' laboratories.

FDA collects a wide variety of samples, many of which are unstable, toxic or hazardous material, e.g., etiological agents, radiation products, chemical, hard swells, etc. Use safety precautions in handling and shipping commensurate with the hazard. See IOM 4.5.5.8.7.

If there is any concern regarding the contents of the package the sample custodian may verify in FACTs the identity of the collector and the product collected prior to opening the package.

**4.5.5.1 - FDA 525 - Sample Package Identification**

Form FDA 525 - Place the FDA 525, sample package identification, near the official seal. Do not affix the FDA 525 on the outside of the shipping container or under the official seal. Enclose a copy of the assignment document in the FDA 525 envelope and provide the following information on the FDA 525:

1. Division or Headquarters' laboratory to which the sample is directed, City, State, and unit symbol (e.g., SRL, HFD-400, HFS-300, etc.).
2. Date.
3. Your division and symbol.
4. Sample Number.
5. Name of dealer.
6. Product Identification.
7. Address of dealer.
8. Enter the reason for collection. (Copy from C/R.) Provide reference to any sampling assignment.
9. Provide information as to the analysis to be made.
10. When entering information for "Package\_\_of\_\_Packages"- number of packages should be the number of sample packages. Also enter any pertinent remarks. Note if your division desires the return of any freezer chests, ice packs, or maximum/minimum thermometers used.
11. Provide any special storage instructions. Mark appropriate block and enter suggested refrigeration temperature if necessary. Elaborate in Remarks if necessary.

12. Print your name.

See IOM 4.5.3.4 when using the FDA 525 as a sample package. See IOM 4.5.5.3.6 for information to include with the FDA 525 for medical device samples.

Outer Wrapper or shipping container - Always place the words, "SAMPLE NO. \_\_\_\_\_" followed by the actual FACTS or OASIS sample number(s)(with appropriate prefix) on the outside of the package near the address label. This alerts the receiving mail room that the package contains a sample and must go to the sample custodian.

**4.5.5.2 - Routing of Samples**

In general, samples will be submitted to an appropriate servicing laboratory with available capacity via the Lab Servicing Table (LST) Dashboard, except as directed by the Compliance Program Guidance Manual, assignment or your supervisor. The following provides general procedures for sample submission.

1. Vitamin and Nutritional Labeling - Submit to FDA, Science Branch (HFR-SE680), 60 Eighth St. N.E., Atlanta, GA 30309.
2. Radiopharmaceuticals for Sterility - Submit samples to WEAC.
3. Drug Residues - Submit to the Denver District Tissue Residue Lab.

**4.5.5.3 - Samples to Administration Laboratories**

When shipping samples to headquarters or other special laboratories follow the procedures for each laboratory.

**4.5.5.3.1 - Split Samples**

Where the sample examination is split between a Headquarters Division, the National Center for Drug Analysis, and a division lab:

1. Follow the above procedures on the portion sent to a Headquarters' laboratory or NCDA.
2. Submit Original C/R and records to the servicing laboratory, whether or not the home division.

**4.5.5.3.2 - National Center for Drug Analysis or Headquarters' Division**

National Center for Drug Analysis or Headquarters' Division analysis alone.

1. Do not forward original C/R and records.
2. Enclose a copy of the assignment memorandum in the FDA 525 envelope.
3. Affix the FDA 525 to the officially sealed sample package.
4. Submit the Original C/R and records to the home division, or forward to the home division if other than the collecting division.

### 4.5.5.3.3 - Center For Food Safety and Applied Nutrition (CFSAN)

Submit samples to CFSAN as directed by a Compliance Program, Field Assignment or with approval of the Office of Compliance, Division of Field Programs and Guidance Compliance Programs Branch (HFS-615).

The Compliance Program, Field Assignment, or approval will provide sample information and instructions for shipping to the appropriate CFSAN laboratory. CFSAN laboratory locations are:

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740

#### [FDA Gulf Coast Seafood Laboratory](#)

Iberville Drive  
Dauphin Island, AL 36528

1. [Office of Regulatory Science](#)
  - a. Division of Bioanalytical Chemistry (HFS-715) - Conducts laboratory investigations in the broad areas of elemental analysis, natural toxins, nutrients in food, ingredients in dietary supplements, and ingredients of cosmetics.
  - b. Division of Analytical Chemistry (HFS-705) - Conducts laboratory investigations in the broad areas of food additives, allergens, pesticides, dietary supplements, seafood toxins, food defense threat agents, and industrial chemicals that may contaminate CFSAN regulated products.
  - c. Division of Microbiology (HFS-710) - Develops, optimizes, and validates methods for recovery, detection, identification, and quantitation of pathogens and toxins from foods and cosmetics, and the processing environment. Maintains FDA's food-related gateway to the PulseNet System. Develops and applies subtyping methods to further enhance data generated for Pulsenet, strain identification, and molecular epidemiological investigations.
2. [Office of Applied Research and Safety Assessment](#)
  - a. Division of Molecular Biology (HFS-025) - Analyzes foods when the chemical methodology is under development or unusual equipment or skills are required, such as radioactivity analysis and migration of food additives from food packaging materials. Microbiologically examines samples for potential food pathogens by rapid molecular biological testing using DNA probes, PCR, and DNA fingerprint analysis.
3. [Office of Cosmetics and Colors](#)
  - a. Division of Color Certification and Technology (HFS-105) - Conducts analyses of color additive samples submitted to FDA for certification, assigns certification lot numbers to compliant lots, and denies certification to non-compliant lots. Develops, optimizes, and validates methods for the determination of components and impurities in certifiable color additives. Develops, optimizes, and validates methods for the determination of color additives in foods and cosmetics. Conducts analyses

of foods and cosmetics for color additive content when special skills and expertise are not available in the field.

4. [Office of Food Safety](#)
  - a. Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory (HFS-400) - Conducts microbiological and chemical investigation of seafood, including bacterial and viral pathogen, natural marine toxins, aquaculture drugs, products of decomposition, and other contaminants when special skills or equipment required for analysis are not available in the field.

### 4.5.5.3.4 - Center For Drug Evaluation And Research Division Of Pharmaceutical Analysis (DPA)

Examines surveillance drug samples collected and shipped under current program directives. Analyzes all heparin and insulin samples.

CDER-OPS-OTR  
Division of Pharmaceutical Analysis (DPA)  
645 S. Newstead, Ave.  
St. Louis, MO 63110

### 4.5.5.3.5 - Center For Biologics Evaluation And Research (CBER)

Sample Custodian  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Avenue  
WO75-G707  
Silver Spring, MD 20993-0002

Examines and reviews biological products not covered by a Compliance Program. Prior to shipping a sample, the division should notify either the Sample Custodian, 301-594-6517, or the [Regulations and Policy Branch](#), 301-827-6210, who in turn will notify the Sample Custodian.

### 4.5.5.3.6 - Center For Devices And Radiological Health (CDRH)

[WEAC](#) (see 1. below) is the primary laboratory for devices and radiation-emitting products. The CDRH Office of Science and Engineering Laboratories accepts medical devices and radiation-emitting products for testing, but only after assignment or approval from CDRH, Office Health Technology. Note: Include in the FDA 525 envelope a copy of the manufacturers finished device specifications test methods and acceptance/rejection criteria.

1. Send samples for sterility analysis to: Winchester Engineering and Analytical Center (WEAC)  
109 Holton Street (HFR-NE400)  
Winchester, MA 01890-1197  
Patrick Regan, Director, Analytical

Telephone: 781-756-9707

FAX: 781-756-9757

2. Send bioburden analysis samples to WEAC.
3. Send bioindicator analysis samples to WEAC.
4. Send device and GWQAP device samples for physical and engineering analysis to WEAC.
5. Send in-vitro diagnostic device samples to WEAC.
6. Send devices used for antibiotic susceptibility testing (including discs) requiring performance testing to WEAC.
7. Send Southwest and Pacific Region condom and glove samples to the Pacific Regional Laboratory (PRS)
8. Send all other condom and glove samples to WEAC.
9. Send radiological health samples to:  
CDRH/OSEL Sample Custodian HFZ-105  
WO62, 10903 New Hampshire Ave., Room 4126  
Silver Spring, MD 20993  
Telephone: 301-796-2558  
FAX: 301-796-9795 Note: Contact Office of Science and Engineering Laboratories, 301-796-2558 prior to collection and shipment of any radiological product sample.

#### 4.5.5.3.7 - Center For Veterinary Medicine (CVM)

##### [Center for Veterinary Medicine](#)

Division of Compliance (HFV-230)

7500 Standish Place (MPN II)

Rockville, MD 20855

240-276-9200

Samples of veterinary products, not specifically covered by one or more of the CVM Compliance Programs, can be sent to the above address for review, evaluation, and comment. This includes documentary samples, and labels/ labeling and advertising materials. There are no laboratory facilities at MPN II. If you have questions about sampling or sample destinations, contact HFV-230 and/or the applicable program contact.

#### 4.5.5.3.8 - Center For Tobacco Products (CTP)

Do not collect samples of tobacco products unless directed by an assignment, approved by the Center for Tobacco Products, Office of Compliance and Enforcement, or by Division Management.

**Send compliance and surveillance samples to: Southeast Regional Laboratory (SRL), Atlanta Center for**

#### Tobacco Analysis. Contact information

on [Atlanta Center for Tobacco Analysis website](#).

#### 4.5.5.4 - Sample Shipment to Outside Agencies

Do not ship any samples outside FDA unless your assignment, applicable program, or your supervisor specifically instructs you to do so.

#### 4.5.5.5 - Notifying Receiving Laboratories

When frozen, perishable, or high priority items are shipped, notify the receiving division or lab by telephone, or e-mail, that you have shipped the sample. Provide the following information:

1. Sample Number
2. Name of Product
3. Number of Parcels in Shipment
4. Carrier's Name
5. Carrier's Waybill Number
6. Carrier's Train, Truck, Bus, or Flight Number
7. Estimated Time and Date of Arrival
8. Relevant Remarks, i.e., "Sufficient Dry Ice to maintain frozen until 8:00 AM, (date)"
9. Place the name and telephone number of the person that is to receive the sample on the outer shipping container near the address with instructions to the carrier to contact the above-named individual upon arrival of the package.

#### 4.5.5.6 - Method of Shipment

Note: If samples are shipped to headquarters laboratories by bus lines, delivery of the sample must be specified on the bus bill. Use the most economical method of shipment consistent with the need for special handling. Shipping costs may be reduced by packing samples addressed to the same consignee into a larger container or by "piggy-backing" (taping a number of larger boxes together and shipping them as one package). Make sure the total package is within the carrier's weight and size limits.

#### 4.5.5.7 - Parcel Post

When samples are shipped by parcel post, do not exceed the parcel post limits as to size and weight.

1. Package Limits
  - a. From a first-class post office to a first-class post office:  
Weight - 40 lbs.  
Size - 84 in. length and girth combined.
  - b. Mailed at or addressed to a second or lower-class post office:  
Weight - 70 lbs.  
Size - 100 in. length and girth combined.
2. Address Labels - The use of franked labels and envelopes is no longer allowed. Affix proper postage to envelope or address label after using division or resident post postal scale and meter. If no postal meter is



available, use the resident post postage scale to weigh the envelope or package and add the proper postage using postage stamps. If no stamps are available purchase them from the post office and claim reimbursement on your voucher. Obtain a receipt for the stamps or postage, if required by your Division Office.

If the package is addressed to an FDA unit, show the FDA routing symbol following the name of the FDA unit.

Note: Wrap parcels shipped "Registered Mail" in kraft paper because the postal service must affix an ink stamp seal to each closure point. Do not wrap the outer package with tape that has a shiny or glossy surface (e.g., masking tape, filament tape, scotch type tape, etc.).

Some items cannot be mailed or can be mailed only in small quantities for safety and legal reasons. Call 1-800-ASK-USPS or visit your Post Office if you have questions.

#### 4.5.5.8 - Common Carrier

Certain Department of Transportation (DOT) regulations exist pertaining to carrier inspection of packages. Instruct the carrier to contact the shipper (FDA) prior to any package inspection requires breaking the official seal. Carriers have broken FDA official seals for package inspection during transit, thereby compromising the sample integrity.

If an FDA 3082 - Shippers Declaration for Dangerous Goods is executed for shipments of restricted items, place a statement in the special handling section that breaking an FDA official seal is not authorized, and to contact the shipper (FDA) if there are any questions regarding the shipment. See IOM Exhibit 4-18.

##### 4.5.5.8.1 - Shipment

You must decide how your samples are shipped. The judgment must be based on your knowledge of the practices and performance of the transportation firms in your area. As a general rule, Parcel Post, United Parcel Service, or current GSA contract carrier should be used for small packages and other express or comparable carriers for packages too large for PP, UPS, or current GSA contract carrier. Before using motor express lines and passenger bus lines determine that their schedules and delivery practices are satisfactory and reliable. Bus lines must not be used for shipments to Washington, DC offices unless delivery at the destination address is specified.

Air express or air freight shall be used only for samples requiring extremely rapid handling or where more economical means of shipment are not available or feasible.

Air freight service is offered by the individual air lines and, although usually not as convenient as express, is more economical and should be used especially for shipments of 50 lbs. or more.

##### 4.5.5.8.2 - Designated Carriers

You may ship by any carrier you wish with the objective of obtaining the best possible service at the most economical rate.

Always indicate on the carrier's shipping document that the shipment is a U.S. Government shipment.

##### 4.5.5.8.3 - Government Bill Of Lading

Prepare Form SF-1103, Government Bill of Lading (GBL), for shipments made by common carrier except as described below. Distribute GBL as follows:

Give the Carrier:

1. Original (White) Form SF-1103
2. Shipping Order (Pink) Form SF-1104
3. Freight Waybill Original (White) Form SF-1105
4. Freight Waybill Carriers Copy (White) Form SF-1106

Submit the remaining 4 copies "Memoranda Copy" (Yellow), Form SF-1103a, and the "Memorandum Copy" (Blue), Form SF-1103b, to your division. If available, obtain the transportation costs or the rate from the carrier and enter it in pencil on the copies submitted to the division.

##### 4.5.5.8.4 - Commercial Bill Of Lading

The use of commercial forms (in lieu of GBL's) and procedures for small shipments is subject to the limitations and instructions set forth in the following paragraphs. The use of commercial forms shall be limited to those carriers that have a letter of agreement with FDA or GSA. The use of commercial forms is to be applied only to the following types of shipments:

1. Shipments for which the transportation charges ordinarily do not exceed \$100.00 per shipment and the occasional exception does not exceed that monetary limitation by an unreasonable amount.
2. Single-parcel shipments via express, courier, small package, or similar carriers, without regard to shipping cost, if the parcel shipped weighs 70 lbs. or less and does not exceed 108 inches in length and girth combined.
3. Multi-parcel shipments via express, courier, small package or similar carriers for which transportation charges do not exceed \$250.00 per shipment.

##### 4.5.5.8.5 - Address Labels

Form HHS-409, address and sample number identification label, is no longer available. Until a new standardized label is issued, investigators need to use the street address of the receiving laboratory or office. Do not use the post office box number as contract carriers may not deliver to PO Box numbers.

Place the words "SAMPLE NO", followed by the appropriate FACTS or OASIS sample number(s) (with appropriate prefix), on the outside of the shipping

package(s) near the address label. The package(s) should be properly identified with the FDA office shipping the sample and the receiving laboratory or other office. This alerts the receiving mail room that the package contains a sample and must go to the sample custodian.

#### 4.5.5.8.6 - Shipment Of Hazardous Or Toxic Items

[The Department of Transportation \(DOT\) regulations](#) require certain packaging, forms, certifications, declarations, and/or statements covering shipment of hazardous or toxic items. Except for dry ice, most of the samples of hazardous or toxic materials we ship are classified as "ORM-D, Consumer commodity". Both dry ice classified as "9", and ORM-D classifications require a certification/declaration for shipment by air but not for shipment by surface transportation.

Shipments containing dry ice - use the dedicated Dry Ice Label (available from the carrier - for an example see IOM Exhibit 4-19). Complete the bottom portion of the sticker and note the amount of dry ice in kilograms. In addition to the label, the package itself must be clearly marked in 1" block letters: "DRY ICE; 9; UN1845".

Contact the carrier involved to execute the necessary forms, certification/declarations, packaging, marking, etc. required for the particular shipment or hazardous or toxic items.

For further information, contact your district Safety Officer or Industrial Hygienist.

#### 4.5.5.8.7 - PRECAUTIONS

The following precautions should be observed when shipping samples:

1. Always pack liquid products in sufficient cushioning and absorbent material to absorb any breakage which might occur. Check with the Post Office or other carriers regarding shipment of liquids.
2. Hard swells may explode. Wrap them heavily in paper and cushioning material for shipment and submit promptly.
3. Observe special precautions when shipping products in pressurized containers to avoid exposure to excessive heat. Air shippers who ship in non-pressurized planes may also have special requirements for this type container. Check Post Office and carrier for regulations, precautions, or restrictions before shipping products in this type container.
4. Special precautions for both packaging and shipping radioactive substances must be observed. If necessary, consult your supervisor, the regional radiological health representative, WEAC or the applicable program.

Note: The compliance program for radioactive drugs directs the manufacturer to ship samples via their normal mode of transportation to WEAC. The Nuclear Regulatory

Commission (NRC) requires that firms manufacturing radioactive drugs ship only to NRC licensed consignees. WEAC's NRC license number is 20-08361-01 Exp. Date 11/30/2026. This license number should be used for any shipments of radioactive products to WEAC.

#### 4.5.5.9 - Certified and First Class Mail

Where speed is essential and a record of receipt of the sample is desired, small samples may be sent by express mail or certified air mail, or, in situations where speed is a factor but the receipt is not necessary, by first class air mail. Where other methods of shipment do not suffice, larger samples may be shipped certified or first class as a last resort. Normally do not use certified or first class for routine samples.

#### 4.5.6 - Payment Of Shipping Charges

1. Cash Payment - Agencies have authority to use imprest funds (pay cash) for Cash On Delivery (COD) payment of transportation charges. See IOM 4.5.5.8.1 and 4.5.5.8.2.
  - a. Shipments between divisions may be shipped COD when the conditions cited above are met.
  - b. Shipments to headquarters may be shipped COD but you must enter on the firm's commercial bill of lading that the FDA billing unit is as follows:

Food and Drug Administration  
Division of Accounting (HFA-120)  
1350 Piccard Dr.  
Rockville, MD 20850

2. Other Means of Payment - If you do not pay cash or the shipping cost exceeds those circumstances in IOM 4.5.5.8.4, you must use one of the following payment methods:
  - a. Postal meter or postage stamps - You can use these for shipments under 70 lbs/ when it is cost effective.
  - b. Billed shipments - Those shipments meeting the criteria in IOM 4.5.5.8.1 and IOM 4.5.5.8.4 and are billed by an invoice from the carrier.
  - c. Government Bill of Lading (GBL) - If the other methods discussed above are not appropriate, a GBL must be issued at the time of the shipment.
  - d. In an emergency, if you are without a GBL or the carrier refuses to accept a GBL at the time of shipment, you can convert the carrier's invoice to a GBL after the completion of the shipment. Avoid this procedure if at all possible.



# CHAPTER 4 EXHIBITS AND SAMPLE SCHEDULES

## 4-1 FACTS SAMPLE COLLECTION SCREEN

Action Edit Options Related Info Navigate Tracing Help Window

Maintain Sample Collection

Page 1 2

### Sample Collection

**Sample Number:** 786776 **Sample Class:** Normal Everyday Sam **Sampling District:** CIN-DO **Status:** In Progress **Modif Count #:**

**Collector:** Cartwright, Guy W **Collection Date:** 12/12/2012 **Lot Size:** 125 cases, 12/100 tablet bottles

**Sample Origin:** Domestic **Sample Basis:** Compliance **Sample Type:** Documentary

**FIS Sample Number:** 13 208647 **Episode Number:** **Related Sample:** **Compliance Number:**

**Sample Description:** No physical sample collected. Documentation accompanying sample includes copies of records documenting interstate commerce.

**Collection Reason:** Collected during EI of Dealer dated 12/10-12/12 to document cGMP deviations. No analysis necessary.

**Collection Remarks:** "Product Description" (continued): with a white screw-on cap with a clear plastic seal. Bottle has yellow wrap around paper la

#### Associated Firms

**Resp Firm Type:** Dealer **FEI Number:** **Firm Type:** **Firm Name:**

<input type="checkbox"/> Dealer is Consumer	3007888982	Dealer	ARO Pharmaceuticals, 356 N	Add
	1021745	Ingredient Supplier	Master Supply, 123879 Prige S	Delete
	1021745	Shipper	Master Supply, 123879 Prige S	

#### Product

**Product Code:** 60 L B A 05 B **Brand Name:** Vlaprin Arthritis Formula

**Product Name:** Aspirin (Analgesic); Human - Non/Rx Combination Ir **Product Description:** Aspirin tablets packaged in a clear, non-flexib

**Product Label:** Finished product: Label on bottle reads in part, "\*\*\*VILAPRIN ARTHRITIS FORMULA 100 Tablets\*\*\*Active ingredients: Acetylsal

[Documents Obtained](#) [Manufacturing Codes](#) [Sample Flags](#)

Action Edit Options Related Info Navigate Tracing Help Window

Maintain Sample Collection

Page 1 2

### Sample Collection

**Sample Number:** 786776 **Sample Class:** Normal Everyday Sam **Sampling District:** CIN-DO **Status:** In Progress **Modif Count #:**

**Collection Method:** Copies of records collected during EI at the Dealer dated 12/10-12/2012. Photograph taken on 12/11/2012. Affidavit obtained on 12/1

**State:** **County:** **Country of Origin:**

**Estimated Value:** \$4,500.00 **Sample Cost:** **Payment Method:** **Receipt Issued:** None

**Carrier Name:** Roadway Inc. **Date Shipped:** 06/16/2012 **Consumer Complaint Number:** **Recall Number:**

**How Prepared:** Records and mini CD-R identified as in the "Collector's ID on Package/Document" field. Original copy of digital photographs made using

**Collector's ID On Package/Document:** "DOC 786776 12/12/2012 SHR" **Collector's ID On Seal:** "DOC 786776 12/12/2012 Sylvia H. Rogers"

**Sample Delivered To:** **Sample Delivered Date:**

**CR & Records Sent To FACTS Org:** CIN-DO **Storage Requirement:**

**CR & Records Sent To Non FACTS Org:** **Food Canning Establishment:**  704 (d) Sample

**Dairy Permit Number:** **Crx/DEA Schedule:**  702 (b) Portion Collected

**National Drug Code:**

#### Collection PACs

PAC Code	Description	Add	Delete
56002	DRUG PROCESS INSPECTIONS(DPI)	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>

#### FACTS Org? Physical Sample Sent To

FACTS Org?	Physical Sample Sent To	Add	Delete
<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

Sample Flags

**Sample Flags**

Sample Flag	Remarks
301(k) Sample	

OK  
Add  
Delete

Documents Obtained

Document Type	Document Number	Document Date	Remarks
Affidavit	1.	12/12/2012	Signed by Nicholas I. Herkimer, President
Invoice	2.	06/06/2012	Invoice no. 2346 documenting Master Supp
Bill of Lading	3.	06/16/2012	Bill of lading no. 124679 documenting inter

OK  
Add  
Delete

Manufacturing Codes

**Manufacturing Codes**

Manufacturing Code	Exp Date
"Lot 25C83" (finished product)	8/13
"Batch 5564" (active ingredient)	8/14

OK  
Add  
Delete

**Food and Drug Administration Office of Regulatory Affairs**  
**Collection Report**  
**For Sample Number: 786776**

This is an accurate reproduction of the original electronic record as of 01/30/2015

<b>Flag</b>	<b>Flag Remarks</b>				
301(k) Sample					
<b>Episode Number</b>	<b>Origin</b>	<b>Basis</b>	<b>Sample Type</b>	<b>FIS Smpl Num</b>	<b>Status</b>
	Domestic	Compliance	Documentary	13208647	In Progress
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
3007888982	12/12/2012	60LBA05	Dealer	56002	.5
<b>Compliance Num</b>	<b>Country of Origin</b>				

<b>Related Smpl Num</b>	<b>Position Class</b>	<b>Sampling District</b>	<b>NDC Number</b>	<b>Permit Number</b>	<b>Storage Rqmnt.</b>
	INV	CIN-DO			
<b>Dealer is Consumer</b>	<b>Crx/DEA Schedule</b>	<b>Recall Num</b>	<b>Consumer Compl. Num</b>	<b>Brand Name</b>	
No				Wilaprin Arthritis Formula	

**Product Description**

Aspirin tablets packaged in a clear, non-flexible plastic bottle (See "Remarks")

**Product Label**

See continuation.

**Reason for Collection**

Collected during EI of Dealer dated 12/10-12/12 to document cGMP deviations. No analysis necessary.

**MFG Codes**

"Lot 25C83" (finished product)  
 "Batch 5564" (active ingredient)

**Expiration Date**

8/13  
 8/14

<b>Firm Legal Name</b>	<b>Address</b>	<b>Type of Firm</b>	<b>Firm FEI</b>	<b>FCE</b>
ARO Pharmaceuticals	356 Northview Dr Powell, OH 43065-9479 US	Dealer	3007888982	
Master Supply	123879 Prige Street Henderson, KY 42420 US	Ingredient Supplier	1021745	
Master Supply	123879 Prige Street Henderson, KY 42420 US	Shipper	1021745	

<b>Size of Lot</b>	<b>Est. Value</b>	<b>Rcpt Type</b>	<b>Carrier Name</b>	<b>Date Shipped</b>
125 cases, 12/100 tablet bottles	\$ 4,500.00	None	Roadway Inc.	06/16/2012

**Description of Sample**

See continuation.

**Method of Collection**

Copies of records collected during EI at the Dealer dated 12/10-12/2012. Photograph taken on 12/11/2012. Affidavit obtained on 12/12/2012.

**How Prepared**

See continuation.

**Collector's Identification on Package and/or Label**

"DOC 786776 12/12/2012 SHR"

**Collector's Identification on Seal**

"DOC 786776 12/12/2012 Sylvia H. Rogers"

<b>Sample Delivered To</b>	<b>Date Delivered</b>	<b>Orig C/R &amp; Records To</b>
		CIN-DO
	<b>Lab w/Split Sample</b>	<b>Lab</b>

<b>Document Number</b>	<b>Document Date</b>	<b>Document Type</b>	<b>Document Remarks</b>
1.	12/12/2012	Affidavit	Signed by Nicholas I. Herkimer, President. (1 page.)
2.	06/06/2012	Invoice	Invoice no. 2346 documenting Master Supply's sale

Date: 01/30/2015

Page: 1 of 3

**Food and Drug Administration Office of Regulatory Affairs**  
**Collection Report**  
**For Sample Number: 786776**

This is an accurate reproduction of the original electronic record as of 12/12/2012

3.	06/16/2012	Bill of Lading	of 1 - 250 lb. drum of acetylsalicylic acid batch no. 5564 to the Dealer. (1 page.) Bill of lading no. 124679 documenting interstate shipment of 1 - 250 lb. drum of acetylsalicylic acid from Master Supply, Henderson, KY to the Dealer via Roadway Inc. (2 pages.)
4.	06/16/2012	Other	"Raw Material Inventory Record" documenting the receipt of acetylsalicylic acid batch no. 5564. (1 page.)
5.	11/21/2012	Other	"ARO Pharmaceuticals Batch Record" for Wilaprin Arthritis Formula lot 25C83 documenting the manufacturing, packaging and labeling of the finished product and the related quality records. (20 pages.)

**Remarks**  
See continuation.

<b>Payment Amount</b>	<b>Payment Method</b>	<b>704(d) Sample</b>	<b>702(b) Portion</b>	<b>Collector's Name</b>
Sylvia H. Rogers		No	No	Sylvia H. Rogers
		<b>Date &amp; Time of Signature</b>		<b>Meaning</b>
				12/12/2012 12:40 PM ET Collector

**Food and Drug Administration Office of Regulatory Affairs  
Collection Report****For Sample Number: 786776**

This is an accurate reproduction of the original electronic record as of 12/12/2012

**Continuation:****Product Label**

Finished product: Label on bottle reads in part, "\*\*\*\*WILAPRIN ARTHRITIS FORMULA 100 Tablets\*\*\*Active ingredients: Acetylsalicylic acid 500 mg.\*\*\*Lot 25C83\*\*\*EXP 8/2013\*\*\*ARO Pharmaceuticals\*\*\*Powell, OH 43065\*\*\*." Paperboard carton reads in part, "WILAPRIN ARTHRITIS FORMULA 100 Tablets\*\*\*Active ingredients: Acetylsalicylic acid 500 mg.\*\*\*Lot 25C83\*\*\*EXP 8/2013\*\*\*ARO Pharmaceuticals\*\*\*Powell, OH 43065\*\*\*." Printing on cardboard box reads in part, "\*\*\*\*WILAPRIN ARTHRITIS FORMULA\*\*\*12/100 Tablet Bottles\*\*\*Lot 25C83\*\*\*EXP 8/2013\*\*\*ARO Pharmaceuticals\*\*\*Powell, OH 43065\*\*\*." (Labeling attached as part of the "Master Pharmaceuticals Batch Record" on pages 13 - 15.)

Active ingredient: Label on drum reads in part, "\*\*\*\*Acetylsalicylic Acid UPS\*\*\*Batch No. 5564\*\*\*Use by 8/14\*\*\*Net Weight 250 lbs.\*\*\*Master Supply Henderson, KY 42420\*\*\*." (Photograph attached on page 26.)

**Description of Sample**

No physical sample collected. Documentation accompanying sample includes copies of records documenting interstate commerce and cGMP deviations, one photograph and an affidavit.

**How Prepared**

Records and mini CD-R identified as in the "Collector's ID on Package/Document" field. Original copy of digital photographs made using a mini CD-R, which was officially sealed in a FDA 525 envelope as in the "Collector's ID on Seal" field.

**Remarks**

"Product Description" (continued): with a white screw-on cap with a clear plastic seal. Bottle has yellow wrap around paper label with black printing. Bottle packaged in a white paperboard carton with black printing. Packed 12 cartons per box in a brown corrugated cardboard box with black printing.

Refer to EIR of Dealer dated 12/10-12/2012. FDA 483 dated 12/12/12 observation nos. 1 through 5 are cGMP observations related to this product.



## 4-2 FACTS SAMPLE COLLECTION SCREEN

**FACTS Version 4.9.01 - [Maintain Sample Collection]**

Action Edit Options Related Info Navigate Tracing Window Help

Page 1 2

### Sample Collection

**Sample Number:** 2357   
 **Sample Class:** Normal Everyday Sam   
 **Sampling District:** MIN-DO   
 **Status:** In Progress   
 **Modif Count #:**

**Collector:** Rogers, Sylvia H   
 **Collection Date:** 10/08/2005   
 **Lot Size:** one X-ray unit

**Sample Origin:** Domestic   
 **Sample Basis:** Compliance   
 **Sample Type:** Documentary

**FIS Sample Number:** 05 901869   
 **Episode Number:**   
 **Related Sample:**   
 **Compliance Number:**

**Sample Description:** No physical sample obtained. Sample consists of photographs and records  
**Collection Reason:** FU to Assembler's report. Possible violation X-ray performance standard  
**Collection Remarks:** No shipping record issued. Unit was picked up at the manufacturer by the Dealer

### Associated Firms

**Resp Firm Type:** Manufacturer   
 **FEI Number:** B   
 **Firm Type:**   
 **Firm Name:**

<input type="checkbox"/> Dealer is Consumer	3000900973	Manufacturer	Acme X-ray Corp., 20 Spruce	<b>Add</b>
	3000900974	Dealer	Dr. Gunther Krankheit, 555 5t	<b>Delete</b>

### Product

**Product Code:** 80   
 **Brand Name:** Acme X-ray Corp.

**Product Name:** Device, General Medical   
 **Product Description:** General purpose diagnostic x-ray unit.

**Product Label:** Serial # "1234" stamped on metal plate.

[Documents Obtained](#)   
 [Manufacturing Codes](#)   
 [Sample Flags](#)

**FACTS Version 4.9.01 - [Maintain Sample Collection]**

Action Edit Options Related Info Navigate Tracing Window Help

Page 1 2

### Sample Collection

**Sample Number:** 2357   
 **Sample Class:** Normal Everyday Sam   
 **Sampling District:** MIN-DO   
 **Status:** In Progress   
 **Modif Count #:**

**Collection Method:** Sample consists of dealer affidavit, invoice, and 8 photographs of the x-ray unit.

**State:** MN   
 **County:** CARVER   
 **Country of Origin:** United States

**Estimated Value:** \$5,000.00   
 **Sample Cost:** \$0.00   
 **Payment Method:** No Charge   
 **Receipt Issued:** None

**Carrier Name:**   
 **Date Shipped:**   
 **Consumer Complaint Number:**   
 **Recall Number:**

**How Prepared:** Photographs developed by Speed Foto 214th Street, Brooklyn Park, MN. Photographs & records identified as below. Negatives official

**Collector's ID On Package/Document:** "DOC 2357 10/8/05 SHR"   
 **Collector's ID On Seal:** "DOC 2357 10/8/05 Sylvia H. Rogers"

**Sample Delivered To:** United States Mail, Minneap   
 **Sample Delivered Date:** 10/08/2005

**CR & Records Sent To:** NYK-DO   
 **Storage Requirement:** Ambient

**CR & Records Sent To Non FACTS Org:**   
 **Food Canning Establishment:**   
 704 (d) Sample

**Dairy Permit Number:**   
 **CRx/DEA Schedule:**   
 702 (b) Portion Collected

**National Drug Code:**

### Collection PACs

PAC Code	Description	
82Z800	SHORT TERM ASSIGNMENTS/CDRH INITIATED	<b>Add</b>
		<b>Delete</b>

### FACTS Org? Physical Sample Sent To

<input type="checkbox"/>		<b>Add</b>
<input type="checkbox"/>		<b>Delete</b>
<input type="checkbox"/>		

**4-3 AFFIDAVIT (IN-TRANSIT) – FDA 1664b**

<b>AFFIDAVIT</b> <i>(In-transit Sampling)</i>		SAMPLE NO.  <b>55522</b>
STATE OF <b>UTAH</b>	COUNTY OF <b>UINTAH</b>	
Before me, <u>Sylvia H. Rogers</u> , an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations and affidavits, personally appeared <u>Wayne J. Ellmore</u> .  _____, in the county and State aforesaid, who, being duly sworn, deposes and says: I am employed by <u>Trans-National Truck Lines, Tulsa, OK</u> <i>(Carrier or firm name, city &amp; state)</i>  _____ as _____ <b>Driver</b> _____ <i>(Title of position)</i>  On <u>October 14, 2001</u> , at <u>Vernal, Utah</u> <i>(Date) (City &amp; state where sampled)</i>  The above named FDA employee collected a sample consisting of <u>two crates (48 heads per crate) of Polar brand Iceberg lettuce packed by Delbert Brothers Lettuce Suppliers, Fresno, CA</u> <i>(Description and number of units sampled)</i>  _____ from <u>Tractor Trailer #321, Oklahoma Lic. #3672TR, 2001</u> <i>(Enter type and number &amp; License number of truck, bus, RR car, airplane, etc. or Firm name and shipping dock)</i>  _____, from shipment(s) of goods consigned to or being shipped to <i>address if from dock)</i>  <u>Mid Central Distributors, 33 Front St., Minneapolis, Minnesota</u> <i>(Consignee name and address)</i>  _____  The aforesaid sampled shipment(s) was (were) identified to the FDA collector by <u>Wayne J. Ellmore</u> <i>(Name of individual)</i>  _____, <b>Truck Driver</b> <i>(Title of person making identification)</i>  _____, making identification)  (Copy of) Shipping Record(s) <u>F/B</u> , number <u>A-32196</u> <i>(Type record – B/L, Waybill, etc.)</i>  dated <u>10/14/01</u> , issued by <u>Trans-National Truck Lines</u>  _____, which were identified by <u>Wayne J. Ellmore, Driver</u> <i>(Name &amp; title of individual)</i>  _____, and furnished to the FDA collector cover this (these) shipment(s). <i>(Identifying records)</i>		
AFFIANT'S SIGNATURE  <i>Wayne J. Ellmore</i>		
Subscribed and sworn to before me at <u>Vernal, Utah</u> <i>(City and State)</i>		
this <u>14th</u> day of <u>October</u> , <u>2001</u> .		
<u>Sylvia H. Rogers</u> <i>(Employee's Signature)</i>		

4-4 CARRIER'S RECEIPT FOR SAMPLE - FDA 472

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NO. 300 S. Riverside Plaza, Suite 550 South Chicago, IL 60606	
TO	NAME AND TITLE OF INDIVIDUAL John B. Carr, Driver		DATE 11-6-04
	NAME AND ADDRESS OF CARRIER Transcontinental Trucking, 10 Front St. Dallas, TX 75204		SAMPLE NUMBER 27269
CONSIGNEE AND ADDRESS <i>(Street, City, State and ZIP Code)</i> XYZ Wholesale 111 S. Water Market Chicago, IL 60601		CONSIGNOR AND ADDRESS <i>(Street, City, State and ZIP Code)</i> Best Yet Packing Co. 3 First St. Young Town, TX 75002	
SAMPLE(S) REMOVED FOR EXAMINATION			WAYBILL OR FREIGHT BILL NUMBER
AMOUNT OF SAMPLE	PRODUCT		
2 cases (48 ct)	Lettuce – Best Yet Brand		A-23764
SAMPLE COLLECTOR'S NAME Sylvia H. Rogers	TITLE Investigator	SIGNATURE <i>Sylvia H. Rogers</i>	

FORM FDA 472 (10/01)

PREVIOUS EDITION MAY BE USED UNTIL

CARRIER'S RECEIPT FOR SAMPLE

SUPPLY IS EXHAUSTED.

**4-5 RECEIPT FOR SAMPLES - FDA 484**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER 850 Third Avenue Brooklyn, NY 11232 718-340-7000	
2. NAME AND TITLE OF INDIVIDUAL Richard A. Frost, General Manager		3. DATE 12-4-06	4. SAMPLE NUMBER 25563
5. FIRM NAME Quality Wholesale Drug Co.		6. FIRM'S DEA NUMBER AB3632918	
7. NUMBER AND STREET 3146 Front Street		8. CITY AND STATE (Include Zip Code) Brooklyn, NY 11232	
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)  The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form. (NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)  One Box of 25 - 1 cc ampoules, Dilaudid HCl (hydromorphone) 2 mg/cc, lot # 0103213 manufactured by Knoll Pharmaceutical Co., Orange NJ.			
10. SAMPLES WERE <input type="checkbox"/> PROVIDED AT NO CHARGE <input checked="" type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> CASH <input type="checkbox"/> BILLED <input type="checkbox"/> VOUCHER <input type="checkbox"/> CREDIT CARD \$15.00	
		12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.) <i>Richard A. Frost</i>	
13. COLLECTOR'S NAME (Print or Type) Sylvia H. Rogers		14. COLLECTOR'S TITLE (Print or Type) Investigator	
		15. COLLECTOR'S SIGNATURE <i>Sylvia H. Rogers</i>	

**FORM FDA 484 (3/06) BACK****Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:**

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

**Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 U.S.C 360 ii (b)] is quoted in part below:**

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-

(1) \*\*\*\*

(2) \*\*\*\*

(3) \*\*\*\*

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products"

**21 Code of Federal Regulations 1307.02 is quoted below:**

"1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA Form FDA 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

**Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:**

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

4-6 FIELD WEIGHT SHEET - FDA 485

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> FOOD AND DRUG ADMINISTRATION										1. DATE <p style="text-align: center;">9-16-05</p>		
3. PRODUCT  Spaghetti in plastic bags: "Genoa Semolina Vermicelli***Delmonico Foods, Inc. San Francisco, Calif.***Net Weight 12 ozs."										2. SAMPLE NUMBER <p style="text-align: center;">55532</p>		
										4. TYPE OF BALANCE <p style="text-align: center;">Gurley</p>		
5. RESPONSIBLE FIRM AND ADDRESS (Zip Code) Delmonico Foods, Inc. 4701 Canal Street San Francisco, California					6. ADDRESS WHERE WEIGHED Medicine Bow Wholesalers 23 Railroad Ave. Cheyenne, Wyoming							
7. WAREHOUSE		a. TYPE Wholesale Grocery Warehouse					b. TEMPERATURE 80° F		d. HUMIDITY est. 20%			
8. NO. OF		a. CASES IN LOT 325 48/12 oz.			b. CASES SAMPLED 12			c. SUBS WEIGHED FROM EACH CASE 4 from each of 12 cases				
9. GROSS WEIGHT (Submit a minimum of 12 subs with at least one from each case examined. Submit the subs indicated by the asterisks adding others where necessary to identify additional subs submitted. Determine six tares. Where tares may vary widely, determine up to 12 where practical.)												
CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT	
1	1	11.40	4	13	12.08	7	25	11.32	10	37	12.00	
1	2	11.72	4	14	11.68	7	26	12.00	10	38	12.04	
1	3*	11.60	4	15*	11.42	7	27*	11.34	10	39*	11.64	
1	4	11.30	4	16	12.40	7	28	11.34	10	40	11.72	
2	5	11.32	5	17	11.32	8	29	11.34	11	41	12.10	
2	6	11.40	5	18	11.34	8	30	11.40	11	42	11.70	
2	7*	12.00	5	19*	11.40	8	31*	11.40	11	43*	11.40	
2	8	11.38	5	20	11.42	8	32	11.36	11	44	11.50	
3	9	11.34	6	21	12.02	9	33	12.04	12	45	11.32	
3	10	11.40	6	22	11.70	9	34	12.00	12	46	11.30	
3	11*	11.42	6	23*	12.08	9	35*	11.38	12	47*	11.24	
3	12	12.02	6	24	12.10	9	36	11.36	12	48	11.36	
<b>TOTAL</b>		138.30				140.96				138.28		
										<b>GRAND TOTAL</b>	556.86	
10. PRELIMINARY TARE						11. WEIGHING RESULTS						
TARE NO.		WEIGHT		TARE NO.		WEIGHT		a. AVERAGE GROSS		11.60		
1		0.22		4		0.23		b. PRELIMINARY AVERAGE TARE		.22		
2		0.22		5		0.21		c. AVERAGE NET		11.38		
3		0.21		6		0.22		d. DECLARED NET		12.00		
<b>TOTAL</b>		0.65		<b>TOTAL</b>		0.66		e. SHORTAGE		.62		
<b>GRAND TOTAL</b>						1.31		12. PRELIMINARY % SHORT		5.2%		
*NUMBER OF TARES WEIGHED						6		13. REMARKS (List observations of lot or storage conditions affecting net weights) Lot has been in storage since 9-1-05.				
PRELIMINARY AVERAGE TARE						0.22						
14. DISTRICT DEN-DO			15. EMPLOYEE SIGNATURE <i>Sidney H. Rogers</i>				16. EMPLOYEE TITLE Investigator					

4-7 AFFIDAVIT - "301(k) Sample" - FDA 463a

<b>AFFIDAVIT</b>		SAMPLE NO. <b>55533</b>
STATE OF <b>Kansas</b>	COUNTY OF <b>Sedgwick</b>	
<p>Before me, <u>Sidney H. Rogers</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>Joseph H. Roe</u> in the county and State aforesaid, who, being duly sworn, deposes and says:</p> <p>I am the Vice President in charge of production of the Doe Bottling Co., Inc., 123 Main, Thistown, Kansas 67201; and as such I have knowledge of the raw material receiving and use, and carbonated beverage production at this firm.</p> <p>The sample consisting of two cases, 48- 10 ounce bottles, of Kola Cola, coded ABCD, collected by Investigator Rogers on November 15, 1999 was from a lot of 2668 cases produced by this firm on October 7, 1999. The copies of our production records for October 7, 1999 consist of a Syrup Room Report dated 10-6-99, a two-page Production Report dated 10-7-99, an undated in-line Control record, and a Finished Drink Control Record dated 10-7-99. Copies of these records were provided to the investigator and cover our production of this lot.</p> <p>The above described lot was made in part from a portion of a lot of bulk liquid sugar received October 3, 1999 from the Sweet Sugar Co., Boise, Idaho, in railroad tank car ATSF 98765, unloaded October 6, 1999. The copies of the Sweet Sugar Co. invoice number 468 dated Sept. 26, 1999; freight waybill number UP-3579 dated Sept. 27, 1999 issued by the Union Pacific Railroad Co.; and our receiving report number 01-23 dated October 3, 1999 were provided to the investigator and cover this shipment.</p> <p>The above described lot was also made in part from a portion of a lot of Kola Cola syrup base received September 23, 1999 from the Kola Cola Co., Thattown, Texas. The copies of Kola Cola Co. invoice number KCO1928 dated Sept. 20, 1999; freight bill number X-98125 dated Sept. 21, 1999 issued by Speedy Truck Line Co.; and our receiving report number 01-01 dated Sept. 23, 1999 were provide to the investigator and cover this shipment.</p> <p>The above described lot of Kola Cola was identified to the investigator by William S. Doe, Production Supervisor. I identified and provided copies of the records to the investigator.</p>		
AFFIANT'S SIGNATURE AND TITLE <i>Joseph H. Roe</i> , Production Vice President		
FIRM'S NAME AND ADDRESS (Include ZIP Code) Doe Bottling Co., Inc. 123 Main, Thistown, Kansas, 67201		
Subscribed and sworn to before me at <u>Thistown, Kansas</u> this <u>15<sup>th</sup></u> day of <u>November, 1999</u> .		
<p><u>Sidney H. Rogers</u> (Employee Signature)</p>		
<small>Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.</small>		

**4-8 COPY OF INVOICE/SHIPPING RECORD - FD 1662**

1. LOCATION Pine Bluff, Arkansas		2. NAME OF SAMPLE COLLECTOR Sylvia H. Rogers		3. DATE COLLECTED 10-8-05		4. SAMPLE NUMBER 55566	
<b>SECTION I - COPY OF INVOICE</b>							
5. CONSIGNOR (Name, Street, City, and State) Captain Sam Seafood, Inc. 719 Butler Ave. New Orleans, LA				6. CONSIGNEE (Name, Street, City, and State) Razor Back Super Market 1207 Little Rock Dr. Pine Bluff, AR			
7. GUARANTEE -----see reverse-----				8. INVOICE NUMBER 477		9. INVOICE DATE 9-20-05	
10 QUANTITY	11 UNIT SIZE	12 DESCRIPTION OF ARTICLE(S)		13 UNIT PRICE		14 TOTAL	
10 cs.	24/4.5 oz.	Horseshoe Brand Canned Medium Shrimp		2	84	56	80
5 cs.	10/5 lb.	Frozen Green Hills 21-25 Shrimp		1	10	275	00
		*****					
5cs.	24/8 oz.	Horseshoe Brand Canned Cove Oysters		5	25	52	50
		*****					
2 cs.	6/4 lb.	Frozen C&P Small Shrimp		1	50	72	00
<b>15. TOTAL</b>						<b>642</b>	<b>80</b>
<b>SECTION II - COPY OF SHIPPING RECORD</b>							
16. SHIPPER (Name, Street, City, and State) Captain Sam Seafood, Inc. NOLA				17. CONSIGNEE (Name, Street, City, and State) Razor Back Super Market 1207 Little Rock Dr. Pine bluff, AR			
18. CARRIER (Name, City, and State) Sea Breeze Trucking, Inc. NOLA							
19. CAR OR EQUIPMENT NUMBER Van 109		20. WAYBILL DATE & NUMBER N/A		21. TYPE OF RECORD (Specify) F/B		22. RECORD NO. 06641	23. RECORD DATE 9-20-05
24. SHIPPED FROM (City and State) NOLA		25. ROUTE N/A			26. DATE SHIPPED 9-20-05		
27 DESCRIPTION OF ARTICLE(S)				28 NO. PKGS.	29 WEIGHT	30 RATE	31 CHANGES
Canned Food				20	300	172	5.16
Frozen Seafood				8	350	224	7.84
32. RECEIVED BY P. Montoux s/s		33. DATE REC'D 9-26-05		34. <b>TOTAL</b>		28	650
							13.00



**4-9 AFFIDAVIT (PARCEL POST) - FDA 463**

<b>AFFIDAVIT</b> <i>(Parcel Post/Parcel Service)</i>		SAMPLE NO. <p style="text-align: center;">2358</p>
STATE OF <p style="text-align: center;">Colorado</p>	COUNTY OF <p style="text-align: center;">Pueblo</p>	
<p>Before me, <u>Sidney H. Rogers</u> an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20U.S.C.3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>Joseph D. Bullard</u> in the county and state aforesaid, who, being duly sworn, deposes and says: (I) (My firm) received on or about the day of <u>July 10th, 2005</u>, in response to an order previously given by me, two (packages, containers, etc.) consisting in whole or in part of a product designated "<u>4 ounces NET***Johnson's Eye Ease***Reservation Special</u>" via: (parcel post, United States mail) (United Parcel Service) from <u>Old Indian Herb Co. 294 N. Blackfoot St., Boise, Idaho 30854</u> and covered by attached copy of invoice number <u>C-20</u> dated <u>7-2-05</u>; after unpacking the goods the (parcel post) (parcel service) wrapper was destroyed; and on the 12th day of July, 2005, Inspector/Investigator Rogers obtained from me a sample consisting of <u>10-4 oz. bottles of Johnson's Eye Ease coded "J-638" on the bottle label</u>, shipped and described as aforesaid and for which he paid me the sum of <u>\$25.00</u> in (cash) (voucher) (billed).</p> <p>Remarks: I first learned of this product while reading the January 2005 issue of "The Retired Engineer." I use it to relieve the burning and itching in my eyes after working in the heat and dryness.</p>		
AFFIANT'S SIGNATURE AND TITLE  <i>Joseph D. Bullard</i>		
FIRM'S NAME AND ADDRESS <i>(Include ZIP Code)</i> -----		
Subscribed and sworn to before me at <u>Crow, Colorado</u> this <u>13th</u> day of <u>July, 2005</u> . <p style="text-align: center;"><small>(City &amp; State)</small></p>		
<u>Sidney H. Rogers</u> <small>(Employee's Signature)</small>		
<small>Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.</small>		

**4-10 AFFIDAVIT - FDA 463a**

AFFIDAVIT		SAMPLE NO. <b>55555</b>
STATE OF <b>Oregon</b>	COUNTY OF <b>Klamath</b>	
<p>Before me, <u>Sidney H. Rogers</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>George W. Hughes</u> in the county and State aforesaid, who, being duly sworn, deposes and says:</p> <p>I live at 482 Abrecia Ave., Klamath Falls, Oregon. On October 18, 1999, my neighbor, Dr. Samuel Thompson, asked me to pick up some medical instruments from a firm in Santa Rosa, California for him. Later that same day I drove to Santa Rosa in my 1997 Dodge Ram pick-up truck which has Oregon license plates, number FAS 682. My Oregon driver's license number is OR0123-45-6789.</p> <p>The next morning, October 19, 1999, I drove to Charles Brown &amp; Associates at 920 Grape St., Santa Rosa, California and picked up 4 containers bearing the label: "Fancy Medical Device, quantity 1." Each container contained a medical device.</p> <p>I drove back to Klamath Falls, Oregon after picking up a load of wine for my wine cellar, and arrived home on or about 11:00 PM.</p> <p>The next morning, October 20, 1999, I delivered the 4 containers to Dr. Samuel Thompson at his office, 2209 Timberline Ave., Klamath Falls, Oregon.</p> <p>I did not charge Dr. Thompson for the pick-up and delivery because I make regular trips to pick up wine in Santa Rosa for my wine cellar.</p>		
AFFIANT'S SIGNATURE AND TITLE		
<i>George W. Hughes</i> , Owner		
FIRM'S NAME AND ADDRESS (Include ZIP Code)		
Hughes Wine Cellar, 483 Abrecia Ave., Klamath Falls, 97210		
Subscribed and sworn to before me at <u>Klamath Falls, Oregon</u> this <u>4<sup>th</sup></u> day of <u>November, 1999</u> .		
<p><u>Sidney H. Rogers</u> (Employee Signature)</p>		
Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.		

4-11 AFFIDAVIT - FDA 463a

<b>AFFIDAVIT</b>		SAMPLE NO. <b>166455</b>
STATE OF <b>Florida</b>	COUNTY OF <b>Orange</b>	
<p>Before me, <u>Paul A. Revere</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>Nicholas I. Herkimer</u> in the county and State aforesaid, who, being duly sworn, deposes and says:</p> <p>I am the Warehouse Manager at ABC Distribution Company, 200 Harding Street, Orlando, FL 32806 and have held this position for 3 months. Previously, I held the position of Traffic Manager here for 10 years. As such, I am familiar with and can identify records associated with the receipt, storage and shipment of goods at my firm.</p> <p>On or about 3/1/01, my firm received a shipment of 500 cases, 24-½ fl. oz. bottles/case of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops from Sawyer Corporation, 51 Summer Street, Andover, MA 01810. This shipment was delivered to my firm by Yellow Freight Company, 1553 Fairlawn Street, St. Louis, MO 63126 and is covered by Sawyer Corporation invoice number 1500 dated 3/1/01 and bill of lading number 2000 dated 3/1/01.</p> <p>On 4/1/01, I identified and provided Investigator Revere copies of the documents described in this statement. On 4/1/01, Investigator Revere collected a sample consisting of 96 - ½ fl. oz. bottles of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops, lot number 020101, from the shipment described above. This sample was provided to the FDA at a cost of \$192.00, which will be billed.</p> <p style="text-align: center;"><i>I read this statement and agree it is true.</i></p>		
AFFIANT'S SIGNATURE AND TITLE <u>Nicholas I. Herkimer</u> , Warehouse Manager		
FIRM'S NAME AND ADDRESS (Include ZIP Code) ABC Distribution Company, 200 Harding Street, Orlando, FL 32806		
Subscribed and sworn to before me at <u>Orlando, FL</u> this <u>1<sup>st</sup></u> day of <u>April, 2001</u> .		
<p><u>Paul A. Revere</u> (Employee Signature)</p>		
<small>Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.</small>		

4-12 AFFIDAVIT - (Dealer/Warehouseman) - FDA 1664

AFFIDAVIT (Dealer/Warehouseman)		SAMPLE NO. 55563	
STATE OF <b>Arkansas</b>		COUNTY OF <b>Jefferson</b>	
Before me, <u>Sidney H. Rogers</u> , an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared <u>Henry O'Rourke</u> , in the county and State aforesaid, who, being duly sworn, deposes and says: The sample consisting of <u>Two Cases (24/8 oz. Each) Horseshoe Brand Canned Cove Oysters</u> collected by the above FDA employee on <u>3-10-99</u> was from shipment(s) received by us from <u>Captain Sam Seafood, Inc. New Orleans, LA</u> on <u>3-7-99</u> and so identified to the collector:			
That the copy of invoice(s):			
NUMBER	DATE	NUMBER	DATE
1) 06641	3/6/99	2) 06643	3/7/99
and (copy of) shipping record(s):			
TYPE: (B/L, F/B)	NUMBER	DATE	ISSUING FIRM OR CARRIER
1) F/B	4778	3/6/99	Acme Freight Lines, Inc. NOLA
2) F/B	A-9321	3/7/99	Thru-Fast Lines, Little Rock, AR
3)			
which were identified and furnished the collector, cover this (these) shipment(s):			
That said shipment(s) was (were) entered for the account of <u>N/A</u> under Lot no. _____.			
The collector paid me the sum of \$ <u>21.32</u> (in cash) ( <del>by voucher</del> ) ( <del>to be billed</del> ) for the sample.			
REMARKS			
AFFIANT'S SIGNATURE & TITLE <i>Henry O. O'Rourke</i> , Warehouse Manager Plant #12			
FIRM (Name and address, include ZIP Code) Southeastern Seafood Distributors, Inc. #4 Canal Street Dock Red River Basin Area, Little Rock, AR 72901			
Subscribed and sworn to before me at <u>Little Rock, AR</u>			
(City and State)			
this <u>10<sup>th</sup></u> day of <u>March</u> , 1999			
<u>Sidney H. Rogers</u> (Employee's Signature)			
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.			

FORM FDA 1664(4/83)

PREVIOUS EDITIONS ARE OBSOLETE

4-13 AFFIDAVIT - FDA 463a

<b>AFFIDAVIT</b>		SAMPLE NO. <b>55545</b>
STATE OF <b>Tennessee</b>	COUNTY OF <b>Shelby</b>	
<p>Before me, <u>Sidney H. Rogers</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>George R. Applegate</u> in the county and State aforesaid, who, being duly sworn, deposes and says:</p> <p>I am manager of John's Curb Market, 342 East Johnson St., Memphis, Tennessee. As such, I have knowledge of purchasing and receipt of products at the market.</p> <p>On September 2, 1999, FDA Investigator Sidney H. Rogers collected from my firm a sample consisting of six - 4 pound cans of Red River Brand Pure Sorghum. This sorghum was collected from a lot of six cases, each containing 4 - 4 pound buckets (cans) purchased by me from Ted Buymore who regularly sells sorghum in this area. Ted delivered this lot of six cases to my market on August 28, 1999 in a red panel GM truck with Alabama license plates. I do not know the license number.</p>		
AFFIANT'S SIGNATURE AND TITLE <i>George R. Applegate, Manager</i>		
FIRM'S NAME AND ADDRESS (Include ZIP Code) John's Curb Market, 342 East Johnson St., Memphis, TN 38110		
Subscribed and sworn to before me at <u>Memphis, Tennessee</u> this <u>2<sup>nd</sup></u> day of <u>September 1999</u> .		
<p><u>Sidney H. Rogers</u> (Employee Signature)</p>		
Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.		

4-14 AFFIDAVIT - (Jobber) - FDA 1664a

AFFIDAVIT ( <i>Jobber</i> )		SAMPLE NO. <b>55563</b>																												
STATE OF <b>Arkansas</b>	COUNTY OF <b>Jefferson</b>																													
<p>Before me, <u>Sylvia H. Rogers</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared <u>Patrick T. Palmer</u>, in the county and State aforesaid, who, being duly sworn, deposes and says: The lot of <u>The lot of 325 cases, (24/ 4 1/2 oz. cans) of Jolly Miller Canned Mushrooms</u>.</p> <p>_____.</p> <p>which we invoiced and sold to <u>Patriot Markets, Inc. Frankford, Pennsylvania</u>, _____.</p> <p>_____ on <u>4-12-99</u>.</p> <p>was a portion/all of a parcel shipped to us by <u>Northern Light Foods, Inc. Duluth, Minnesota</u>.</p> <p>_____.</p> <p>and is covered by submitted (copy of) invoice(s):</p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">NUMBER</th> <th style="width: 15%;">DATE</th> <th style="width: 15%;">NUMBER</th> <th style="width: 15%;">DATE</th> <th style="width: 15%;">NUMBER</th> <th style="width: 15%;">DATE</th> </tr> </thead> <tbody> <tr> <td>1) 3914</td> <td>4/4/99</td> <td>2)</td> <td></td> <td>3)</td> <td></td> </tr> </tbody> </table> <p>and (copy of) shipping record(s):</p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">TYPE: (B/L, F/B)</th> <th style="width: 15%;">NUMBER</th> <th style="width: 15%;">DATE</th> <th style="width: 55%;">ISSUING FIRM OR CARRIER</th> </tr> </thead> <tbody> <tr> <td>1) B/L</td> <td>20018</td> <td>4/5/99</td> <td>Northern Freight Carriers</td> </tr> <tr> <td>2)</td> <td></td> <td></td> <td></td> </tr> <tr> <td>3)</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>REMARKS</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>AFFIANT'S SIGNATURE &amp; TITLE <u>Patrick T. Palmer, Warehouse Manager Plant #12</u></p> <p>FIRM (Name and address, include ZIP Code) <b>Liberty Wholesale Grocers</b> <b>3210 11th Ave. Frankford, PA 19105</b></p> <p>Subscribed and sworn to before me at <u>Frankford, PA</u> _____. <span style="float: right;"><small>(City and State)</small></span></p> <p>this <u>28<sup>th</sup></u> day of <u>April</u>, <u>1999</u></p> <p><u>Sylvia H. Rogers</u> <small>(Employee's Signature)</small></p> <p>Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.</p>			NUMBER	DATE	NUMBER	DATE	NUMBER	DATE	1) 3914	4/4/99	2)		3)		TYPE: (B/L, F/B)	NUMBER	DATE	ISSUING FIRM OR CARRIER	1) B/L	20018	4/5/99	Northern Freight Carriers	2)				3)			
NUMBER	DATE	NUMBER	DATE	NUMBER	DATE																									
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1) B/L	20018	4/5/99	Northern Freight Carriers																											
2)																														
3)																														

### 4-15 FACTS SAMPLE COLLECTION SCREEN

**FACTS Version 4.9.01 - [Maintain Sample Collection]**

Action Edit Options Related Info Navigate Tracing Window Help

Page 1 2

---

**Sample Collection**

**Sample Number:** 123658   
 **Sample Class:** Normal Everyday Sam   
 **Sampling District:** NOL-DO   
 **Status:** Completed   
 **Modif Count #:**

**Collector:** Rogers, Sylvia H   
 **Collection Date:** 10/04/2005   
 **Lot Size:** Approx. 1,454 metric tons

**Sample Origin:** Domestic   
 **Sample Basis:** Surveillance   
 **Sample Type:** Official

**FIS Sample Number:** 05 985672   
 **Episode Number:**   
 **Related Sample:**   
 **Compliance Number:**

**Sample Description:** Approx. 20 lbs. of pelleted dried distillers grain  
**Collection Reason:** To analyze for fish meal per CP71009  
**Collection Remarks:**

**Associated Firms**

Resp Firm Type	FEI Number	Firm Type	Firm Name
Dealer		Dealer	Joe Sixpak, 3501 N. Cause S
<input type="checkbox"/> Dealer is Consumer			

Buttons: Add, Delete

---

**Product**

**Product Code:** 71 F Y 99 B   
 **Brand Name:**

**Product Name:** Brewery/Distillery Byprod N.E.C.; Not Elsewhere Cl   
 **Product Description:** bulk pelleted dried distillers grain in barge MEM

**Product Label:** none

Buttons: Documents Obtained, Manufacturing Codes, Sample Flags

**Sample Flag**

Find %

- Sample Flag Description
- 301(k) Sample
- Complaint Sample
- Dealer Voluntarily Holding
- Exhibit Sample
- Factory Food Sample
- Fumigated
- Inv. Samples of Fifth Exhibits
- Pesticide Sample
- Reconditioned
- Split Sample
- Survey Sample
- Under State Embargo

Buttons: Find, OK, Cancel

4-16 FACTS SAMPLE COLLECTION SCREEN

FACTS Version 4.9.01 - [Maintain Sample Collection]

Action Edit Options Related Info Navigate Tracing Window Help

Page 1 2

**Sample Collection**

Sample Number: 2358 Sample Class: Normal Everyday Sam Sampling District: MIN-DO Status: In Progress Modif Count #:

Collector: Rogers, Sylvia H Collection Date: 10/04/2005 Lot Size: 20 cs/10 ctns/24/9 oz. bars

Sample Origin: Domestic Sample Basis: Compliance Sample Type: Official

FIS Sample Number: 05 901863 Episode Number: Related Sample: Compliance Number:

Sample Description: Sample consists of 1 carton of 24/9 oz. chocolate candy bars.

Collection Reason: FU to EI of 10-8-2004 Re: Check for insect filth & bact. contamination. (CP Food Safety) Pesticide Examination

Collection Remarks: Dealer voluntarily holding until 10-28-2005

**Associated Firms**

Resp Firm Type	FEI Number	Firm Type	Firm Name
Manufacturer	B		
<input type="checkbox"/> Dealer is Consumer			

Add Delete

**Product**

Product Code: 34 F F T 01 B Brand Name: Burton Milk Chocolate Bars

Product Name: Chocolate Candy Bar, without Nuts and Fruit, Paper Product Description: Chocolate candy bars

Product Label: Bars labeled in part with overwrap label \*\*\*\*9 oz. Net Wt. \*\* Sweet Milk Chocolate\*\*\*Ingredients - Milk Chocolate, stabilizers, Mar

Documents Obtained Manufacturing Codes Sample Flags

FACTS Version 4.9.01 - [Maintain Sample Collection]

Action Edit Options Related Info Navigate Tracing Window Help

Page 1 2

**Sample Collection**

Sample Number: 2358 Sample Class: Normal Everyday Sam Sampling District: MIN-DO Status: In Progress Modif Count #:

Collection Method: collected two bars from each of 12 previously unopened ctns selected at a rate of 1 ctn from each of 12 previously unopened cases

State: County: Country of Origin:

Estimated Value: \$480.00 Sample Cost: \$5.30 Payment Method: Cash Receipt Issued: None

Carrier Name: Date Shipped: Consumer Complaint Number: Recall Number:

How Prepared: Each bar wrapper identified as below with sub numbers "1a,1b" to "12a,12b". The 24 bar carton sealed as below.

Collector's ID On Package/Document: "2358 10/4/05 SHR" Collector's ID On Seal: "2357 10/4/05 Sylvia H. Rogers"

Sample Delivered To: United States Mail, Minneap Sample Delivered Date: 10/04/2005

CR & Records Sent To FACTS Org: SEA-DO

CR & Records Sent To Non FACTS Org: Storage Requirement: Ambient

Dairy Permit Number: Food Canning Establishment:  704 (d) Sample

National Drug Code: CRx/DEA Schedule:   702 (b) Portion Collected

**Collection PACs**

PAC Code	Description
03803D	FOOD SAFETY / MICROBIOLOGICAL SAMPLE:
04004A	PEST & INDUS CHEM IN DOM & IMP FOODS - P

Add Delete

**FACTS Org?**

Physical Sample Sent To
<input checked="" type="checkbox"/> PRL-NW
<input type="checkbox"/>
<input type="checkbox"/>

Add Delete



**Accomplishment Hours**

---

**Operation**

Operation Code: 31 - Sample Collection      Work Subject / Title: Ad Hoc Collection

Sample Number: 2358      Performing Organization: MIN-DO

Assignment Status: Completed      Status Date: 10/05/2005      Reimbursable:

---

**Assignees Accomplishment Hours**

Lead	Collector	Employee Name	Position Class	Hours Credited To	PAC	Hours
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Rogers, Sylvia H	INV	MIN-DO	03803D	2.0
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Rogers, Sylvia H	INV	MIN-DO	04004A	2.0
<input type="checkbox"/>	<input type="checkbox"/>	Richards, Harold I	INV	MIN-DO	03803D	2.0
<input type="checkbox"/>	<input type="checkbox"/>	Richards, Harold I	INV	MIN-DO	04004A	2.0
<input type="checkbox"/>	<input type="checkbox"/>					
<input type="checkbox"/>	<input type="checkbox"/>					

**Total Hours :** 8.0

**Sample Basis**

Find %

Sample Basis	Code
Compliance	P
Surveillance	O

**4-17 OFFICIAL SEAL - FDA 415a**

The form is a rectangular seal with a header on the left containing the text "U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES" and "FOOD AND DRUG ADMINISTRATION", along with the FDA logo and the acronym "HAFW4". The main body of the seal is divided into several sections: "SAMPLE NO. 2358" and "DATE 12/5/05" at the top; "SIGNATURE *Sylvia H. Rogers*" in the middle; and "PRINT NAME & TITLE (Investigator, Inspector, Analyst, etc.) Sylvia H. Rogers, Investigator" at the bottom. On the right side, there are two vertical columns: "SEAL BROKEN BY" and "DATE". A vertical label "FDA-415a (10-1-15)" is on the far right. Callouts 1 through 6 point to the sample number, date, signature, name, title, and HAFW4 field respectively.

- 1 Insert sample number. When applicable, use prefix, e.g. "INV", "FS", "DOC", "PS", etc. (See IOM 4.4.10.2)
- 2 Insert date sealed. Use figures, month, day, year. (See # 7 below when seal is broken for any purpose.)
- 3 Sign your signature.
- 4 Print your name same as signature. (A rubber name stamp may be used if desired but use it carefully and do not smear.)
- 5 Print your title.
- 6 Print your divisional affiliation acronym (ie. HAFW4, DPQOII).

This is a partial view of the official seal form, showing the header with "U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES" and "FOOD AND DRUG ADMINISTRATION", the FDA logo, and the acronym "HAFW4". The main body shows "SAMPLE NO. 2358", "SIGNATURE *Sj*", and "PRINT NAME Sylvia".

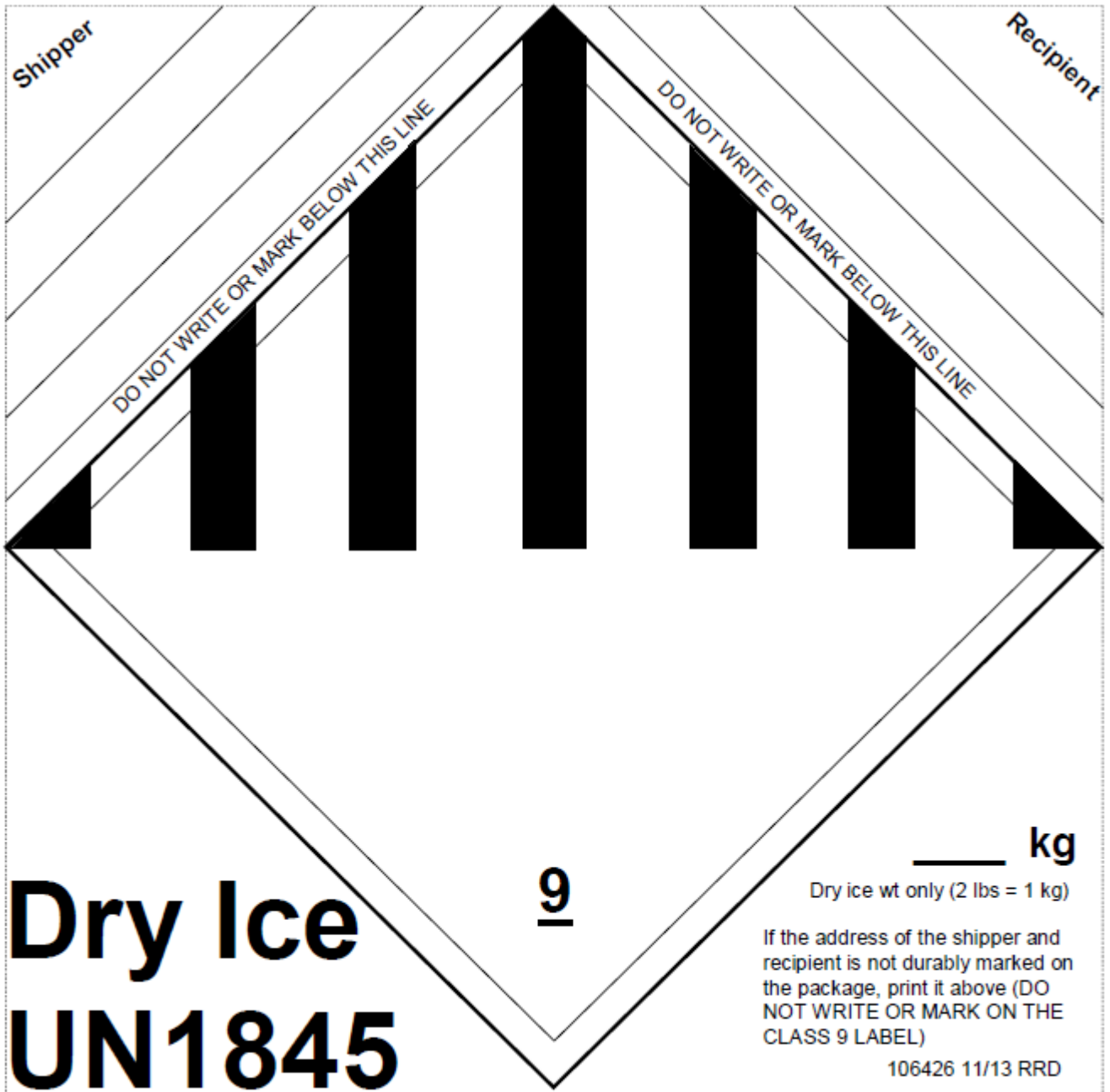
This is another partial view of the official seal form, showing the bottom and right sections. It includes "DATE 12/5/05", "SIGNATURE *Sylvia H. Rogers*", "& TITLE (Investigator, Inspector, Analyst, etc.) Sylvia H. Rogers, Investigator", "SEAL BROKEN BY *SHR*", and "DATE 12/6/05". A callout 7 points to the date field.

- 5. When seal is broken for any purpose, initial here and enter the date broken. Submit broken seal with sample records.

**4-18 DECLARATION FOR DANGEROUS GOODS**

Shipper <b>U. S. FOOD &amp; DRUG ADMINISTRATION</b> 6601 N.W. 25 <sup>th</sup> St. Room 236 Miami, FL 33122				Air Waybill No. Delta 7012-6140 <hr/> Page 1 of 1 Pages Collection Report Number <p style="text-align: right;">2555</p>					
Consignee Food and Drug Administration 60 Eighth Street Atlanta, GA 30309				<h2 style="margin: 0;">U.S. GOVERNMENT SHIPMENT</h2>					
Two completed and signed copies of this Declaration must be handed to the operator				<b>WARNING</b>  Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.					
<b>TRANSPORTATION DETAILS</b>									
This shipment is within the limitations prescribed for <i>(delete non-applicable)</i> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; text-align: center;"> <b>PASSENGER AND CARGO AIRCRAFT</b> </td> <td style="width:50%; text-align: center;"> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center;"><del>CARGO</del></td> </tr> <tr> <td style="text-align: center;"><del>AIRCRAFT ONLY</del></td> </tr> </table> </td> </tr> </table>		<b>PASSENGER AND CARGO AIRCRAFT</b>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center;"><del>CARGO</del></td> </tr> <tr> <td style="text-align: center;"><del>AIRCRAFT ONLY</del></td> </tr> </table>	<del>CARGO</del>	<del>AIRCRAFT ONLY</del>	Airport of Departure  Miami, FL			
<b>PASSENGER AND CARGO AIRCRAFT</b>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center;"><del>CARGO</del></td> </tr> <tr> <td style="text-align: center;"><del>AIRCRAFT ONLY</del></td> </tr> </table>	<del>CARGO</del>	<del>AIRCRAFT ONLY</del>						
<del>CARGO</del>									
<del>AIRCRAFT ONLY</del>									
Airport of Destination  Atlanta, GA			Shipment type <i>(Delete non-applicable)</i> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; text-align: center;"><b>NON-RADIOACTIVE</b></td> <td style="width:50%; text-align: center;"><del>RADIOACTIVE</del></td> </tr> </table>			<b>NON-RADIOACTIVE</b>	<del>RADIOACTIVE</del>		
<b>NON-RADIOACTIVE</b>	<del>RADIOACTIVE</del>								
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b>									
Dangerous Goods Identification									
PROPER SHIPPING NAME OF ARTICLE as listed in the Restricted Articles Tariff Federal Aviation Regulations or IATA Restricted Articles Regulations,	Class Or Division	UN Or ID No.	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization			
DRY ICE (CARBON DIOXIDE SOLID)	ORM A OR 9	UN 1845	N/A	5 Fiberboard containers net weight 20 lbs. dry ice each container	173.615 or 615				
Note: Include these notations on all Dry Ice shipments.									
Additional handling Information  <b>DO NOT OPEN THIS PACKAGE, IF PROBLEMS ARISE, CONTACT SHIPPER AT (305)555-3344</b>									
I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked and labeled, and are in all respects in the proper condition for transport by air according to the applicable International and National Government Regulations				Name/Title of Person Signing <b>Sidney H. Rogers</b> Investigator					
				Place and Date Miami, FL (9-8-99)					
				Signature <i>(See warning above)</i>  <i>Sidney H. Rogers</i>					

4-19 DRY ICE LABEL



## 4-20 Environmental Sampling for Detection of *Listeria monocytogenes*, CFSAN Guidance

### BACKGROUND

*Listeria monocytogenes* has been associated with such foods as raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. Its ability to grow at temperatures as low as 0°C permits multiplication in refrigerated foods.<sup>4</sup> Listeriosis is a foodborne illness of major public health concern because of the severity of the disease (meningitis, septicemia, and pregnancy complications such as miscarriage or stillbirth), a high case-fatality rate, and a long incubation period. *Listeria monocytogenes* differs from most other food-borne pathogens because it is widely distributed, resistant to diverse environmental conditions, including low pH and high NaCl concentrations, and is microaerobic. The multitude of ways it can easily enter food processing plants and its ability to grow and survive for long periods of time (in the environment, in/on foods, and in food processing plants) under adverse conditions have made it a major concern for many manufacturing industries in recent decades.<sup>2</sup>

### SAMPLE COLLECTION

DO Collect Samples From:	DON'T Collect Samples From:
Moist/wet areas with standing water	Dry, clean areas
<b>Direct food contact surfaces</b>	Employees – work shoes, hands etc
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Hand wash or eyewash stations
Sanitizing foot mats – if disinfectant is not maintained this can be a good harboring source and point of transfer to other areas of the facility	Packaging materials – jars, lids, etc
Cleaning Equipment – automated floor cleaning equipment, brooms, mops, waste containers especially underside, etc	Raw agricultural products – raw peanuts etc or any food contact surface used exclusively for raw foods.
Air conveying equipment – pressurized air lines, air hoses, condensate from pressurized air lines, HVAC evaporators and evaporator condensate pans	Outside the plant – roof, parking lot, walkways, etc.
Product conveyors – cables, belts, joints, where product residue accumulates, exposed bearings and rollers, sponge or felt rollers used to remove moisture from product	Zone 4
Motor and Electrical Housings – that are not cleaned and/ or sanitized.	
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks, etc.	
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies.	
Doorways - floor area leading directly into production areas	
Drains – Not during production	
Ice Makers – inside, scoops, underside of top of ice chamber	
Ceilings and Walls – in production areas coolers and freezers	
Door gaskets to coolers and freezers; damp insulation around pipes	

### References:

1. FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling
2. Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2<sup>nd</sup> Ed. Pgs 383-403.
3. Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2<sup>nd</sup> Ed. Pgs 55 – 67
4. Bad Bug Book. *Listeria monocytogenes* , Page 100
5. Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready to Eat Foods Draft Guidance.

**4-21 Environmental Sampling for Detection of Salmonellae, CFSAN Guidance**

BACKGROUND

Salmonellosis has been known to be a food-borne disease since the late 1800s. It still remains a major food safety concern throughout the world, is the major cause of bacterial foodborne illness in the U.S and is a pathogen of significant interest to FDA. The major reservoirs for Salmonellae are raw meats, poultry and eggs; the organism is also isolated from aquaculture products and fruits, vegetable and nut meats. Salmonellosis outbreaks have been associated with a variety of foods, including raw seafood, fresh produce, egg products, cake mixes, unpasteurized milk, peanut butter, chocolate and salad dressings. Salmonellae are known to survive and grow in the natural environment, including water sources. It is ubiquitous and has been recovered from some insects and nearly all vertebrates and invertebrates. This makes the recovery and identification of Salmonellae critical as an environmental contaminant.

SAMPLE COLLECTION

<b>DO Collect Samples From:</b>	<b>DON'T Collect Samples From:</b>
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Employees – work shoes, hands etc.
Sanitizing foot mats – if dry	Hand wash or eyewash stations
Cleaning Equipment – central vacuum systems, automated floor cleaning equipment (e.g., Tenent type walk-behind or riding sweepers, brooms, mops, etc.) Pay particular attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks.	Packaging materials – jars, lids, etc.
Air conveying equipment – air filters; air ducts and intake and exhaust vents; food residue on equipment and floors if old and dry	Direct food contact surfaces –cleaned often, would be unlikely to have residual organism growth.
Product conveyors – cables, belts, joints, where product residue accumulates, if the residue is old and dry	Raw ingredients– raw peanuts refined sugar, etc.
Unsealed control and drive chambers; electrical/mechanical service boxes that are not cleaned and/ or sanitized. Look for dry dust and residue in these boxes.	Outside the plant – roof, parking lot, etc
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	Areas with running water and very wet areas
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks etc.	Zone 4
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies if dry.	
Doorways - floor area in doorways leading into or out of the production facility or onto the roof	
Pallets – Floor under wooden or plastic pallets and pallets themselves	
Floor drains - use a sponge to scrub dry residue from floor drain grids and walls	

References:

- 1.FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling
2. Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2nd Ed. Pgs 141-178.
- Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2nd Ed. Pgs 55 – 67

# 1- SALMONELLA SAMPLING PLAN

## PURPOSE:

To determine the presence of *Salmonella* in processed foods and soils/water used for the growth of foods intended for human consumption.

## APPLICABILITY:

This sampling plan is applicable to the inspection of either a continuing series of production lots or to isolated lots consisting of an identifiable collection of process units (cans, bags, packages, or similar units). Additionally, the soil plan is for use during on-farm investigations requiring the sampling of soil for the presence of *Salmonella*. This plan is for use by FDA for regulatory purposes.

## FOOD CATEGORIES:

Foods are listed in three categories based on the number of *Salmonella* hazards and whether a food is to be consumed by infants, the aged, or infirm.

The three defined *Salmonella* Hazards of foods are:

1. The food or an ingredient of the food is a significant potential source of *Salmonella*;
2. The manufacturing process does not include a controlled step that destroys *Salmonella*; and
3. The food has significant potential for microbiological growth if "abused" in distribution or by consumers.

## Classification of Foods:

Foods have been classified into three food Categories for regulatory sampling purposes. The foods are listed in the Categories by Product Code sequence.

NOTE: For products not listed, check with your supervisor. The Division will request categorization from the Office of Field Programs/Center for Food Safety and Applied Nutrition (HFS-600), or, when time is of essence, the Division will make the categorization and obtain later concurrence from CFSAN.

### Category I

This includes all foods that would normally be in Category II except that they are intended for consumption by the aged, the infirm, and infants.

### Category II

This includes the foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM
03	Bread, rolls, buns, sugared breads, crackers, custard and cream filled sweet goods
05	Breakfast cereals, ready to eat
07	Pretzels, chips and specialty items
09	Butter and butter products; pasteurized milk and raw fluid milk and fluid milk products for consumption; pasteurized and unpasteurized concentrated liquid milk products for consumption; dried milk and dried milk products for consumption
12	Cheese and Cheese products
13	Ice cream from pasteurized milk and related products that have been pasteurized; raw ice cream mix and related unpasteurized products for consumption.
14	Pasteurized and unpasteurized imitation dairy products for consumption

15	Pasteurized eggs, egg products from pasteurized eggs; unpasteurized eggs and egg products from unpasteurized eggs for consumption without further cooking
16	Cured fish, vertebrates; other fish products; fresh and frozen raw oysters and raw clams, shellfish and crustacean products; smoked fish, shellfish and crustaceans for consumption
17	Unflavored gelatin
20-22	Fresh, frozen and canned fruits and juices, concentrates and nectars; dried fruit for consumption; jams, jellies, preserves and butters
23	Nuts and nut products for consumption
26	Oils consumed directly without further processing and oleomargarine
27	Dressings and condiments (including mayonnaise) salad dressing and vinegar
28	Spices including salt; flavors and extracts
29	Soft drinks and water
30	Beverage bases
31	Coffee and tea
33	Chewing gum and candy
34	Chocolate and cocoa products
35	Pudding mixes not cooked prior to consumption, gelatin products
36	Syrups, sugars and honey
38	Soups
39	Prepared salads

Category III

This includes the following foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

<b>PRODUCT CODE</b>	<b>FOOD ITEM</b>
02	Whole grain, processed grain and starch products for human use
04	Macaroni and noodle products
16	Fresh and frozen fish; vertebrates (except that eaten raw); fresh and frozen shellfish and crustaceans (except raw oysters and raw clams for consumption); other aquatic animals (including frog legs)
24	Fresh vegetables, frozen vegetables, dried vegetables, cured and processed vegetable products normally cooked before consumption
26	Vegetable oils, oil stock and vegetable shortening
35	Dry dessert and pudding mixes that are cooked prior to consumption
37	Frozen dinners, multiple food dinners
45-46	Food chemicals (direct additives)

SAMPLE COLLECTION

Each sub will consist of a minimum of 100 g (approx. 3.53 oz). The usual subsample is a consumer size container of a product. Subsamples should be obtained at random to ensure that the total sample is representative of the lot. When a lot consists of identifiable subsamples (e.g., different codes), sub samples should be obtained from subsamples in the proportion that the subsamples are to the whole lot.



More than one subsample may be collected from large institutional or bulk containers when the number of sub samples required exceeds the number of containers in the lot. A subsample will consist of more than one container when the lot consists of containers smaller than 100 g (e.g., 4 - 25 g containers is a subsample).

When a sample is collected by transferring it to sample containers, a sample control must be submitted which consists of an empty sample container that is exposed to the same conditions under which the sample is collected. See IOM 4.3.6.2 and 4.3.6.5 on controls. Use aseptic technique when sampling from bulk containers.

**SAMPLE SIZE**

The following sample sizes also apply to the finished product portion of in-line samples when analyzed for Salmonella. Each subsample will consist of at least 100 gm (approx 3.5 oz).

The 702(b) [21 U.S.C. 372(b)] portion is included in these subsamples, however all subs must be collected for proper analysis. Do not reduce the number of subsamples when collecting import samples.

<b><u>FOOD CATEGORY</u></b>	<b><u>NUMBER OF SAMPLE UNITS (SUBS)</u></b>
I	60
II	30
III	15

**SAMPLE SUBMISSION**

Submit all samples collected to your division's microbiological servicing laboratory unless directed otherwise by your supervisor or assignment. See IOM 4.5.5.2.

**FARM INVESTIGATIONS – SOIL AND WATER SAMPLES**

**Soil Samples**

When conducting an investigation at a farm that was implicated as the source of produce contaminated with Salmonella, and the crop is exposed to soil or water splash from the soil, such as leafy greens, cantaloupes, or cucumbers, soil samples may yield important information as to how the produce was contaminated, especially if a soil amendment such as animal manure or compost was used, or if the crops on that field were rotated and animals grazed on the land previously.

Unless specific instructions were provided by the office issuing the assignment, generally 5 sub samples are collected per field, one from the growing area on each corner, and one near the center. Additional samples may be collected based on observations, such as animal incursion, areas where water may drain, portions of the field susceptible to road dust or runoff, etc. Each field should be issued a separate sample number for ease of identification and review of data. A 1000 ml whirlpack should be filled with soil from a depth of 1 to 3 inches using a sterile scoop and double bagged. Take a photograph of each area where samples are collected and indicate the location and subsample number on a diagram of the field.

Soil samples should be submitted to the lab at 4°C (39°F) or below.

Water Samples

If specialized equipment such as a peristaltic pump are not available, collect water in a sterile, 1000 ml Nalgene sample bottle from wells and surface water. When collecting a surface water sample, a sterile pipette with a re-usable suction bulb is recommended. Using the end of the pipette, stir the surface of the sediment until the water becomes cloudy and then collect this water. *Salmonella* may form a biofilm or colonize sediments and be recovered well past the outbreak period.

Water samples should be submitted to the lab at 4 °C (39 °F) or below.

Environmental samples will be submitted as Investigational Samples (INV).

## 2- SAMPLING SCHEDULE FOR LOW-ACID CANNED AND ACIDIFIED FOODS

### Low Acid Canned Foods

#### Field Examination

1. At the beginning of the inspection, conduct visual exams of warehouse stock/product offered for import for evidence of abnormal cans including swollen and leaking cans, wet cases, swarms of fruit flies around isolated pallets, etc.
2. If the visual exam or inspectional evidence indicates possible problems, such as under processed lots, lots with questionable seam integrity, or abnormal cans, exam the affected lots. Preferably field examine lots that have been warehoused at least 14 days.
3. A lot to be examined will be one production code.
4. Follow the chart below for the field examination. If abnormal containers are found, always collect an official sample of the lot, if possible. For lots with abnormal cans collect an investigational sample ONLY when there is not enough product available to collect an official sample. In all cases, include on the collection report: the lot size, the number of containers examined, and the number of abnormal containers found by type (e.g., hard swells).
5. The chart provides instructions on the number of cans/cases to examine depending on the size of the lot. **When the maximum number of containers / cases have been examined for the specified lot size, collect a sample if one or more abnormal containers are found.** The exam can be discontinued early based on the number of abnormal containers found. For example, if examining a lot consisting of 3409 or more cans, if 11 abnormal cans are found after examining 1000 cans, discontinue the exam and collect a sample
  - a. Flippers. Only one end is slack or slightly bulged and the end remains flat if pressed in. Cans which bulge when sharply and squarely struck end-down on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.
  - b. Springers. One end of a can bulges. Manual pressure on the bulged end forces the opposite end out or the same end will spring out with release of pressure. If both ends bulge, but only one will remain flat when pressed, the can is a springer. Springers result from moderate positive pressure in the can. Buckling or extensive denting of the side wall may produce a springer.
  - c. Swells. Both ends of the can are bulged. Neither end will remain flat without pressure. Soft swells yield to manual pressure, but no impression can be made manually on hard swells. Swells result from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acid products, may result from chemical reaction between the contents and the container.

NOTE: Other abnormalities or defects, such as visibly leaking cans, severe dents around seams, gross seam defects, severely rusted containers should be reported on C/R, (with numbers of cans defective cans observed) but not counted as "abnormal containers" for the purposes of the sequential field examination. Do not collect leakers, but report the number observed. It may be necessary to collect samples of other defects (e.g. seam defects) to support observations and document the severity of the defects. In some cases, photographs may be a suitable substitute for collection of physical samples.

If a sample is collected, identify on the C/R, by sub-sample number, the condition of each container in the sample (e.g., sub-sample 1 - flipper; sub-sample 2 - hard swell; - sub-sample x - normal). Report the results of the warehouse stock examination in the EIR and in FACTS. See IOM 5.1.5.3

Special Sample Handling: If you are shipping swollen cans, double bag and ground ship the sample. If the cans are moderately swollen or worse you should ship the sample with ice packs.

When the 'Reason for Collection' on the Collection Report includes can seam analysis, the CSO shall collect the can seam specifications for the cans in the sample. This is specific to the can manufacturer and can size collected in the sample. The can seam specifications will be submitted in the FD-525 along with the Collection Report for the servicing laboratory.

Lot Size Contain	Number to Examine	PACKED 48/CASE		PACKED 24/CASE		PACKED 12/CASE		PACKED 6/CASE		*Number Abnormal Containers to Discontinue Examination Early
		Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	
192 or less	All	1 - 4	all	1 - 8	All	1 - 16	All	1 - 32	all	3
193 - 288	192	4 - 6	4	8 - 12	8	16 - 24	16	32 - 48	32	5
289 - 384	all for $\leq$ 298 298 if greater	6 - 8	6	12 - 16	12	24 - 32	25	48 - 64	all $\leq$ 50 50 if greater	6
385 - 576	363	8 - 12	8	16 - 24	15	32 - 48	30	64 - 96	61	7
577 - 912	433	12 - 19	9	24 - 38	18	48 - 76	36	96 - 152	72	8
913 - 1488	480	19 - 31	10	38 - 62	20	76 - 124	40	152 - 248	80	9
1489 - 3408	529	31 - 71	11	62 - 142	22	124 - 284	44	248 - 568	88	10
3409 or more	576	71 or more	12	142 or more	24	284 or more	48	568 or more	96	11

1. Sample Size for Samples Collected as a Result of a Field Exam:

a. Official Sample

The sample will consist of all abnormal containers and the number of normal cans specified under "2. Official Samples" below (e.g., if 8 abnormal containers are observed during the examination of a lot containing 696/ 2 lb. cans the sample will consist of the 8 abnormal cans and 48 normal cans, collected 2 cans from each of 24 cases). Open additional cases, if necessary to meet this requirement. This will provide enough product for complete analysis, including: can seam, incubation, aerobic and anaerobic growth, pH and water. Note that the sample size given for normal cans includes the 702(b) portion.

b. Investigational Sample and Import Sample.

Samples for laboratory examination will consist of all abnormal and 12 normal containers.

2. Other Sampling

Official Samples

a. Filth, Micro, etc. (Includes 702(b) [21U.S.C.372 (b)] portion)

**Collect each subsample to duplicate from a separate case, if possible. Mark subs 1a, 1b, 2a, 2b, etc. Collect as follows:**

NET WEIGHT	SIZE OF LOT	MIN TOTAL CANS	CANS/CASE
795 gr (28 oz) and smaller	Up to 50 cases	48	2 from 24
	More than 50 cases	96	2 from 48
Over 795 gr (28 oz)	Up to 600 cases	48	2 from 24
	More than 600 cases	72	2 from 36

b. Standards Assay (Includes 702(b) portion)

NOTE: Sample sizes listed below are based upon the requirements of the Standards (21 CFR 145.3). When sampling products which are likely to be non-uniform throughout the lot because of variations from standards of quality, identity, fill-of-container, grade, etc., collect each subsample in triplicate from a separate case. Mark subs 1a, 1b, 1c, 2a, 2b, 2c, etc. Collect as follows:

NET WEIGHT	NUMBER OF CANS OR PACKAGES	MIN TOTAL CANS	CANS/CASE
1 kg (2.2 lbs) or less	4800 or less	48	3 from 16
	4801 to 24,000	72	3 from 24
	24,001 to 48,000	96	3 from 32
	48,001 to 84,000	144	3 from 48
	84,001 to 144,000	264	3 from 88
	144,001 to 240,000	384	3 from 128
	Over 240,000	600	3 from 200
Greater than 1 kg (2.2lbs), but less than 4.5 kg (10 lbs.)	2400 or less	48	3 from 16
	2401 to 15000	72	3 from 24
	15001 to 24000	96	3 from 32
	24001 to 42000	144	3 from 48
	42001 to 72000	252	3 from 88
	72001 to 120,000	384	3 from 128
Greater than 4.5 kg (10 lbs)	Over 120,000	600	3 from 200
	600 or less	48	3 from 16
	601 to 2000	72	3 from 24
	2001 to 7200	96	3 from 32
	7201 to 15000	144	3 from 48
	15001 to 24000	252	3 from 88
	24001 to 42000	384	3 from 128
Over 42000	600	3 from 200	

### Acidified Foods

A lot is defined as one production code.

#### Field Examination

Conduct a reconciliation examination and check for damaged or destructive container closures. For example, during a visual examination the following may be observed: 1) glass containers with obvious closure defects such as excessive torque on the lid and/or insufficient security, 2) plastic and semi-rigid containers with obvious defects such as leakers and poorly sealed lids, or 3) metal containers with damage or obvious container defects to the double seam.

Conduct a field examination if abnormal containers are observed during the reconciliation examination. Follow the applicable instructions provided above (see Low-Acid Canned Food "Field Examination" section, including chart) when performing a field examination.

#### Sample Collection

For acidified products, the equilibrium pH determines whether the product will support organisms of public health significance. Spoilage in such products is usually due to inadequate heat treatment to kill spoilage organisms. Spoilage may be significant because high numbers of microorganisms may affect the adequacy of the thermal process. Molds and some bacteria can grow in an acid environment and actually utilize acid as one of their nutrients; and thus, raise the pH to a level above 4.6 where *Clostridium botulinum* or other toxin-producing microorganisms can grow.

Microbial spoilage can be detected by observing swollen lids on jars or swollen can ends. The liquid may be turbid and a whitish deposit may be visible on the product or in the bottom of the jar. See the Guide to Inspection of Acidified Food Manufacturers for additional information: [http://www.fda.gov/ora/inspect\\_ref/igs/iglist.html](http://www.fda.gov/ora/inspect_ref/igs/iglist.html) Collect samples for pH testing. Samples must be collected randomly from the entire lot. **Sample size does not include 702(b) portion.**

- # 10 cans – Use the following sample size for containers larger than 795 gr (28 oz): Randomly select 1 normal container from each of 12 randomly selected cases (if available) in the lot. Sample size is 12 containers.
- # 2 half (1/2) cans – Use the following sample size for containers equal to 795 gr (28 oz) or smaller: Randomly select 2 normal containers from each of 12 randomly selected cases (if available) in the lot. Sample size is 24 containers.

If abnormal containers are encountered, collect all abnormal containers (up to a maximum of 24) in addition to the normal containers collected for pH testing (referenced above). Indicate on the C/R the total number of containers examined and the number of each type of abnormality and defect observed. Also indicate the estimated percentage of abnormal containers in the lot.

### 3- PESTICIDE SAMPLES

(includes 702(b) portion)

#### DO NOT FUMIGATE PESTICIDE SAMPLES

#### INTRODUCTION

The objectives of FDA's pesticide monitoring program are to gather information on levels and incidences of pesticide residues in the nation's food supply and to initiate enforcement actions against shipments of foods and feeds found to contain illegal pesticide residues. To meet both objectives, it is necessary to collect samples of foods and feeds for pesticide residue analysis. This section describes procedures for the collection of raw agricultural and processed commodity samples. These procedures apply to both domestic and import arenas. Additionally, a separate set of procedures for collecting samples in conjunction with special investigations, such as samples collected to determine levels of pesticide residues in soil, water, and growing crops, is included.

For pesticide samples, the laboratory will maintain a portion of the composited sample as the 702(b) [21 U.S.C.372(b)] portion.

Pesticide sample sizes no longer differentiate between Surveillance and Compliance Samples. All pesticide samples will be collected as directed below. Remember to include the state and county or country of origin in the Flag. See IOM 4.4.10.1.8.

For appraisal purposes, you must Flag each Domestic as to the basis for sampling in accordance with the definitions below.

**Pesticide Compliance Sample.** Collected on a selective basis as a result of inspectional or other evidence of suspected misuse of a pesticide on a food or feed commodity or as a follow-up to a "Pesticide Surveillance Sample" that was found to contain actionable levels of pesticide residues. Flag "Pesticide Compliance".

**Pesticide Surveillance Sample.** Collected on an objective basis where there is no evidence or suspicion of pesticide misuse on a food or feed commodity. Flag "Pesticide Surveillance".

Divisions have the option to collect 1 intact shipping case of fresh produce from packing sheds or large produce warehouses. The one case must meet the minimum sample size specified below. This "one case" option may be used on any import sample or on domestic Pesticide Surveillance Samples, if the collector can be assured that the "one case" collected is representative of the lot or field. If the collector is not assured of this, collect the samples according to the instructions below. This "one case" sampling does not apply to large items such as melons.

**NOTE:** If "one case" option is used for surveillance samples of domestic produce, describe in the Remarks Section of the CR, the basis for determining that the sample is representative of the lot or field.

**Plant products: description of primary samples and minimum size of laboratory samples (total weight of all subs or units collected).**

Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
<b>1. PRIMARY FOOD COMMODITIES OF PLANT ORIGIN</b>			
<b>All fresh fruits, All fresh vegetables, Frozen bulk produce (not retail) except dry pulses</b>			
<b>Small sized products</b> units generally < 25 g	Berries, peas, olives	whole units, or packages, or units taken with sampling device	1 kg (2.2 lbs)
<b>Medium sized products</b> units generally 25 - 250 g	Apples, oranges, corn on the cob, potatoes	whole units, or units taken with sampling device	1 kg (2.2 lbs) (at least 10 units)
<b>Large sized products</b> units generally > 250 g	Cabbages, lettuce, cucumbers, grapes (bunches, except for sulfites), sweet potatoes	whole units, units taken with sampling device	2 kg(4.4 lbs) (at least 5 units)
<b>Pulses, Cereal grains</b>	soy beans, peas, lentils, rice, wheat (except from rail carloads)		1 kg (2.2 lbs) 1 kg (2.2 lbs)
<b>Tree nuts</b>	(except coconuts) coconuts		1 kg (2.2 lbs) 5 units
<b>Oilseeds</b>	peanuts		0.5 kg (1.1 lb)
<b>Seeds for beverages and sweets</b>	See CP 7304.004		0.5 kg (1.1 lb)
<b>Herbs</b> (for dried herbs see section 3 of this Table)	fresh parsley others, fresh	whole units or units taken with sampling device	0.5 kg (1.1 lb) 0.2 kg (0.5 lb)
<b>Spices</b>	dried	whole units or units taken with sampling device	0.1 kg (0.25 lb)
<b>2. PRIMARY ANIMAL FEED COMMODITIES</b>			
<b>Primary feed commodities of plant origin</b>			
<b>Legume animal feeds, and other forages and fodders</b>		whole units, or units taken with sampling device	1 kg (2.2 lbs) (from at least 10 units)
<b>Straw, hay and other dried products</b>		whole units, or units taken with sampling device	1 kg (2.2 lbs) (from at least 10 units)
<i>Note. See IOM Sample Schedule Chart 4, Wheat Carload Sampling for guidance in the collection of samples by trier from railcars and trucks.</i>			
<b>3. PROCESSED FOODS OF PLANT ORIGIN</b>			
<p><b>Secondary food commodities of plant origin</b>, dried fruits, vegetables, herbs, milled cereal products  <b>Derived products of plant origin</b>, teas, vegetable oils, juices, by-products for animal feed and miscellaneous products  <b>Manufactured foods (single ingredient) of plant origin</b>,  <b>Manufactured foods (multi-ingredient) of plant origin</b>, including products with ingredients of animal origin where the ingredient(s) of plant origin predominate(s), and breads</p>			
<b>Products of high unit value</b>		packages or units taken with a sampling device	0.1 kg* (0.25 lb)
<b>Solid products of low bulk density</b>	Hops, Tea	packaged units, or units taken with a sampling device	0.2 kg (0.5 lbs)
<b>Other solid products</b>	bread, flour, apple pomace, dried fruit	packages or other whole units, or units taken with a sampling device	0.5 kg (1.1 lbs)
<b>Liquid products</b>	vegetable oils, juices	packaged units, or units taken with a sampling device	0.5 L or 0.5 kg
<i>* A smaller laboratory sample may be taken from a product of exceptionally high value but the reason for doing so should be noted in the collection report.</i>			
<b>4. EGGS AND DAIRY PRODUCTS</b>			
<b>Poultry eggs</b>			
<b>Eggs, except quail and similar</b>		whole eggs	12 whole chicken eggs, 6 whole goose or duck eggs
<b>Eggs, quail and similar</b>		whole eggs	24 whole eggs
<b>Milks</b>		whole unit(s), or unit(s) taken with a sampling device	0.5 L
<b>5. PROCESSED FOODS OF ANIMAL ORIGIN</b>			
<p><b>Secondary food commodities of animal origin</b>, skimmed milks, evaporated milks and milk powders  <b>Derived edible products of animal origin</b>, milk fats, butters, butter oils, creams, cream powders, caseins, etc.</p>			



Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
<p><b>Manufactured food (single ingredient) of animal origin,</b>  <b>Manufactured food (multi-ingredient) of animal origin,</b> (including products with ingredients of plant origin where the ingredient(s) of animal origin predominates(s))</p>			
<p><b>Liquid milk, milk powders, evaporated milk and cream, cream, dairy ice cream, yogurt</b></p>		<p>packaged unit(s), or unit(s) taken with a sampling device</p>	<p>0.5 L (liquid) or 0.5 kg(solid)</p>
<p><i>Notes. (i) Evaporated milks and evaporated cream in bulk must be mixed thoroughly before sampling aseptically.                  (ii) Milk powder in bulk should be sampled aseptically, passing a dry borer tube through the powder at an even rate.                  (iii) Creams in bulk should be mixed thoroughly with a plunger before sampling but foaming, whipping and churning must be avoided.</i></p>			
<p><b>Butter and butter oils</b> (butter, whey butter, low fat spreads containing butter fat, anhydrous butter oil, anhydrous milk fat)</p>		<p>whole or parts of packaged unit(s), <b>or</b> unit(s) taken with a sampling device</p>	<p>0.2 kg or 0.2 L</p>
<p><b>Cheeses, including processed cheeses</b></p>	<p>units 0.3 kg or greater</p>	<p>whole unit(s) or units taken aseptically with a sampling device</p>	<p>0.5 kg</p>
	<p>units &lt; 0.3 kg</p>	<p>whole unit(s)</p>	<p>0.3 kg</p>
<p><i>Note. Cheeses with a circular base should be sampled by making two cuts radiating from the center. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides.</i></p>			
<p><b>Liquid, frozen or dried egg products</b></p>		<p>unit(s) taken aseptically with a sampling device</p>	<p>0.5 kg</p>

**9. GRAPES FOR SULFITES**

Collect approximately 900 - 1800 g (2 - 4 lbs) of grapes [10/100 - 200 g (1/4 to 1/2 lb) subs]. Each subsample will consist of individual grapes, not bunches, and will be collected from different lugs (cases) on as many different pallets in the lot as possible. No grapes that are damaged during the sampling procedure should be included in the sample. However, grapes with damage prior to sampling may be included in the sample.

If sulfiting pads are present, grapes sampled should be selected from areas closest to and directly under the pad.

**Monitoring activities should be focused upon lots of grapes with the highest potential for violative sulfite residues.**

Direct efforts to lots of grapes sulfited through fumigation or to lots with multiple fumigations especially towards the end of the harvesting season and also to lots with significant numbers of damaged grapes (split, crushed, or unusually wet, if such damage is apparent).

Sample lots of grapes sulfited through the use of sulfiting pads, with or without additional fumigation. If at all possible, sample lots subjected to the following conditions, which could cause high sulfite residues:

- Lots subjected to un-refrigerated storage of 2 or more hours during warm weather.
- Unusual shipping conditions (ships at sea during heavy storms).
- Lots with significant numbers of damaged grapes.
- Lots containing evidence of sulfite pad damage sufficient to cause spilling of sulfiting agent onto grapes.

**Special Sample Handling**

Place sample in tightly closed airtight glass mason jar(s) or sealed plastic bag(s). Although no effort should be made to commingle subsamples, more than one subsample may be placed in the same container for shipping convenience.

**Appropriate cooling procedures are:**

Place samples in shipping container or cooler with sufficient ice or other refrigerant to keep sample refrigerated until arrival at the laboratory. Sample should be placed immediately in a refrigerator at or below 7 degrees C. If sample is not to be analyzed within a few hours, the sample should be placed in a freezer, which is maintained at or below -20 degrees C.

Or, if the sample is frozen, place the sample in a container with sufficient dry ice to keep the sample frozen until arrival at the lab. The sample should then be placed in freezer upon arrival at the laboratory.

**1. FISH AND SHELLFISH PRODUCTS**

NOTE: THIS SAMPLE SIZE FURNISHES SUFFICIENT FISH FOR HEAVY METAL ANALYSIS.

Packaged Fish, fresh, frozen, smoked, cured, or shellfish (except oysters)

Collect 12 subs - minimum sub size is 453 g (1 lb)

Bulk Fish - .453 - 1.35 kg (1 - 3 lb)/fish

Collect 12 subs, each sub to consist of 453 g (1 lb) of edible fish

Bulk Shellfish (except oysters)

Collect 12 - 453 g (1 lb) subs

Canned Fish and Shellfish Products (except oysters)

Collect 12 subs - 5 cans per sub

Other Fish and Shellfish Products

Oysters - Collect 12 1 pint subs

Fish Flour and Meal

Follow the guidance in section 5 above.

**SWORDFISH FOR HEAVY METALS**

These sample sizes must be used whenever sampling swordfish, either for audit, surveillance, or compliance purposes.

Whole Fish (dressed, head removed)

Characterize lot in terms of fish sizes, i.e., small, medium, and large. The following dressed weight ranges are used for classification:

Small Fish - Weighs less than 36.4 kg (80 lbs)

Medium Fish - Weighs 36.4 - 54.5 kg (80 - 120 lbs)

Large Fish - Weighs more than 54.5 kg (120 lbs)

For lots consisting of 12 or more fish, the representative sample to be collected will be determined by the following formula:

$$ns = (n) (Ns)/N$$

ns = the number of fish in a given weight range from which subsamples must be taken

n = total number of subsamples to be collected from the lot. (In using this formula n will always equal 12)

Ns = the number of fish in a given weight range in the lot

N = the total number of fish in the lot

Example: If a lot consists of 25 fish and is characterized as: 5 small fish [less than 36.4 kg (80 lbs)], 15 medium fish [36.4 - 54.5 kg (80 - 120 lbs)], and 5 large fish [greater than 54.5 kg (129 lbs)], the sample should be collected as follows:

$$\text{small fish } \frac{(12)(5)}{25} = 2.4 = 2$$

$$\text{medium fish } \frac{(12)(15)}{25} = 7.2 = 7$$

large fish  $\frac{(12)(5)}{25} = 2.4 = 2$

TOTAL SAMPLE: 11 sub samples

Usually, the total sample will consist of 12 subsamples. However, due to rounding numbers of subsamples determined by the formula may be 11 or 13 in some instances. The total sample should consist of the specific number of sub samples determined by the formula in all cases.

Each sub sample should consist of approximately a 0.5 kg (1 lb) steak cut from just below the nape of the fish. Care should be taken to avoid mutilation of fish. The sub must consist of edible flesh. If a private laboratory is conducting the analysis, individual fish from which the sub sample is taken should be identified with a tag or other suitable method. This will permit FDA to take audit samples from the same fish sampled by the private laboratories.

For lots consisting of 12 or less fish, collect 1 sub from each fish.

Swordfish Loins (slabs or sides cut from dressed whole fish which has been boned or trimmed).

Use the same formula stipulated for whole fish, with the exception that the following weight ranges should be used to characterize the lot:

- Small fish loins = weighs 9.1 - 18.2 kg (20 - 40 lbs)
- Medium fish loins) = weighs 18.2 - 36.4 kg (40 - 80 lbs)
- Large fish loins = weighs over 36.4 kg (80 lbs)

Swordfish Steaks

Collect 12 sub samples, i.e., 12 steaks, at random from different containers in the lot (as many as possible)

Canned Swordfish

Collect 12/453 g (1 lb) sub samples at random

**11. RETAIL CONTAINERS CANNED, FROZEN AND DRIED FOODS**

Collect retail containers equal to the number of primary units specified above.

**12. SPECIAL INVESTIGATIONS**

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. DO NOT composite subs. In addition, diagram the field in the

For leafy vegetables, such as lettuce, cabbage, etc.: INV Samples collected in the growing field should be representative of local commercial harvesting practices. If the local practice is to strip outer leaves at the time of harvest, this practice should be followed when collecting field samples. In head lettuce, for example, the lettuce may be packed directly into shipping cartons in the field, in which case 6 or 8 outer leaves are left on the head to be removed at the retail outlet. In other instances, each head is stripped of 2 or 3 outer leaves and individually wrapped in plastic, placed in shipping cartons, and the consumer receives the produce in this condition. Describe sampling method on C/R and describe how packing shed handles produce prior to shipping (e.g., washing, waxing, stripping, etc.).

Soil Samples

Collect soil samples from fields according to the following 3x3 grid diagram:

	a	b	c
1	o	o	o
2	o	o	o
3	o	o	o

Sample at the 9 locations indicated by the "o". If the field being sampled is very large, you may have to sample it using a 4x4, 5x5, or even larger grid pattern.

Subs are to be placed in clean quart glass jars, which have been washed in water, rinsed in methanol, and air dried. If methanol is not available, use washed, air dried jars and submit an empty jar as a control. Note on CR that jars were or were not rinsed with methanol.

Obtain two "6 in" deep plugs (1-2 in. in diameter from each sampling location. Place two plugs from each location in cleaned glass jars, place clean aluminum foil over top of jar and seal with screw cap.

Soil samples should be submitted to the lab at 4° C (39° F) or below.

Water Samples - Collect 3 quarts of water from the same sampling source (e.g., faucet, stream, lake, etc.) and place in cleaned, washed and methanol rinsed jars as described under "Soil Samples".

Submit water samples to lab at 4° C (39 ° F) or below.

Remarks Section of the C/R and indicate sub number where each sub was collected.

### GENERAL

Official Samples shall be collected whenever feasible unless they are not required to accomplish the objective of the assignment. Investigational Samples shall be collected only when Official Samples are not readily available.

Consult with your supervisor in cases of doubt as to sample cost, size, or collection technique.

When collecting samples in glass jars, line the lids with aluminum foil which has been certified by the laboratory as contaminant free or use Teflon lined lids.

If shipment of shell eggs is required and breakage may result during transit, subs may be broken, shells discarded, and liquid magma collected in clean glass jars. Each sub jar should be properly identified.

Samples collected at Packing Sheds should be representative of the produce as shipped in commerce. DO NOT strip outer leaves from subs collected at packing sheds from bulk lots, shipping cartons ready for shipment, in-transit lots or at final destination. If the packing shed practice is to strip outer leaves prior to shipment, follow this practice when collecting the samples. Describe the sampling method on the C/R.

**DO NOT USE** magic markers, etc. to identify sub bags, because the ink may affect assay results. Use stick on labels to identify sub bags.

Collect samples in the container in which the dealer is packaging the product. If the dealer is packaging the product in plastic bags, collect sample in these bags. If the firm is not packing the product, collect the samples in paper bags, cardboard cartons, etc. Do not use plastic bags as this may interfere with the analysis, unless the bags are certified as contaminant free by your division laboratory.

Samples must be delivered as promptly as possible to the laboratory if regulatory action is to be taken against actionable lots.

Hold samples in cold storage until ready to be shipped or delivered to the laboratory. If the sample is of a hard fruit or vegetable (such as apples, pears, butternut squash), and is shipped overnight delivery, it can be shipped to the laboratory unrefrigerated, but the FDA 525 should direct refrigeration upon receipt.

Use aseptic technique, where applicable, when collecting samples of finished products from bulk containers.

## 4- WHEAT CARLOAD SAMPLING

### I. SAMPLING NORMAL CARS

**CAUTION: WHEN USING A GRAIN PROBE, BE CAREFUL NOT TO CLOSE THE TRIER COMPARTMENT DOORS ON YOUR FINGERS. Collect samples only of specific assignment.**

#### A. Equipment

1. Double tube compartmented trier, 60 in. long
2. Sampling cloth at least 60 in. long
3. 1000 ml plastic graduate
4. Paper bags or other suitable containers capable of holding more than one quart of sample and do not use canvas bags.
5. FDA Metal Car Seals for resealing railroad cars
6. Aluminum ladder
7. Block and tackle to open railcar door

#### B. Drawing Sample

Principal sources of grain samples are railcars, barges, and trucks. Draw 5 probes (in duplicate) for each sample taken as described below. However, if the sample is to be Field Examined, an initial sample of 5 probes drawn as indicated below will be sufficient.

#### Probe samples from railcars and trucks as follows:

Probe #1 - From Center of car

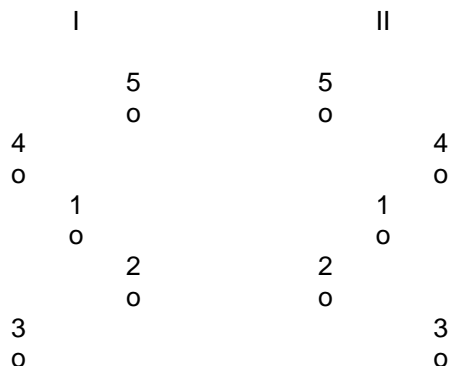
Probe #2 - From 3-5 feet back from door post toward end of the car and approximately 2 feet from the side of the car.

Probe #3 - From 3-5 feet from the same end of the car, but approximately 2 feet from the opposite side of car as Probe #2.

Probe #4 - Same as Probe #2, but opposite end of car.

Probe #5 - Same as Probe #3, but opposite end of car.

Sketches I and II below are alternatives showing the approximate sampling locations.



Insert trier in the grain at an angle of about 10° from the vertical, with the slot up and closed. Open slots. Give trier 2 or 3 short up and down motions, so that the openings will fill. Close slots (SEE CAUTION AT BEGINNING OF SCHEDULE), withdraw trier and carefully empty over sampling cloth. The cloth should be long enough to catch product from each compartment separately when you open the trier compartment doors; e.g. about 6 feet long.

### C. Field Examination

Examine each pocket of the probe separately, looking for evidence of pink wheat, rodent pellets, insect damage and uneven loading or plugging. Note any insect infestation and record types of insects and whether live or dead. Count and report for each probe the number of rodent pellets, or rodent pellet fragments. Follow procedure in I.C.2 below. Count as pellets any that are sufficiently large to be readily identified by size, shape, surface coating, and/or presence of rodent hairs. Report the number of rodent pellets per sub. Measure the volume of each sub (probe) in quarts and calculate the average number of pellets per quart per I.C.2.a below. Place pellets from each sub in separate vials and submit with each wheat sub. Place each of the wheat subs in clean, paper bags.

#### Do not use canvas bags or take glass jars into railcars.

Substantially larger loads will require additional probing or larger samples taken from falling grain during loading or unloading operations.

Submit all suspect samples to laboratory for confirmatory analysis.

1. **Non-Violative Samples.** When field examination shows sample as non-violative, return grain to the car, unless collected for pesticide analysis. Report results in the Remarks Section of the C/R.
2. **Violative Samples**
  - a. **Rodent Pellet Contamination.** The guideline for determining whether wheat is violative due to rodent contamination is: "9 mg or more rodent excreta pellets and/or fragments of rodent excreta pellets per kg of wheat."

NOTE: Since it is impractical to weigh rodent pellets and wheat in the field, the following estimations can be used. Mouse pellets average approximately 8.7 mg each and a kilogram of wheat about 2.35 pints. This translates roughly as 1 pellet per quart of wheat or 1/2 pellet per pint.

Where your field examination reveals one or more rodent pellets (or you can estimate that sufficient fragments of rodent pellets exist to equal one pellet) in a quart of wheat, take duplicate probes to furnish the claimants portion. Take the duplicate probes from the same locations as the original probes. Place the duplicates in separate containers and identify these to correspond with the original probes.

- b. **Pink Wheat.** Where evidence of pink wheat or other fungicide treated wheat is found, collect 15 probe samples. Take 5 probes from each end of the car and 5 probes from the center of the car. Submit the three 5-probe portions separately, using new clean containers.

- c. **Insect Damaged Kernels.** The violative status of these samples should be established by laboratory analysis. When any evidence of insect damage is revealed by cursory examination, collect duplicate samples and submit for laboratory analysis.
- 3. **Resealing Cars** See IOM 4.3.4.
- 4. **Procedures for Actionable Cars.** If field examination reveals an average of one or more rodent pellets per quart or gross evidence of insect-damaged kernels, evidence of plugging, or "pink wheat" contamination, determine any movement of the car or other disposition of the grain and notify your supervisor immediately.
- 5. **Preparation of Sample for Laboratory Analysis.** If a sample can be delivered to the laboratory promptly and confirmatory analysis handled expeditiously, freezing of the FDA subsamples is not necessary. The claimant's (702(b)) portion of the sample, however, must be frozen. It is preferable to freeze the subsamples in paper bags. If a freezer is not available, the subsamples (in paper bags) can be placed in a cooler box with dry ice. Do not use glass jars with dry ice. Officially seal all subsamples. If dry ice is used, you must label the shipping container as described in IOM 4.5.5.8.6. See Exhibit 4-19. Indicate frozen storage on the FDA 525.

**D. Special Reporting**

Submit an Analyst Worksheet (FDA-431) for each sample analyzed and found in compliance. See IOM 4.3.7.1. If field examination shows the sample is possibly actionable, report analytical results in Remarks Section of the C/R.

**II. SAMPLING PLUGGED CAR**

If uneven loading, layering or "plugging" is suspected, contact your supervisor as to whether to sample or not. A "plugged" car is a railcar, truck, or barge load of grain where the contamination is suspected of being in only one portion or layer of grain. Plugging is usually the deliberate mixing of violative grain below the surface or in isolated pockets of grain.

**A. Equipment**

Equipment needed is the same as in 1.A. above except:

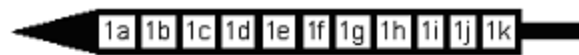
- 1. Double tube grain probe must have individual compartments permanently separated.
- 2. Small containers of sufficient size to hold the contents of each compartment of each grain probe.

**B. Procedure**

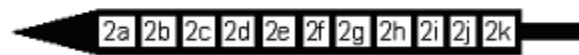
- 1. In the Remarks Section of the C/R, draw a diagram showing actual "plugging" pattern suspected.
- 2. Each sample consists of thirty probes of grain with each probe compartment maintained as a separate sub. Each sample thus consists of 300-330 subs depending on whether a 10 or 11 compartment probe is used and if grain depth is sufficient to insert the probe to fully cover all compartments of the probe.
- 3. Probe each load and number the probes as follows:
 

1	4	7	10	13	16	19	22	25	28
2	5	8	11	14	17	20	23	26	29
3	6	9	12	15	18	21	24	27	30
- 4. Identify the subs by probe number plus compartment letter starting with small "a" as the compartment nearest the tip of the probe.

Example:



Probe #1



Probe #2

- 5. Submit sample to your division's servicing laboratory. See IOM 4.5.5.2.

## 5- IMPORTED WHITEFISH SAMPLING SCHEDULE

### GENERAL

This Sample Schedule objective is to maintain import lot integrity from time of importation thru FDA inspection or examination and final action.

Shipments will be special manifested from non-lab ports to DO cities and other cities designated by the DD as FDA inspection points. These shipments will arrive in Customs bonded trucks under seal applied by Customs at the port of entry. Customs Entry documents and commercial invoice will accompany each shipment. The commercial invoice contains a description of the lots in the shipment and will serve as a guide in the selection of the lots to be sampled.

1. Special Manifested Shipments:
  - a. Determine if seals are intact and record seal number.
  - b. FDA metal seals may be broken and lots checked against invoice.
  - c. Customs seals may be broken only if authorized by Customs.
  - d. Lots which are not to be examined will be released by completing the "MAY PROCEED" block of the FDA-701.
  - e. Sample lots to be examined by using either the Single or Sequential Sampling Plan depending on whether examination is made at the DO Lab or at the dock. The Sequential Plan can only be used where additional fish are immediately available for cutting.
2. Definition of a Lot & Selection for Examination.
  - a. A lot is defined as "Each group of fish of a distinct size, listed in the invoice as from a distinct lake, will be considered as a separate lot. Where an invoice does not list lakes of origin of boxes of fish in a shipment, fish of the same size and kind will be considered to comprise a single lot. When the size of the fish or lakes of origin in a shipment are not specified, the shipment will be treated as a single lot."
  - b. Limit sampling to lots containing 5 or more boxes unless deliberate splitting up of lots is suspected.
  - c. Basis for Sampling. Select lots for sampling on either a "selective" or "objective" (random) basis. The criteria in selective sampling may be prior knowledge or suspicion that fish listed as from a given lake are likely to have excess cysts; that the shipper has been known to manipulate shipments; etc. Regardless of the reason for selective sampling, record the basis for sampling each lot in your examination report. Simply list the basis as "selective" or "objective" next to the results of each lot sampled.

- d. Normally, select boxes in a lot for sampling at random. However, where there's evidence of layering, selectively sample the suspect boxes.
3. Sampling Schedule.
  - a. Imported samples of whitefish & related fish for parasites. The sampling schedules estimate lot quality more precisely, thereby reducing the likelihood of passing a lot which should be detained, or vice versa, due to an inadequate sample. SCHEDULE A below is a single sample plan for use in collecting samples for examination in the division lab or other location where it is impossible or undesirable to return and obtain additional fish. SCHEDULE B below contains sequential sampling plans for use when the exam is made at a customs office or a carrier's dock where you have immediate access to the lot and can obtain additional fish, if necessary. The sequential plan for lots of 20 to 100 boxes is presented in tabular form. The sequential sample plan for lots of 100 or more boxes is presented in a sampling chart. For small lots of 5-20 boxes, a sequential sample plan is not feasible. All import sampling plans are based on lot size and the sizes of the fish in the lot. When lots are very good or very poor quality, in terms of cyst infestation, double sample plans require a smaller sample size on the average than single sampling plans, to reach a decision.
    - b. Domestic Samples for Parasites.
      - i. For Laboratory Examination. Lots of 11 or more boxes; Collect at least 25 fish from a representative number of boxes. For small lots, under 11 boxes; Collect 12 fish from a representative number of boxes.
      - ii. For Examination in Other Than Laboratory. Cut a preliminary sample in accordance with the appropriate double sampling plan, Schedule B. Cut the additional sample where indicated or bring the additional sample to the laboratory for examination.

### SCHEDULE A - SINGLE SAMPLE PLAN

Number of Boxes in Lots	NUMBER OF KG'S (POUNDS) IN A SAMPLE <sup>1/</sup>		
	Jumbo or Large <sup>2/</sup>	Medium <sup>2/</sup>	Small <sup>2/</sup>
5 - 19 boxes	12.7 kg (28lbs)	10.5 kg (23lbs)	7.3 kg (16lbs)
20 - 100 boxes	24 kg (73lbs)	20.5 kg (45lbs)	15 kg (33lbs)
100 or over	32 kg (70lbs)	25.5 kg (56lbs)	17.8 kg (39lbs)

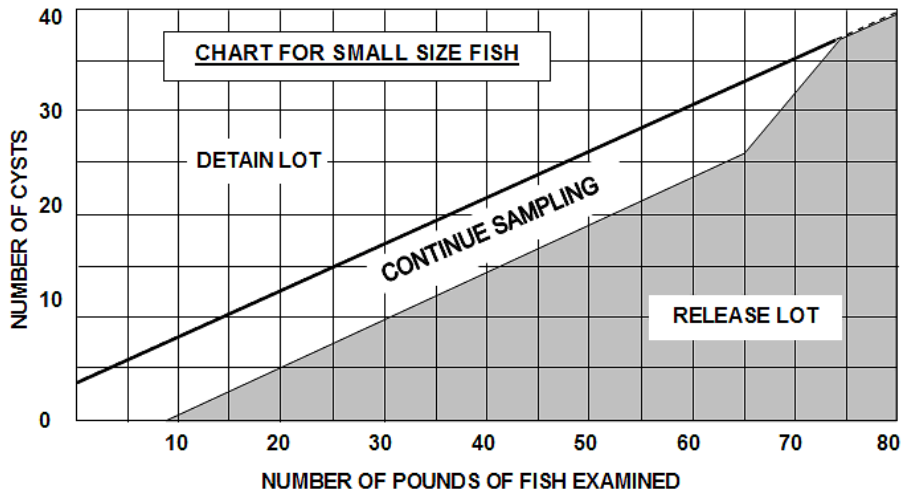
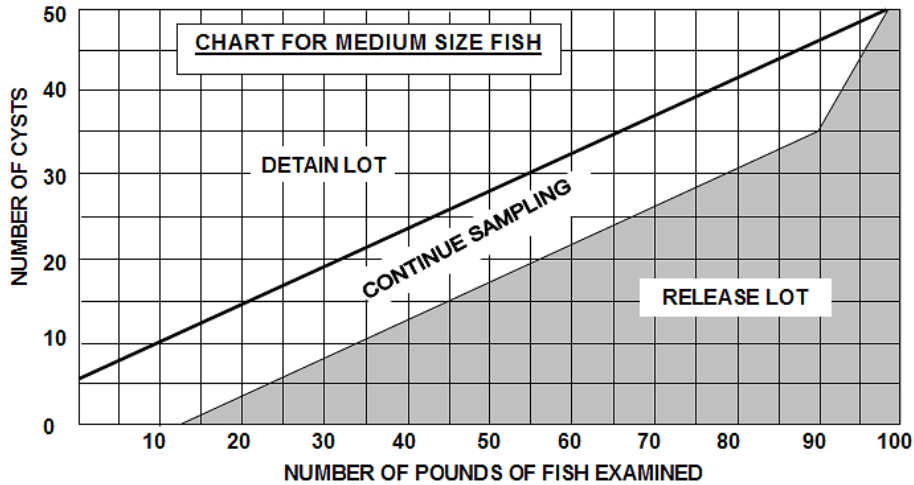
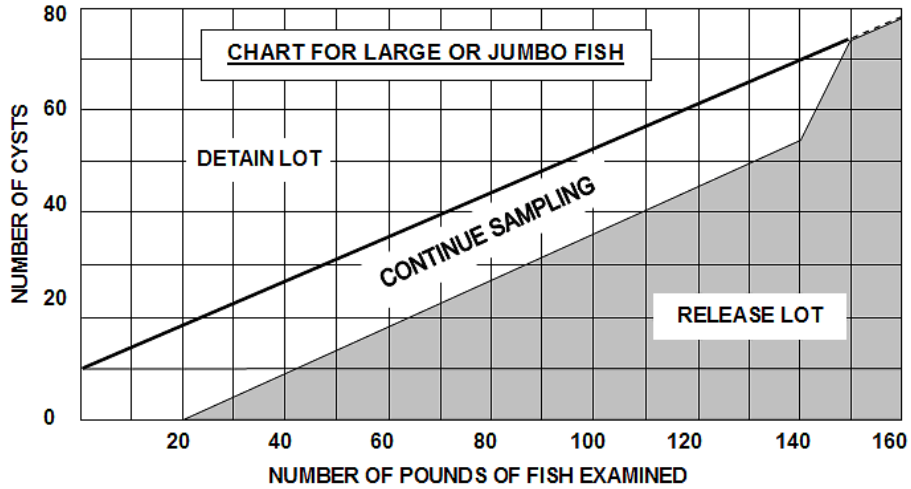
1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.

- 2/ RANGE OF WEIGHT OF FISH IN EACH SIZE CLASS:
- SMALL Under 675 g (1 1/2lbs)
  - MEDIUM 675 g (1 1/2lbs) & under 1.4 kg (3lbs)
  - LARGE 1.4 kg (3lbs) & under 1.8 kg (4lbs)
  - JUMBO Over 1.8 kg (4lbs)

SCHEDULE B - SEQUENTIAL SAMPLE PLAN							
1. Limited to lots of 20 - 100 boxes. 454 kg (1000lbs) to 2272 kg (5000lbs)							
Size of Fish <sup>1/</sup>	Size of preliminary Sample	Cysts/45.5 Kg (100lbs) in Preliminary Sample			Size of ADD'L SMPL	Cysts/45.5 Kg (100lbs) in sample	
		PASS	DETAIN	TAKE ADD'L SMPL		PASS	DETAIN
Large & Jumbo	16 kg (35lbs)	30 or less	70 or more	31-69	28.6kg (63lbs)	49 or less	50 or more
Medium	12.3 kg (27lbs)	26 or less	67 or more	27-66	19.5 kg (43lbs)	49 or less	50 or more
Small	8.2 kg (18lbs)	38 or less	61 or more	39-61	11.8kg (26lbs)	49 or less	50 or more

<sup>1/</sup> When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.  
<sup>2/</sup> For lots of 100 boxes or over, use the Sequential Sampling Chart for the particular size fish in the lot.

**WHITEFISH SEQUENTIAL SAMPLING PLAN (WHEN LOT SIZE EXCEEDS 100 BOX)**





**6- AFLATOXIN SAMPLE SIZES**

Sample sizes of human food samples for all other mycotoxins can be found in CP7307.001 Domestic & Import Mycotoxin Compliance Program

Use "Commodity particles relatively small" for Sample sizes of complete feed and pet food for all other mycotoxins.

**PRODUCT SAMPLE SIZES FOR AFLATOXIN ANALYSIS**

(Includes 702(b) [21U.S.C. 372(b)] portion - each sample unit, contains product for the reserve portion, no duplicate subs are necessary)

**NOTE: COMPLIANCE SAMPLE SIZES MAY DIFFER FROM SURVEILLANCE SAMPLE SIZES.**

**COMPLIANCE SAMPLE COLLECTION ONLY**

PRODUCT	PACKAGE TYPE	LOT SIZE	NUMBER OF SAMPLE UNITS*	UNIT SIZE (minimum)	TOTAL SAMPLE SIZE (minimum)
Peanut Butter (smooth)	Consumer or	NA	24	225 gm (8 oz)	5.4 Kg (12 lbs)
	bulk		12	454 gm (1 lb)	5.4 kg (12 lbs)
Tree nuts - paste			12	454 gm (1 lb)	5.4 kg (12 lbs)
Brazil Nuts in-shell (in import status)	Bulk	< 200 bags	20	454 gm (1 lb)	9 kg(20 lbs)
		201-800"	40	454 gm (1 lb)	18 kg (40 lbs)
		801-2000"	60	454 gm (1 lb)	27 kg (60 lbs)
Pistachio nuts in-shell (in import status)	Bulk	multiples of 34,100 kg (75,000 lbs.)	20 % of units	---	50 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Pistachio nuts shelled (in import status)		multiples of 34,100 kg (75,000 lbs.)	20 % of units	---	25 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Corn - shelled, meal flour or grits	Consumer or bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Oil seed meals - Peanut meal, cottonseed meal	Bulk	NA	20	454 gm (1 lb)	9 kg (20 lbs)
Ginger Root dried whole	Bulk	"n" units	Sq root "n"	---	6.8 kg (15 lbs)
	Consumer	NA	16	160-280 gm (1 oz)	4.5 kg (10 lbs)
Milk - whole, skim low fat	Consumer or bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Small grains - wheat sorghum, barley, etc	Bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Mixtures containing commodities susceptible to mycotoxin contamination	Consumer	NA			
Commodity particles relatively large			50	454 gm (1 lb)	22.7 kg (50 lbs)
Commodity particles relatively small***			10	454 gm (1 lb)	4.5 kg (10 lbs)

**Surveillance and follow-up COMPLIANCE SAMPLE COLLECTION**

Peanut Butter (Crunchy) Peanuts shelled roasted, or unroasted, Peanuts ground for topping	Consumer or bulk	NA	<b>SURVEILLANCE SAMPLE</b>		
			10	454 gm (1 lb)	4.5 kg (10 lbs)
			<b>COMPLIANCE SAMPLE</b>		
			48	454 gm (1 lb)	21.8 kg (48 lbs)
Peanuts, roasted in shell (only for domestic runner variety)	Consumer or bulk	NA	<b>SURVEILLANCE SAMPLE</b>		
			15	454 gm (1 lb)	6.8 kg (15 lbs)
			<b>COMPLIANCE SAMPLE</b>		
			75	454 gm (1 lb)	34 kg (75 lbs)

Tree nuts (except in-shell Brazil Nuts and all pistachio nuts in import status) shelled, in-shell slices, pieces, or flour	Consumer or bulk	NA	<b>SURVEILLANCE SAMPLE</b>	
			10	454 gm (lb) 4.5 kg (10 lb)
			<b>COMPLIANCE SAMPLE</b>	
			50	454 gm (1 lb) 22.7 kg (50 lbs)
Edible seeds** melon pumpkin, sesame, etc	Bulk	NA	<b>SURVEILLANCE SAMPLE</b>	
			10	454 gm (1 lb) 4.5 kg (10 lb)
			<b>COMPLIANCE SAMPLE</b>	
			50	454 gm (1 lb) 22.7 kg (50 lb)
Dried fruit** - e.g.: Figs	Consumer or bulk	NA	<b>SURVEILLANCE SAMPLE</b>	
			10	454 gm (1 lb) 4.5 kg (10 lb)
			<b>COMPLIANCE SAMPLE</b>	
			50	454 gm (1 lb) 22.7 kg (50 lb)

NOTE: Containers for samples of unprocessed, intact nuts, seeds, or grains must be sufficiently porous to provide for dissipation of moisture produced by respiration of the nut, seed, or grain.

\* To be collected from as many random sites in the lot as possible. For surveillance samples, you may combine subs prior to shipping to the laboratory. For compliance samples, you must maintain sub integrity.

\*\* Optional sampling program for seeds or dried fruit with a low incidence of contamination. Take initial 10 x 454 g (1 lb) sample. If any aflatoxin is detected, resample 50 x 454 g (1 lb) sample for determination of contamination level on which to base regulatory judgment.

\*\*\* CVM Classifies complete feed and pet food as a “commodity particles relatively small”

## 7- CANNED FRUIT - FILL OF CONTAINER - AUTHENTIC PACK

Collect samples only on a specific assignment or during inspections when it appears that the firm is not filling the containers to capacity.

1. INVESTIGATIONAL SAMPLES: Authentic Pack Preparation. Procedure for preparing authentic factory packs.
    - a. Remove 72 cans, 3 at a time, from packing line after fruit has been added and before syruing.
    - b. Mark 24 cans with the sub numbers A-1, A-2, A-3, etc.; 24 cans with sub numbers B-1, B-2, B-3; and 24 cans with sub numbers C-1, C-2, C-3, etc. See IOM 4.5.2.3.
    - c. Drain water from the "B" subs by inverting each can for 10 seconds, holding the fruit so it doesn't fall out.
    - d. Obtain gross weight of each can and record data for each series of sub on 3 separate FDA-485 - Field Weight Sheets.
    - e. Add additional fruit of the same kind and style to the "C" subs until the cans are filled to capacity. Do not tamp the contents or crush the fruit.
    - f. Record the number of fruit pieces added where the size of the fruit makes the procedure reasonable. Do not make time consuming counts of small pieces of fruit or berries.
  2. OFFICIAL SAMPLES  
See Sample Schedule Chart 2 for sample size.
  3. SPECIAL REPORTING AND PRECAUTIONS
    - a. Report coding of cans and shipping cases.
    - b. Obtain label specimen(s) for the slack filled products.
    - c. Report shipments made before the inspection or since previous inspection in the same canning season.
    - d. Do not prepare Authentic Factory Samples when the cannery is packing for USDA fill-of-container certification unless:
      - i. USDA inspection is not continuous.
      - ii. USDA Certification is for quality only.
      - iii. USDA recommendations for weights are not being followed.
  4. SAMPLE SUBMISSION  
Submit samples to your division's designated workplan servicing laboratory
- g. Obtain the gross weight of the "C" subs after additional fruit is added and record on "C" series Field Weight Sheet.
  - h. Return all 72 cans to the filling line for syruing, exhausting, sealing, etc. in normal cannery operation.
  - i. Remove cans after cooking and cooling.
  - j. Identify cans with a single INV Sample number.
  - k. Attach FDA-485 - Field Weight Sheets to C/R.

**8- IMPORTS - COFFEE, DATES AND DATE MATERIAL**

FACTS and the sample collection time is reported as an import sample collection. All necessary documents for an import sample collection must be completed.

1. Coffee - Import Field Examination - Note: Examine a minimum of six bags of coffee beans regardless of lot size. If a significant number of defective beans or significant contamination is found during the examination of these six bags, continue the examination using the following schedule, which applies for both Import Field Examination and samples for laboratory analysis:

LOT SIZE	NO. BAGS TO BE SAMPLED
100 or less	6 bags
101 - 200	10 bags
201 - 1000	15 bags
over 1000	20 bags

- a. Sample each bag with a trier, collecting 1/2 pt. of beans from the top and 1/2 pt. from the bottom of the bag. The total quantity of beans taken from each bag must be the same, since both wharf and laboratory examinations are to be performed on a composite sample of all beans collected. Shake each sub on a #8 sieve nested in a pan. Dump the sifted beans from each sub into a bag of sufficient size to hold and permit mixing all of the subs collected from the lot. Composite the subs. Do not maintain individually.
- b. Macroscopic Filth Examine the siftings for macroscopic filth (live and dead whole insects, excreta pellets, extraneous material and sweepings), reporting findings for each sub separately. See IOM 4.3.7.4. Transfer macroscopic filth, including all sifted material to a second bag and submit to the laboratory for confirmation. If live insect infestation is encountered, freeze the filth portion containing the insects and the composite coffee bean sample. The lot will be detained if a live insect infestation is encountered, however, proceed with the defect bean examination since the reconditioning process will depend on the results.
- c. Defect Bean Examination Thoroughly mix the composite sample of coffee beans and remove three-hundred beans at random. Examine each individual bean visually (or at a 5X magnification) for insect tunneling and mold damage. Count as moldy only those beans with 1/4 or more of the surface being moldy. Note: Each division office has examples of the various types of reject beans. Accept the lot if twenty or less rejects are found and discard the sample. Report your wharf examination into FACTS or OASIS, depending on your assignment; no Sample Collection Report is necessary.
- d. If twenty-one or more rejects are detected, return beans examined to the composite and submit to the laboratory. You may discontinue the examination when twenty-one rejects are detected. When a sample is submitted to the laboratory, all import field examination time is reported as a field exam in

2. Dates & Date Material - Filth

In the laboratory, dates, like in-shell nuts are sampled in accordance with a sequential sampling program, i.e. all subsamples are composited, and 100 dates are sampled at a time, repetitively, until such time they either exceed or fall under certain reject numbers. It is not uncommon to have to examine 3 to 6 (100 date) repetitions. It is therefore important for each subsample to contain at least 200-300 dates or 2 lbs of date material. Sample according to the following schedule:

NUMBER OF SUBSAMPLES REQUIRED

NO. CONTAINERS IN LOT*	WHOLE DATES	DATE MATERIAL
100 or less	3	4
101 - 600	8	6
601 - 1200	14	8
1201 - 2000	26	10
2001 - 2800	36	12
2801 - 6000	44	14
6001 - 9600	56	16
9601 - 15000	68	18
Over 15000	82	22

\* Schedule is based upon unit containers weighing between twenty and one-hundred pounds. For containers exceeding one-hundred pounds each, consider as two or more containers. For example, a one-hundred and fifty-pound container is considered as two containers; a three-hundred pound container as three containers, etc.

- a. Identify each subsample separately.
- b. Each lot will be a separate sample. Reconditioning, if possible, will be based on lot numbers.
- c. Jujube sampling – collect according to the above schedule for dates and date material. Do not identify jujube samples as dates, *Phoenix dactylifera*. Jujubes, *Zizphus jujube*, are usually labeled as Chinese Red Dates, Dried Red Dates, or Honey Dates and are not misbranded when labeled as such due to long standing use of these names.
- d. If live insects are noted, include these as part of the sample collected and report on the C.R. which subs contained the insects and how many insects, adult or larvae, were noted. If live infestation is noted, place all subs from the lot sampled in large plastic whirl-pak bags and freeze or place in a cooler on dry ice.

**9- SAMPLING SCHEDULE FOR COLOR CONTAINING PRODUCTS & COLOR ADDITIVES**

The following schedule provides general guidance for collecting samples of foods and cosmetics to determine whether non-permitted colors are present, rather than to determine the actual level of a particular color. This schedule was developed with the assumption that color distribution in the lot will be homogeneous. In the case of heterogeneous products, your supervisor should contact Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement (HFS-605) to determine sample size.

INDUSTRY SAMPLE SIZE  
CODE (DO NOT COMMINGLE CODES) (Min. 225 g (8 oz)/pkg Unless otherwise specified)

GRAIN AND BAKING

02	Whole grains, Milled Grain Products and Starch	2 retail packages
03	Bakery Products, Doughs, Bakery Mixes, and Icings	2 retail packages
04	Macaroni and Noodle Products	2 retail packages
05	Cereal Preparations	2 retail packages
07	Breakfast Foods Snack Food Items (Flour, Meal, or Vegetable Base)	2 retail packages

DAIRY

09	Milk, Butter, and Dried Milk Pdts	Liquid Pdts: 2 pts where possible Solid: 2 packages
12	Cheese and Cheese Products	2 retail packages
13	Ice Cream and Related Products	6 items per sample (If item is single serving; i.e., cup, popsicle, bar, etc.) 2 pt containers where possible, or 1 quart or 1/2 gal
14	Filled Milk and Imitation Milk Products	2 pints

EGGS

15	Egg and Egg Pdts	2 dozen whole eggs (e.g. colored hard-boiled Easter eggs) 2 retail pkg of egg pdts
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FISH

16	Fishery/Seafood Pdts	2 retail packages. Any collection of smoked salmon should be selective, based on inspectional evidence
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MEAT & SIMULATED MEAT PRODUCTS

17	Meat, Meat Products and Poultry	2 retail packages
18	Vegetable Protein Pdts	2 retail packages

FRUIT, NUT AND VEGETABLE PRODUCTS

20-22	Fruit & Fruit Pdts	2 retail packages canned or glazed. 12 fresh fruit (e.g., oranges, etc.).
23	Nuts & Edible Seeds	2 retail packages
24-25	Vegetable & Vegetable Products	2 retail packages
26	Vegetable Oils & Olive Oil	Liquids - 2 pints Solids - 2 retail packages

DRESSINGS AND SPICES

27	Dressings & Condiments	2 retail packages
28	Spices, Flavors, & Salts	Extracts - 2 pints Solids - 2 retail packages

BEVERAGES

29	Soft Drinks & Waters	6 Retail Units (Cans, Bottles, Packets)
30	Beverage Bases, Concentrates, and Nectars	Liquids - 1 pint Solids (Powder mix, packets) - 6 Consumer Pkg Solids - 2/225 g (8 oz) or larger containers
31	Coffee and Tea	2 retail packages
32	Alcoholic Beverages	2 pints or 1 quart

CONFECTIONS AND DESSERTS

33	Candy w/o chocolate, Candy Specialties, and Chewing Gum	2 retail packages
34	Chocolate & Cocoa Pdts	2 retail packages
35	Gelatin, Rennet, Pudding Mixes,	6 pkgs - smallest consumer size

	& Pie Fillings	
36	Food Sweeteners (Nutritive)	2 pints
<u>MULTIPLE FOODS, SOUPS, SALADS, BABY FOOD AND DIETARY</u>		
	Multiple Food Dinners	Single Serving Dinners, etc - 4 pkgs
37	Gravies, Sauces and Specialties	Two Consumer Pkgs when 1 pkg serves more than 2
38	Soups	Same as 37 Above
39	Prepared Salad Products	Same as 37 Above
40	Baby (Infant and Junior) Food Pdts	Sufficient retail pkgs to total at least 454 g (1 lb) of food
41	Dietary Conventional Foods and Meal Replacements	Same as 37 Above

COLORS AND COSMETICS

		1. Straight Color 28 g (1 oz) powder.
		2. Color Mixtures 110 g (4 oz) Liq, paste or powder.
50	Color Additives for Foods Drugs, and Cosmetics	If mixture contains over 50% pure dye, 55 g (2 oz) is sufficient  Four retail packages of the same lot code for each shade (color) in the product line, if the product is strongly colored. (e.g., Lipsticks, hair coloring products, eye mascara, eye liners, make up pencils of all types)
53	Cosmetics	Sufficient number of retail packages to equal 1 lb or 1 pt of sample if the product is lightly colored. (e.g., creams, lotions, shampoos, bath products, shaving preparations, and perfumes.) Note: Always collect a minimum of two retail units of each product.

MISCELLANEOUS

Bulk Items (Any bulk food or cosmetic)	Dry - 454 g (1 lb) Liquid - Min 36 fl oz
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**10- DRUG SAMPLING SCHEDULES**

(Does not include Antibiotic Preparations)

STERILITY TESTING VITAMINS, DEVICES, & DRUGS

Type of Product	Sample Size <sup>1</sup>	
	INV Sample <sup>2</sup>	Official [702(b) & Check] <sup>3</sup>
DRUGS	36	86
DEVICES	46	106

**LEGEND:**<sup>1</sup>Double sample size requirements when individual containers are 2 ml (2 g) or smaller.<sup>2</sup>INV sample includes units (30 for Drugs & 40 for devices) for examination and 6 units for bacteriostasis.<sup>3</sup>Official Sample includes units (30 for drugs & 40 for devices) for examination, units (30-40) for check, 20 units for 702(b) [21 U.S.C. 372(b)] and 6 for bacteriostasis.

Note: If a lot is aseptically filled into 200 finished units or less, sample no less than 10% of lot.

DISSOLUTION TEST - USP & NF

Unless directed otherwise by your assignment or supervisor, submit samples to your normal servicing laboratory.

SAMPLE SIZE

Collect a 200 tablet portion for drug potency analysis by the collecting division lab, plus a separate 100 tab portion to be split for dissolution testing.

MICROBIOLOGICAL EXAMINATION OF DRUGS (Other than for Sterility)

PRODUCT	<u>MINIMUM SAMPLE SIZE (Includes 702(b) portion)</u>	
	<u>Sub Size</u>	<u>Nos. of Subsamples</u>
Dosage Form Drugs (See #1 below), Bulk Drugs, or Raw Materials for Manufacturing	90 g or 90 ml	10

SAMPLING INSTRUCTIONS

1. Contact the laboratory (which has microbiological testing capabilities) serving your division for sample size requirements before sampling dosage form drugs containing less than 3 grains, 200 mg, or 25% of the suspect ingredient.
2. Use aseptic technique when collecting samples from raw materials or bulk containers. Implements and sample containers used must be sterile. Submit controls. See IOM 4.3.6 through 4.3.6.5.
3. Submit samples to the laboratory with microbiological testing capabilities which serves your division unless directed otherwise.

**11- VETERINARY PRODUCTS, FEEDS, & BY- PRODUCTS FOR ANIMAL FEEDS**

1. GENERAL

This sampling schedule may be used as a guide in the collection of surveillance or compliance samples resulting from division assignments or as a follow-up to violative inspections and/or investigations. Before collecting follow-up samples to violative inspections or investigations, contact your supervisor since it may be necessary for your division to consult with the Atlanta Center for Nutrient Analysis (HFR-SE680) when unscheduled compliance sampling is contemplated.

2. SAMPLE PRODUCT, SIZE, & SPECIAL INSTRUCTIONS

Vitamin-mineral testing, sampling instructions and information. Sample size includes 702(b) portion.

Unless excessive cost is a factor, collect at least 3 intact containers from each lot or control number. When sampling from bulk lots, collect appropriate subs from a minimum of 3 different bulk containers in the lot.

**DOSAGE FORM VITAMIN-MINERAL PREPARATIONS (Single/Multiple Ingredients)**

PRODUCT	NO. SUBSAMPLES	MINIMUM TOTAL SAMPLE SIZE	REMARKS
Injectables	3 vials/amps	30 ml	Split samples for sterility testing (60 vials/amps)
Tabs/Caps	3 retail units	300 Tabs/Caps	Split sample for micro tests (10/50 tab/cap subs)
Liquids	3 retail units	4 fl. oz.	Split sample for micro tests (10/2 fl. oz. subs)
Powders	3 retail units	112 g (4 oz)	Same as above

**FEEDS & BY-PRODUCTS FOR ANIMAL FEEDS (Vitamin-Mineral Claims)**

Vitamin A & D Concentrates, Supplements & (A&D feeding	3 retail units(1/2 gal or less)	3 lbs (1.4 kg) 3 pints	Limit samples to those products containing at least 800 units/g Vit A and/or 80 Feeds units/g Vit D
Vitamin B2 (Riboflavin) Concentrates, Supplements, & feeds	Same	Same	Limit samples to those products containing at least 20 mg/lb
Vitamin B12 (Cyanocobalamin) Concentrates, Supplements & feeds	Same	Same	Limit samples to those products containing at least 1 mg/lb
Multiple Vitamins Concentrates, Supplements, & feeds.	Same	Same	Limit samples to those products meeting vitamin levels listed above.

3. SAMPLE SUBMISSION

Submit all samples for Vitamin Potency analysis to the Atlanta Center for Nutrient Analysis (HFR-SE680). Submit samples for filth analysis, microbiological examination, sterility, etc. to your division servicing laboratory.



## 12- MEDICATED ANIMAL FEEDS SAMPLING

### Medicated Premixes

1. Investigational Samples (INV Samples)  
To demonstrate suspected drug carryover or other chemical contamination during manufacturing, collect 1-900 g (2 lbs) of static residual material in the equipment, and the finished product premixes.
2. Official Physical Samples 702(b) [21U.S.C.372(b)] Portion Included  
For expensive premixes or components, collect a total of 3/170 gm(6 oz) subs; One sub from each of 3 containers. In the case of premixes packaged in plastic; e.g., mini-packs, follow instructions under bagged premixes.
  - a. Bagged Premixes  
Collect 10 - 454 g (1 lb) subs from each lot. Sample all bags in lots under 10 bags, for a total of 10 subs from the lot.  
Collect 454 g (1 lb) subs from at least 10 different bags selected at random in lots of more than 10 bags.
  - b. Bulk Premixes  
Collect at least 10 - 454 g (1 lb) subs, from different locations in the lot providing a minimum total sample of 4.5 Kg (10 lbs).
3. Documentary Samples (DOC Sample) - Refer to IOM 4.1.4.2 for guidance on the collection of DOC Samples.

### Medicated Feeds

1. Investigational Samples (INV Sample)  
Collect 1 - 900 g (2 lb) of static residual material in the equipment and correlate with finished feed samples to show that residues are being carried over into the finished product.
2. Official Samples (Includes 702(b) portion)
  - a. Bagged Complete Feed  
Collect a total sample of not less than 2.3 kg (5 lbs) from each lot. Collect 454 g (1 lb) subs sampling all available bags from lots of 10 bags or less. If lot size is greater than 10 bags, collect 454 g (1 lb) from each of 10 bags selected at random.
  - b. Bulk Complete Feed  
Collect at least 10 - 454 g (1 lb) subs from different points in the bulk lot to obtain a minimum total sample of 4.5 kg (10 lbs).
  - c. Concentrates/Supplements  
If the concentrate or supplement is relatively inexpensive, follow the sampling procedures for complete feeds. Limit sampling of more expensive drug materials, concentrates, or supplements to no more than 3 containers taking a 170 g (6 oz) or 6 fl. oz. sub from each of the 3 containers.
3. Documentary Samples (DOC Sample)
  - a. Feed Subject to MFA Approval - Collect DOC Samples of products processed without required MFA approval. Where the plant does not ship in IS commerce, but ingredients are received from IS sources, document the IS nature of drug ingredients and the "Held For Sale" status of the finished feed. Labeling of drug ingredients must be submitted.
  - b. Misbranded Products - Collect a DOC Sample for misbranding or labeling deficiencies. The failure to provide warning and/or withdrawal statements which could present danger to animals or man, or gross evidence of false and misleading therapeutic claims, are factors for consideration.

### Sampling Precautions (See IOM Sample Schedule Chart 4)

1. Insert the trier the full length of the bag when sampling bagged premixes, or complete feeds.
2. Clean trier between sampling the different lots of premixes or complete feeds.
3. Place subs in a clean, airtight container, preferably clean glass jars.
4. Do not fumigate samples intended for potency analysis, drug carryover or cross-contamination.

### Sample Submission

Submit samples to your division's servicing laboratory or as directed by your assignment or supervisor. See IOM 4.5.5.2.

**13- SAMPLE SIZES WITH APPLICATION TO FOOD PRODUCTS FOR ALLERGENS**

(Listed below is the sample size needed for lab analysis. Collect all samples in duplicate, with the duplicate serving as the 702 (b) reserve sample)

Product	Package type	Number of sample units	Unit size	Total sample
Non-liquefied foods, i.e., cereals, cookies	Consumer	20	1 lb	20 lbs
Pre-liquefied foods, i.e., ice cream, chocolates	Consumer	10	1 lb	10 lbs
Paste or slurry type	Consumer	24	8 oz	12 lbs
		12	1 lb	12 lbs
Fluid, i.e., beverages	Consumer	10	16 fl. oz	160 fl. oz

**IMPORTANT! WHEN TO SAMPLE:** At the time of submission of this table to the IOM, only “for cause” allergen samples for peanut contamination should be collected. Test methods for additional allergens are under development and the field will be notified when they are available for regulatory purposes. The allergen compliance program, when issued, will provide additional sampling guidance. “For cause” sampling should be limited to instances where there is a reasonable probability that a product may contain an allergen and the labeling of the suspect product does not indicate the presence of the allergen. This probability may result from a consumer complaint, a downstream consignee laboratory analysis, or other evidence of the presence of the allergen. Also reference IOM Chapter 8, 8.2.3.2.4, Allergen Samples, which indicates that allergen samples are to be collected after consultation with OCM/OEIO and CFSAN.

<sup>a</sup> See Laboratory Information Bulletin (LIB) # 4341, Application of Validated, Multiple Laboratory *Performance Test Methods*<sup>SM</sup> for the Detection of Peanuts in Food, Vol 21(2) 2005 for details regarding the analysis and quantitation of analytical samples.

Note: To be collected from random sites. May combine subs or maintain sub integrity depending on purpose of sampling

Note: Prepare composite following proper grinding and mixing procedures. Separate four 1-lb portions from composite.

*Adapted from U.S. Food and Drug Administration, Office of Regulatory Affairs, Investigations Operations Manual, Chapter 4, Sample Schedule 6, Mycotoxin Sample Sizes*

## 4-22 PRODUCT LABELING EXAMPLE



## WILAPRIN ARTHRITIS FORMULA

100 Tablets

Fever Reducer and Pain Reliever

Active Ingredients: Acetylsalicylic acid 500 mg.

Inactive Ingredients: Corn Starch, powdered cellulose

LOT 25C83      Manufactured in an approved facility

EXP 8/2013

ARO Pharmaceutical

100 Main Street

Powell, OH 43065

See Carton for Complete Labeling

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# CHAPTER 5 - ESTABLISHMENT INSPECTIONS

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## SUBCHAPTER 5.1 - INSPECTION INFORMATION

### 5.1.1 - AUTHORITY TO ENTER AND INSPECT

See IOM 2.2 for discussion of statutory authority.



It is your obligation to fulfill the following requirements because failure to do so may prevent use of evidence and information obtained during the inspection.

There may be occasions where you may be accompanied on your inspection or investigation by other officials. These officials may be state or local officials who have their own inspectional authority or other officials who do not have authority to enter the firm. You should obtain permission from the firm's most responsible person if officials without inspection authority wish to accompany you during your inspection/investigation. You should document in your EIR when other non-FDA officials accompany you during your inspection, and whether they entered under their own authority or the responsible individual at the firm gave permission (identify, by name and title, the responsible individual giving permission). See IOM 5.2.2 and 5.11.4.3.3.

### 5.1.1.1 - FDA Investigator's Responsibility

Your authority to enter and inspect establishments is predicated upon specific obligations to the firm as described below. It is your responsibility to conduct all inspections at reasonable times and within reasonable limits and in a reasonable manner. Proceed with diplomacy, tact and persuasiveness.

During inspections or investigations, when you have evidence of conditions whereby there is a reasonable probability the associated products will cause imminent and serious adverse health consequences or death, you should notify your supervisor immediately to consider a Risk Control Review (RCR) evaluation.

### 5.1.1.2 - Credentials

Display your credentials to the top management official be it the owner, operator, or agent in charge. See IOM 5.2.2.

NOTE: Although management may examine your credentials and record the number and your name, do not permit your credentials to be photocopied. Federal Law ([Title 18, U.S.C. 701](#)) prohibits photographing, counterfeiting, or misuse of official credentials. Do not permit a firm to take your fingerprints, contact your SCSO for more information.

### 5.1.1.3 - Written Notice

After showing the firm's representative your credentials, issue the original, properly executed, and signed FDA 482, Notice of Inspection, to the top management official. Keep a copy for submission with your report. A notice of inspection is not required to be issued during foreign inspections; however, credentials should be presented to the top management official.

### 5.1.1.4 - Written Observations

Upon completing the inspection and before leaving the premises, provide the highest management official available your inspectional findings on an FDA 483 - Inspectional Observations or an FDA 4056, Produce Farm Inspection Observations, for produce safety inspections. See Section [704\(b\) of the FD&C Act](#) [21 U.S.C. 374 (b)] and IOM 5.2.3 and 5.2.7.

### 5.1.1.5 - Receipts

Upon completion of the inspection, furnish the top management official the original of the FDA-484 - Receipt for Samples describing any samples obtained during the inspection. See IOM 5.2.4.

### 5.1.1.6 - Written Demand for Records

In low-acid canned food and acidified food EI's, an FDA 482a - Demand for Records (exhibit 5-2) is required under [21 CFR 108.35\(h\)](#) and [21 CFR 108.25\(g\)](#) to obtain records required by [21 CFR 113](#) and [114](#).

### 5.1.1.7 - Written Requests for Information

There are several methods of requesting records. These may include a request for information under LACF or AF inspections, and FDA 482d Request for FSVP Records, 703 written requests, and requests for records under the BT Act (IOM 5.4.1.3).

#### 5.1.1.7.1 – LACF / AF Food Inspections

In low-acid canned foods and acidified foods EI's, an FDA 482b, Request for Information (exhibit 5-3), is required under [21 CFR 108.35\(c\)\(3\)\(ii\)](#) and [21 CFR 108.25\(c\)\(3\)\(ii\)](#) to obtain information concerning processes and procedures required under [21 CFR 113](#) and [114](#).

#### 5.1.1.7.2 – Requests for Records under Section 703 of the FD&C Act

Per [CPG Sec. 160.300](#), Requests for Records under [Section 703](#) [21 U.S.C. 373], evidence obtained in response to a specific written request under Section 703 cannot be used in a criminal prosecution of the person from whom obtained. With Supervisory approval, in certain circumstances, you may decide to issue a 703 written request when the importance of the evidence is crucial to protecting the public health.

**Procedure:** All 703 written requests must comply with IOM 4.4.7.2.2. Consider obtaining the evidence from other sources before using the 703 written request. In the case of foods and feeds, if there is a risk or threat of serious adverse health consequences, the division program division should invoke the BT Act records access authority. All BT Act records requests must comply with IOM 5.4.1.3.

### 5.1.1.8 - Business Premises

Authority to inspect firms operating at a business location is described in IOM 5.1.1 and requires issuing management an FDA 482, Notice of Inspection, and presenting your credentials. A warrant for inspection is not necessary unless a refusal or partial refusal is encountered or anticipated.

### 5.1.1.9 - Premises Used for Living Quarters

All inspections where the premises are also used for living quarters must be conducted with a warrant for inspection unless:

**Owner Agreeable** - The owner or operator is fully agreeable and offers no resistance or objection whatsoever. Clearly document in the EIR that you are inspecting a residence and the owner was agreeable. or;

**Physically Separated** - The actual business operations to be inspected are physically separated from the living quarters by doors or other building construction. These would provide a distinct division of the premises into two physical areas, one for living quarters and the other for business operations, and you do not enter the living area.

In both the latter cases, proceed as any other inspection with the appropriate presentation of credentials and issuance of a Notice of Inspection. For safety precautions, it is recommended that two credentialed FDA employees are present when conducting inspections in a residence.

### 5.1.1.10 - Facilities where Electronic Products are Used or Held

[Section 537\(a\) of the FD&C Act](#) provides the FDA with the authority to inspect the facilities of manufacturers in certain circumstances. The electronic product radiation control provisions were originally enacted as the Radiation Control for Health and Safety Act of 1968 (P.L. 90-602)

It is lawful for FDA personnel to enter the facilities of an electronic product distributor, dealer, assembler or user for the purpose of testing an electronic product for radiation safety when the entry is voluntarily permitted. Congress has not specifically prohibited FDA from conducting such voluntary examinations and such examinations would clearly agree with the congressional declaration of purpose expressed in section 532(a) of the RCH&S Act.

Under the Medical Device Authority, electronic products utilized in human and/or veterinary medicine, e.g., x-ray, laser, ultra-sound, diathermy, etc. can be considered prescription devices. In these cases the authority of [Section 704 of the FD&C Act](#) [21 U.S.C. 374] can be used to obtain entry to inspect the user facility. If the Medical Device Authority is utilized, credentials must be displayed and a FDA 482, Notice of Inspection, must be issued.

### 5.1.1.11 - Multiple Occupancy Inspections

You are required per [FD&C Act 704\(a\)\(1\)](#) [21 U.S.C. 374(a)(1)] to issue a Notice of Inspection, FDA 482, to each firm inspected. When firms have operations located in different sites or buildings, you should use judgment to determine when multiple FDA 482 forms need to be issued. For sites located a distance apart, it is preferable to issue a FDA 482 to the most responsible person at each site. One rule of thumb which can be used is if the sites or buildings are within walking distance, your original Notice of Inspection can be considered sufficient to cover both. During your initial interview with management, after you issue the FDA 482, make sure you clearly indicate the facility and sites you intend to inspect. The Act requires the issuance of a Notice of Inspection, but does not prohibit issuing multiple notices if management so requests. As with all of our work, good judgment, and knowledge of the OEI and the FD&C Act are necessary in deciding what legally must be done.

### 5.1.1.12 - Authority for Examinations and Investigations

[Section 702\(a\) of the FD&C Act](#) [21 U.S.C. 372 (a)] authorizes examinations and investigations for the purpose of enforcing the Act.

### 5.1.1.13 - Authority to Implement Section 702(e)(5) of the FD&C Act

[Section 702\(e\) of the FD&C Act](#) [21 U.S.C. 372 (e)] contains certain authorities relating to counterfeit drugs including the authority to seize ("confiscate") counterfeit drugs and containers, counterfeiting equipment, and all other items used or designed for use in making counterfeit drugs prior to the initiation of libel proceedings. This authority has been delegated, with certain restrictions, to holders of official credentials consistent with their authority to conduct enforcement activities. Additional authority in 702(e) to make arrests, to execute and serve arrest warrants, to carry firearms, or to execute seizure by process under [Section 304 of the FD&C Act](#) [21 U.S.C. 334] have not been delegated.

The agency does intend to utilize the authority contained in Section 702(e) to execute and serve search warrants, but such use does not require delegation from the ACRA.

Section 702(e)(5) contains authority for such delegated persons to confiscate all items which are, or which the investigator has reasonable grounds to believe are, subject to seizure under Section 304(a)(2). Items subject to seizure, and thus to confiscation under Section 702(e)(5), includes most things associated with counterfeit drugs. Confiscation authority does not, however, extend to vehicles, records, or items (i.e., the profits) obtained as a result of counterfeiting.

### 5.1.1.13.1 - SCOPE

Under this delegation, with supervisory concurrence and prior to the initiation of libel proceedings, investigators and inspectors are authorized to confiscate:

1. Any counterfeit drug,
2. Any container used to hold a counterfeit drug,
3. Any raw material used in making a counterfeit drug,
4. Any labeling used for counterfeit drug,
5. Any equipment used to make a counterfeit drug including punches, dies, plates, stones, tableting machines, etc.,
6. Any other thing which you have reasonable grounds to believe is designed or used in making a counterfeit drug.

NOTE: You and your supervisor must be constantly aware of the potential dangers involved in confiscating property from individuals. Special care should be taken to ensure your safety. Arranging for teams of investigators to conduct the investigation, or arranging for assistance by local police, or other agencies with police powers, should be considered in planning the confiscation of counterfeit materials.

### 5.1.1.13.2 - INSPECTIONAL GUIDANCE

Guidance provided for implementing the authority to confiscate drug counterfeits is as follows:

1. The authority is not to be utilized unless there has been an agency determination the drug to be confiscated is a counterfeit and it is a drug which "without authorization, bears a trademark, \*\*\* or any likeness" of a legitimate product. The determination usually is based upon evidence supplied by the firm whose product is being counterfeited. A written agency determination will issue to the Program Division Director from the Office of Enforcement and Import Operations (OEIO), in conjunction with the Center for Drug Evaluation and Research or the Center for Veterinary Medicine.
2. When engaged in counterfeit investigations, you should proceed as follows upon encountering items to be confiscated.
  - a. Evaluate safety needs and check the location to ensure it is safe to proceed. Do not attempt to remove an item by force. If it appears there will be resistance, contact the local police, or other agencies with police powers for backup, if not already done in advance.
  - b. Inventory the items to be confiscated.
  - c. Prepare a written receipt and offer it to the person in charge.
  - d. Remove the items, if possible, from the premises (if they cannot be removed, secure them under seal).
  - e. Place all items removed under lock at a secure location. In most cases, confiscated items will be stored at the program division or resident post office until they are seized.

### 5.1.1.13.3 - FOLLOW UP GUIDANCE

After items are confiscated, certain actions must be taken to bring confiscated items under the control of the court. Proceed as follows:

1. After an item is confiscated, immediately notify your supervisor.
2. Supervisors must then notify the appropriate compliance units of the items confiscated.
3. Compliance units should initiate seizure proceedings against any items confiscated.
4. Office of Medical Products and Tobacco Program Operations (OMPTO) should be advised of any action utilizing this authority.

### 5.1.1.13.4 - SEARCH WARRANTS

[Section 702\(e\)\(2\)](#) contains authority to execute and serve search warrants. Proceed as instructed by your program division after a search warrant has been obtained.

### 5.1.1.14 - Products Imported Under the Provisions of Section 801(d)(3) of the FD&C Act

The FDA Export Reform and Enhancement Act of 1996 (PL 104-134 and 104-180) amended the FD&C Act by adding [Section 801\(d\)\(3\)](#) ("Import for Export") which permits the importation of unapproved drug and medical device components, food additives, color additives, and dietary supplements intended for further incorporation or processing into products destined for export from the United States. Section 801(d)(3) was subsequently amended by Section 322 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ([Bioterrorism Act](#)), Public Law 107-188, which specified certain requirements an importer has to satisfy in order to import a product under this Section. See IOM 6.2.3.4.

#### 5.1.1.14.1 - REQUIREMENTS FOR BIOTERRORISM ACT

These requirements include:

1. A statement confirming the intent to further process such article or incorporate such article into a product to be exported,
2. The identification of all entities in the chain of possession of the imported article,
3. A certificate of analysis "as necessary to identify the article" (unless the article is a device), and
4. Executing a bond providing for liquidated damages in the event of default, in accordance with U.S. Customs. This bond remains in effect until the final product is exported and destroyed.

In addition, the initial owner or consignee must keep records showing the use of the imported articles and must be able to provide upon request a report showing the dis-

position or export of the imported articles. An article imported under this section, and not incorporated or further processed, must be destroyed or exported by the owner or consignee. Failure to keep records or to make them available to FDA, making false statements in such records, failure to export or destroy imported articles not further incorporated into finished products, and introduction of the imported article or final product into domestic commerce are Prohibited Acts under [Section 301\(w\)](#).

Filers making entry under the Import for Export provisions must either identify entry submissions with the OASIS Affirmation of Compliance "IFE" (Import for Export), or supply FDA with written documentation stating the product is entered under the Import for Export provisions. A Certificate of Analysis (as necessary) and identification of all involved entities must be submitted in writing to the import program division. The import program division will forward all written documentation to the home program division of the initial owner or consignee for incorporation into the appropriate Establishment File.

#### 5.1.1.14.2 - INSPECTIONAL PREPARATION

Before conducting an Establishment Inspection, contact your program division's designated individual with access to OASIS/ORADSS Reports to obtain a printout of any import entries made by the establishment under the Import for Export provisions through OASIS. In addition, check the program division factory file for copies of any Import for Export documents forwarded from the import program division where entry was filed. During the inspection examine the firm's records to determine the disposition of any items identified at time of entry as intended for incorporation into products for export. Document any instances in which such products were introduced into domestic commerce or cannot be accounted for (see IOM 6.2.3.4.3).

#### 5.1.2 - INSPECTIONAL APPROACH

An establishment inspection is a careful, critical, official examination of a facility to determine its compliance with the laws and regulations administered by FDA. Inspections may be used to collect evidence to document violations and to support regulatory action, when appropriate, or they may be directed to obtaining specific information on new technologies, good commercial practices, or data for establishing food standards or other regulations. In order to facilitate on-the-job training, multiple points of view, and perspectives of firms being inspected whenever practical, those with assignment authority, should consider assigning different Investigator/s or different Lead Investigators at different times. This is recommended particularly when there have been multiple sequential NAI inspections or when the firm's management has been uncooperative.

The approach and scope (e.g. full scope, limited scope; Level I, II or III; and full or abbreviated) used to conduct an inspection is defined by the compliance program, assignment, and/or your supervisor.

The inspectional approach used is according to the following definitions:

Comprehensive Inspection -directs coverage to everything in the firm subject to FDA jurisdiction to determine the firm's compliance status; or

Directed Inspection -directs coverage to specific areas to the depth described in the program, assignment, or as instructed by your supervisor.

See IOM Subchapter 1.5 and 1.5.5 for information on safety, use of protective gear, trash disposal, dealing with potential hazards and other safety issues.

See special report requirements in IOM Subchapter 1.7.3 when objectionable conditions which may be of public health significance implicate establishments in other division(s).

#### 5.1.2.1 - Depth of Inspection

The degree and depth of attention given various operations in a firm depends upon information desired, or upon the violations suspected or likely to be encountered. In determining the amount of attention to be given in specific cases, consider the:

1. Current Compliance Program,
2. Nature of the assignment,
3. General knowledge of the industry and its problems,
4. Firm history, and
5. Conditions found as the inspection progresses.

#### 5.1.2.2 - Inspection Walk Through

A walk-through inspection of the premises should be conducted as early as possible to become familiar with the operation and to plan the inspection strategy. A walk-through visual inspection of the manufacturing site is helpful in establishing the depth of the inspection, learning about products and processes, identifying sources of manufacturing records and identifying potential areas of concern. The size of the facility, the number of employees, employee practices, environmental conditions inside and outside the plant, raw materials, manual and automated processes, sources of contamination, manufacturing flow, method of data collection including computer terminals, are some of the areas to be taken into consideration in establishing the depth of the inspection. A visual inspection of a manufacturing site should also be used to check obvious potential problem areas such as: general house-keeping, state of operation for processes and processing equipment, and people dependent operations. Visual inspections of areas used for failure investigation, product sampling and testing, product reworks, return goods, and product quarantine areas should be inspected for obvious potential product problems.

Depending on the product being inspected, some of the general inspectional equipment an investigator should have

available, may include, eye and ear protection, boots and protective clothing. Some specialized equipment may include radiation or ethylene oxide (EO) monitoring devices, magnifiers, and timing devices as needed. For some domestic and foreign plant sites, investigators may be required to be inoculated prior to the inspection for protection from potential environmental concerns such as hepatitis, yellow fever, malaria and live biological products which may be encountered in vaccine products. See subchapter IOM 1.5.

### 5.1.2.3 - Signing Non-FDA Documents

Occasionally a firm will request you sign various documents including:

1. A waiver which will exempt the firm from any responsibility or liability should an accident occur, and you are injured on the firm's premises,
2. Form letters concerning access to confidential information the firm does not want released,
3. A training form acknowledging that you were briefed on the personnel gowning procedures,
4. Information/data you request during the inspection be put into writing, etc.

If you receive such a request, inform the firm you are not authorized to sign such documents, letters, requests, waivers, etc., but will report the firm's request in your EIR. All FDA employees are authorized to sign-in and sign-out at a firm and to comply with security measures employed by the firm, including documenting the removal/replacement of seals to inspect vehicles and containers. See IOM 4.3.4.3 and 4.5.4.6. Obviously, the key issue is you are not authorized to waive, without supervisory approval, any of FDA's rights to inspect, sample, photograph, copy, etc. or to sign any interstate shipping record document which could infer the firm could not be prosecuted under the Act.

### 5.1.2.4 - Technical Assistance

If you determine specialized technical assistance is necessary in conducting inspections of new technologies, products or manufacturing procedures, it may be available through Regulatory Technical Assistance Network (rTAN), Produce Safety Network, Programmatic or National experts, other ORA components or Center scientists and engineers. If specialized skills are necessary and are not available locally or through your Division, contact the Division of Domestic Human and Animal Food Operations (DDHAFO) for CFSAN and CVM (food) products or Office of Medical Products and Tobacco Program Operations (OMPTO) for CBER, CDER, CDRH, CTP and CVM medical products. See FMD-142 and IOM 1.9.2.2.1 for additional information.

### 5.1.2.5 - Team Inspections

The use of teams to conduct inspections may be beneficial.

Very often individuals well versed in an analytical or inspectional technique or technology can provide assistance and advice. For combination product inspections, teams may be needed to bring appropriate program expertise to the inspection. (See IOM 5.12.1)

When inspection teams are involved in an inspection, one investigator will be designated as the team leader by the inspecting Division or by DDHAFO or OMPTO if a headquarters directed special inspection is involved. The team leader is in charge of the inspection and bears the overall responsibility for the inspection and the EIR. A team may consist of multiple investigators, laboratory personnel and other FDA employees, and your supervisor/coach, who may participate as part of the ORA Quality Assurance program.

#### 5.1.2.5.1 - TEAM MEMBER RESPONSIBILITIES

Each team member is responsible for preparing those portions of the report pertaining to his/her activities. Team members shall identify their portion of the report, so they can later identify that portion as the part he/she performed and reported. Since reports should be written in the first person, one system might be to head each portion with a statement "The following operation(s) was/were observed and reported by Investigator \_\_\_\_\_", who can then report in the first person.

All team members must sign the EIR. Only those team members present at issuance sign the FDA-483 of FDA 4056. The issuance of the FDA-483 should not be delayed, in the absence of a team member's signature. See IOM 5.2.3 for instructions for signing an FDA 4056 and a multi-page FDA 483.

#### 5.1.2.5.2 - TEAM LEADER RESPONSIBILITIES

The Team Leader shall be responsible for:

1. Issuing unused notebooks for taking regulatory notes during the EI or investigation to headquarters personnel on the team. He/she is also responsible for instructions on their use, if necessary, and when the report is finished, for obtaining the headquarters individual's signature on the original EIR and completed and properly identified regulatory notes and submitting them to the supervisor for filing. See IOM 2.1.3.
2. Directing the overall inspection to accomplish the objectives of the assignment including;
  - a. Planning the inspection,
  - b. Scheduling and coordinating team members' pre-inspection preparations,
  - c. Determining, to the extent possible, the firm will be open and operating,
  - d. Calling to pre-announce an inspection if required
  - e. Planning for needs of visiting scientists if applicable. When the team leader is not familiar with all the processes or technology involved in the inspection, provide for primary coverage of selected areas by other team members,

- f. Determining an orderly, efficient, and effective approach and sequence to be used and discussing the inspection plan with the team,
  - g. Modifying the inspection plan as necessary during the EI, to permit following leads, documenting evidence, etc.,
  - h. Setting team policy on how communications with the firm are to be handled,
  - i. Discussing personal conduct in dealing with headquarters personnel as necessary,
  - j. Assuring an early understanding by team members of their roles in note taking and reporting,
  - k. Assuring communications are open among team members, especially if the team is allowed to separate and work independently,
  - l. Reviewing inspection progress at least daily, discussing remaining objectives with the team members, and setting objectives for the following day,
  - m. Continually assessing the progress of the inspection to evaluate how the inspectional approach is working and to keep the division supervisor advised of the inspection's progress,
  - n. Providing guidance and direction to team members as necessary,
  - o. Advising each team member of reporting responsibilities and dates when drafts are to be provided,
  - p. Following up promptly on any delays or failures to report as required, and
  - q. Assisting the supervisor with further follow up, as indicated.
3. Making sure any person who joins the team after the inspection has started presents credentials and issues an FDA 482, Notice of Inspection to the firm prior to actually taking part in the EI;
  4. Completing and/or correcting the computer-generated coversheet;
  5. Preparing the Summary of Findings;
  6. Completing all headings of an administrative nature in the narrative report;
  7. Compiling and submitting the complete final report; and
  8. Resolving any disputes or differences of opinion among the team members, including items, which may be listed on the FDA 483 or FDA 4056.

### 5.1.2.6 - Post-Inspectional Contacts

If the firm contacts the Investigator after the inspection regarding the inspection or follow-up, the Investigator should refer the request to his or her supervisor or to Compliance Branch if a regulatory action is contemplated. The Investigator should not respond to the firm regarding the adequacy of the firm's response to inspectional observations or any follow-up planned.

After the inspection is concluded, if the Investigator finds that a document or other required information is missing, the Investigator should discuss the needed information and how to proceed with their supervisor.

## 5.1.3 - INSPECTION OF FOREIGN FIRMS

Inspectional requirements apply to all inspections, including foreign inspections. However, there are some exceptions. For instance, the FDA 482 is not issued, unless the firm is a U.S. Military facility. Be guided by relevant Compliance Programs, assignments, and the [Guide to International Inspections](#) and [HHS Travel Manual](#) for other differences.

### 5.1.3.1 – Review of Foreign-Language Document

When reviewing documents in a foreign language, do not use any web and mobile applications translation tools that have not been authorized by FDA for this particular purpose. Use of these tools may result in unauthorized disclosure of non-public information.

If, based on the information you are reviewing, you are confident that manually entering a single word or short phrase into an electronic tool for translation could not possibly jeopardize trade secrets or confidential information, you may do so. Ensure that, if all your searches were read together, the combination of searches would not result in any unauthorized disclosure.”

## 5.1.4 - INSPECTIONAL PRECAUTIONS

Our concern over microbiological contamination emphasizes the need for you to be alert to criticism or allegations that you may have contributed to or caused contamination at a firm. This is especially important in drug firms and high-risk food firms, among others. You must adhere to good sanitation practices to refute any such criticisms. You could also unknowingly introduce or spread disease during inspections of or visits to animal production or sale facilities, conducting environmental investigations at poultry layer facilities, conducting dairy farm inspections or audits of state activities, investigating drug residue reports or working in the veterinary bioresearch area or conducting produce safety inspections. See IOM 5.2.10 for information outlining precautions for you to follow.

Exercise caution in all activities in the firm. Follow the firm's sanitation program for employees and wash and sanitize hands, shoes, vehicles and equipment as indicated. Restrict unnecessary movement between various areas in plants and when possible, complete your activities in one area before moving to the next.

When inspecting areas where sterility is maintained, or sterile rooms are located (especially in pharmaceutical or device firms), follow the sterile program required of the firm's employees. In general, it is unnecessary to enter sterile rooms except in the most extraordinary circumstances. These areas are usually constructed to provide visual monitoring. Take no unsterile items with you (notebook, pencils, etc.). In this type of situation, you can enter your observations in your regulatory notes immediately after leaving the sterile area.

Always use aseptic techniques, including hand sanitizing, when collecting in-line and raw material samples, as well as finished product samples for microbiological examination. See IOM 4.3.6.

Do not use or consume a firm's products at any of a firm's facilities. This could be interpreted as accepting a product as being satisfactory and could possibly embarrass you and the Agency, both during the inspection and in the future. In general, consuming food products in a manufacturing area is considered an objectionable practice.

When conducting inspections of firm's using chemicals, pesticides, etc., ask to review the Material Safety Data Sheets (MSDS) for the products involved to determine what, if any, safety precautions you must take. This could include the use of respirators or other safety equipment.

#### 5.1.4.1 - Clothing

Wear clean coveralls or other protective clothing for each inspection and if circumstances dictate, use a clean pair when returning from lunch, or upon entering certain machinery or critical areas.

Remove all jewelry and secure pens, pencils,, etc., so they cannot fall into the product or machinery. Do not depend on clips on pens, etc., to hold these items in your outer pockets.

Clean protective clothing should be either individually wrapped or placed in clean plastic bags and taped to protect from contamination. If the package has been sterilized, protect the package from possible contamination or puncture. The package should not be opened until you are ready to use the clothing. After use, clothing should be turned inside out as it is removed, and immediately placed in clean paper or plastic bags to prevent spread of contamination until washed and/or sterilized.

Use disposable hair and head coverings throughout the inspection and disposable hand and foot coverings in areas where floor tracking or cross contamination may be a factor. Use hard hats and other protective devices where the situation dictates.

If reusable protective boots are used, wash and sanitize before each use. Always use sterile disposable boot covers when entering machinery such as dryers or where unavoidable contact with product is a factor.

When discarding contaminated disposable head and boot coverings, it is suggested they be placed with used clothing for proper disposal after leaving the plant area.

See IOM 5.2.10.1 for protective clothing and equipment necessary when visiting livestock or poultry producing areas.

#### 5.1.4.2 - PHS Recommendations - Basic Sanitary Practices

FDA personnel are not required by law to have health certificates, take physical exams or submit to requirements, which ensures their compliance with sanitary procedures in the performance of their official duties. However, it is critical you adhere to basic sanitation practices. See IOM 1.5.1.5.

[The Food Code 2017](#) is available electronically from the FDA CFSAN web page under Federal/State Programs-Retail Food Safety References. Printed copies may be ordered from the [National Technical Information Service](#) website.

#### 5.1.4.3 - Representatives Invited by the Firm to View the Inspection

While conducting an inspection, you may find the firm's management has invited individuals who are not directly employed by the firm to view the inspectional process (e.g., representatives from the press, trade associations, consumer groups, congressional staff, other company officials).

Regardless of whom the firm invites to observe the progress of an inspection, the presence of outside representatives should not disrupt the inspectional process. You should continue to conduct the inspection in a reasonable fashion. The presence of these individuals should have no impact on the manner in which the inspection progresses except you should take precautions to preserve the confidentiality of any information you may have obtained as a result of the Agency's statutory authority. This is especially true when the inspection is recorded via videotaping, other photography, and/or audio recordings. Where applicable, refer to IOM 5.3.5 for procedures on how to prepare your own recording in parallel with the firm's recording.

It is the Agency's position that while the investigator must protect privileged information provided to him/her during the inspection, it is the firm's responsibility to protect privileged/confidential information observed or recorded by those individuals invited by the firm.

#### 5.1.5 - GENERAL PROCEDURES & TECHNIQUES

The procedures and techniques applicable to specific inspections and investigations for foods, drugs, devices, tobacco products, cosmetics, radiological health, or other FDA operations are found in part in the IOM (inspectional and investigational policy/procedure), and the Compliance Program Guidance Manual (program specific instructions). Some procedures and techniques which may be applicable to overlapping areas or operations are as follows:

### 5.1.5.1 - Candling

Candling is defined as: "to examine by holding between the eye and a light, especially to test eggs in this way for staleness, blood clots, fertility and growth." Like most techniques learned through the food inspection programs, there are uses for this technique in other program areas such as looking for mold in bottled liquids which could be drugs, devices or biologics. Candling can also be useful in the examination of original documents to see below white-out or to look for over-writing.

Many types of products lend themselves to inspection by some type of candling. For these products, firms generally have candling equipment which may be built into the production lines or may be a separate operation.

Where checking products by candling, it may be possible to utilize the firm's candling equipment. Various other light sources for candling are also available including overhead projectors. Exercise care when using overhead projectors and protect the glass surface and the lens from scratches and damage. All candling is best accomplished when light outside the item being candled is masked so the light passes through the object rather than being diffused around it. A heavy paper or cardboard template can be quickly prepared at the time candling is done.

### 5.1.5.2 - Label Review

Do not undertake a critical review of labels unless instructed by the assignment, program, or your supervisor. Limit your comments to the mandatory label requirements required by the Acts. However, if after review of the formula, it is obvious an active ingredient or an otherwise mandatory ingredient statement does not appear on the label, such discrepancy may be called to management's attention. See also IOM 5.2.3.2 regarding labeling for blood and blood products.

If asked for other label comments, refer the firm to the appropriate Center to obtain a label review.

When the labeling is suspect or when you are requested to collect labels/labeling, **collect a copy** of all labels and accompanying literature for further review. For medical devices, if there is a question regarding the need for a new 510(k) or PMA supplement, it is essential the label and labeling be collected.

### 5.1.5.3 - Field Exams

A field examination is an on-site examination of a domestic product (or a foreign product in domestic channels of trade) sufficient in itself to determine if the product is in compliance with the Acts enforced by FDA. A field exam can be conducted of any commodity in any location. It is important to conduct field examinations during food inspections to detect violations, e.g., undeclared sulfiting agents, Certified color additives and allergens. If the examination does not reveal a violation or the appearance of a violation, a sample of the lot is usually not collected. If

your exam reveals a violation or potential violation, you should collect an official sample. Instructions on how to conduct a field exam are contained in "Guides to Inspection of \*\*\*" and Compliance Programs. The Sample Schedules in Chapter 4 also provide guidance on lot examinations for special situations.

## SUBCHAPTER 5.2 - INSPECTION PROCEDURES

### 5.2.1 - PRE-INSPECTIONAL ACTIVITIES

Prior to the start of any inspection or investigation, you should conduct a number of activities. These will differ based on whether this is an inspection or an investigation. Review establishments history, e.g. previous EIRs, complaints, registration listing, recalls. The purpose of this review is to determine the location of the establishment and obtain an overview of the establishment's operations and products as well as an understanding of their compliance history. Consumer complaint review will also determine if there are any complaints with open assignments, or with the status "Surveillance information for next EI" that need to be closed. You should also review the establishment factory jacket to determine if there were any prior safety issues noted, e.g. documented Investigator safety incidents or whether any specific personal protective equipment is needed prior to the start of the inspection. If there has been a past personal safety incident, you should discuss with your supervisor and develop a Situational Plan prior to the start of the inspection. See IOM 5.2.1.4 – Personal Safety Plan.

Prior to initiating any inspection, you should become familiar with the reporting requirements for the specific assignment, as well as the requirements of IOM Subchapter 5.10.

If the inspection or investigation is a directed assignment from a Center, ORA headquarters or another program division, read the assignment and attached materials to assure you understand the assignment. If the inspection or investigation is being conducted in part or solely as a recall follow-up or complaint, refer to Chapter 7 (Recalls) or Chapter 8 (Investigations) of the IOM for additional guidance.

You should review the eNSpect assignment to determine if the Personal Safety Alert Indicator is set to yes for this specific firm. The reason for the Personal Safety Alert should be listed in the Endorsement for the previous inspection and should be accompanied by a memo to the Establishment File Jacket. See IOM 5.2.1.3 eNSpect Personal Safety Alert.

You should also review the applicable Compliance Program Guidance Manual(s) prior to the start of your inspection or investigation. Division of Domestic Human and Animal Food Operations (DDHAFO)The Centers have issued numerous guidance documents for industry. These



documents are normally posted to the appropriate Center's Internet web site.

Subchapters 5.4-5.9 of the IOM contain additional, program specific pre-inspectional activities, which you should follow.

Imported products cross all program areas and our regulation of them does not stop at the border. Determine if there are any "import for export" follow-up assignments and be prepared to cover them during your inspection. See IOM 6.2.3.4 for guidance. Please be alert to imported products whenever you make an inspection. During inspections of domestic firms, if you encounter imported products that appear adulterated, misbranded, counterfeit, tampered with or otherwise suspect, attempt to fully identify the product and the source of the imported products. Contact your supervisor and Division of Import Operations (DIO) if necessary.

### 5.2.1.1 - Pre-Announcements

Pre-announcements are mandatory for all medical device surveillance inspections in accordance with the criteria and instructions below and some BIMO inspections. Routine produce safety inspections should be pre-announced, unless otherwise directed. In some other program areas, pre-announcements may be made at the discretion of the program division. If you are going to visit facilities where livestock (including poultry) or wild animals are housed or processed, review IOM 5.2.10. In general, it may be inappropriate to pre-announce inspections of food establishments, blood banks, source plasma establishments and some BIMO inspections, but this too is subject to program division discretion.

If a program division believes pre-announcing an inspection of an establishment will facilitate the inspection process, then the procedures below for doing pre-announcements for medical device inspections should be followed. ORA's primary purpose for pre-announcing is to assure the appropriate records and personnel will be available during the inspection. It is not to make an appointment for the inspection. It should not be referred to as an appointment to inspect. When doing a pre-announcement, it is important you communicate to the establishment the purpose of the inspection and a general idea of the records you may wish to review. If you find neither the appropriate personnel nor records available, note this in your Establishment Inspection Report (EIR).

In the case of drug inspections, if efforts to schedule a pre-announced inspection are met with unreasonable delays by the establishment, including requesting a later start date without a reasonable explanation, it may constitute a delay of an inspection under section 501(j) of the FD&C Act [21 U.S.C. 351(j)]. FDA will make reasonable accommodations for local conditions such as weather, holidays, or, where appropriate, manufacturing campaign schedules. However, if faced with an unreasonable delay by the establishment, you may call the responsible person's attention to 501(j) of the Act. Talk with your supervisor to determine whether the length of a particular delay may be

considered unreasonable, even in cases in which the explanation given for the delay may be reasonable.

The Program division may use this data in the future when considering whether this establishment should be eligible for pre-announced inspections.

The Produce Safety Network (PSN) should follow the pre-announcement instructions provided in the Produce Safety Inspections assignment.

The following is the general outline for pre-announcement of medical device inspections. You are advising the establishment's management of the date and time you will be arriving at the establishment to conduct the inspection. The establishment has no authority to negotiate this. If you, as the investigator, feel the need to accommodate the establishment's request, be sure there are sound reasons for doing so and report them in your inspection report.

In the eNSpect "Pre-Announced / Unannounced to Firm" field select "Unannounced" when no notification was provided to the firm in advance of arrival at the firm for inspection. Select "Pre-announced" when the firm was notified of the inspection prior to the CSO arrival at the firm for the inspection.

#### 5.2.1.1.1 - BASIC PREMISES

Pre-announcement of inspections is to be applied only to establishments that meet specific criteria. Pre-announcement may be considered for establishments that manufacture both drugs and devices or biologics and devices. The eligibility of an individual establishment for pre-announced inspection is at the discretion of the inspecting Division using clearly described criteria. (See Criteria for Consideration) The program division does not have the discretion to decide the types of medical device establishments eligible for pre-announcement but may decide the specific establishments' eligibility because they meet the criteria.

The pre-announcement should generally be no less than 5 calendar days in advance of the inspection. Should a postponement be necessary, the decision as to rescheduling rests with the investigator/team, but the new inspection date should not be later than 5 calendar days from the original date. Inspections may be conducted sooner than 5 calendar days if requested by or acceptable to the establishment and if this date is acceptable to the investigator/team.

To participate in the pre-announcement portion of the program, establishments are expected to meet the commitment to have appropriate records and personnel available during the inspection.

Pre-announced inspections will not limit an investigator's authority to conduct the inspection. Inspections will be as thorough as necessary.

**5.2.1.1.2 - CRITERIA FOR CONSIDERATION**

Determine whether an establishment requires or qualifies for a pre-announced inspection (see section 5.2.1.1 Pre-Announcement). Examples include:

1. Pre-market inspections (PMA, 510(k))
2. Foreign inspections
3. Instructed by Compliance Program, assignment or directive
4. Quality System Surveillance Inspections
5. During Health Emergency Crisis; e.g.: epidemic, pandemic

**5.2.1.1.3 - PROCEDURES**

Procedures:

1. The investigator designated to conduct the inspection will contact the most responsible individual at the facility. You should leave a message requesting a return call if the most responsible person at the facility is unavailable at the time the call is made. The program division should use good judgment as to what is a reasonable time frame to await the return call.
2. Changes in dates should be kept to a minimum. If a change is made, a new date should be provided as soon as possible, which will facilitate the inspection and accommodate the investigator's schedule. The establishment should provide a valid reason for requesting a change in the start date. A valid reason should be the same as you would accept if presented with the information during an unannounced inspection.
3. Inform the establishment as to the purpose, estimated duration, and the number of agency personnel expected to take part in the inspection. The products or processes to be covered should be described if this will facilitate and be consistent with the objectives of the inspection.
4. When appropriate, specific records/personnel will be requested at the time the inspection is pre-announced.
5. The notification should be as specific as reasonably possible and specify the date for the start of the inspection.
6. Produce Safety Inspections should follow any additional instructions provided in the Produce Safety Inspection assignment.

Include in your EIR whether or not the inspection was pre-announced and include information on any difficulties experienced in notification or accessing records or personnel, which should have been available as a result of pre-announcing the inspection. For medical device establishment inspections, if not pre-announced, describe briefly in the EIR why not. If an establishment should become ineligible for pre-announcement, the endorsement of the EIR should include this statement. This information will be necessary for making a determination regarding future pre-announced inspections of the establishment. In addition, it is advisable to inform the establishment during the current and subsequent inspections of the action(s), which may have caused them to be ineligible for pre-announcement.

Subchapters 5.4-5.9 of the IOM contain additional, program specific pre-inspectional activities, which you should follow.

**5.2.1.2 - Personal Safety**

ORA considers the safety of investigators, inspectors and all those who meet with regulated industry to be of the utmost importance. Personal safety concerns are defined as those factors FDA employees should maintain awareness of which potentially affect their safety during an inspection, such a threatening situation; or where specific personal protective safety equipment is warranted; or where a particular inspection may be medically contraindicated for specific FDA personnel. When these conditions are noted during an inspection, the investigator should discuss the situation with their supervisor and ensure that the Personal Safety Alert is checked in FACTS/ eNSpect and a Memo to the File is generated – see IOM 5.2.1.3. For information concerning personal protective equipment, see IOM Subchapter 1.5.

Physical resistance to FDA inspections and threats to, or assaults on, FDA employees engaged in their work are extremely rare. However, there will be times you are confronted by unfriendly or hostile persons. ORA has offered various conflict resolution training courses to assist and prepare you for how to diffuse a situation. In most instances, conducting your activities with tact, honesty, diplomacy, and persuasiveness will be enough to diffuse the situation. While at times, you may have to adopt a firm posture, you should not resort to threats, intimidation, or strong-arm tactics. Refer to IOM 5.2.5.4 for Hostile and Uncooperative Interviewees.

Safety is the responsibility of all FDA employees, including you, your supervisor and other Agency management. When you receive an assignment, it is important to evaluate the assignment not only in accordance with IOM Section 5.2.1, but also with respect to your personal safety. If you determine there is the possibility of a threat to your personal safety, consult with your supervisor. You and your supervisor should consider developing a Situational Plan in preparation for the inspection.

**5.2.1.2.1 - PREPARATION**

Below are some suggested items the program division may consider when preparing for your next assignment to assess if there are potential personal safety issues. This list is not meant to be all inclusive.

1. Does the assignment involve working with other Federal Agencies such as U.S. Marshals, Federal Bureau of Investigations, and U.S. Customs in executing search warrants, seizures, etc.?
2. Does the assignment involve working with or contacting FDA's Office of Criminal Investigations (OCI)?
3. Does the assignment involve a firm where there is a suspicion and/or knowledge of questionable or illegal activities?
4. Does the assignment involve a suspected tampering and/or a visit to an individual's residence?

5. What is the past history from a personal safety standpoint with the prior interactions with representatives of this firm? Have the FDA's state counterparts or other Federal and/or local agencies indicated a concern for personal safety? What does the firm's establishment file indicate about personal safety over the past inspections?
6. What is the location of the firm or the operation? Is it in an area which may be unsafe? Have the inspected firm or any of its employees been uncooperative with government officials?
7. Is the firm known to the Agency? Has the Agency any additional information which would assist in your evaluation?

If these questions and/or others result in a concern for your personal safety, then a Personal Safety Plan should be developed and approved by program division management before conducting the assignment. See IOM 5.2.1.4 – Personal Safety Plan.

Due to the unlimited variability of potential safety situations, it is not feasible to prescribe in the IOM what to do in every instance. The decision of what to do in each individual circumstance rests with the investigator and their program division management. Your program division management is most familiar with the specific firm in question, the regulated industry, as well as other local Federal, State and Local officials who may be able to provide you additional information and assistance. In addition, the experience of your program division management combined with the various training courses on conflict resolution may also be consulted. Program divisions should notify OMPTO or OHAFO to inform headquarters of any potential safety concern, so that personal safety issues may be tracked. The headquarter component will also maintain a library of Personal Safety Plans which may also be of use to your Division. The headquarter component may be contacted at the following personal safety e-mail address: [orahqcsosafety@fda.hhs.gov](mailto:orahqcsosafety@fda.hhs.gov).

### **5.2.1.2.2 - PHYSICAL RESISTANCE/THREATS/ ASSAULTS**

If you receive physical resistance or threats, or if you sense the real possibility of an assault, disengage from the confrontation, get to safety, and call your supervisor immediately. Make careful and exact notes later of who said what to whom, who did what, and whether someone tried or succeeded in threatening, assaulting or taking information or equipment or samples from you. Be careful in any descriptions you give or write of such events, just as you are in recording other evidence that may result in a court case. Your safety is more important to the United States than the inspection or the sample collection. FDA will work with law enforcement government officials, e.g., the Federal Protective Service (FPS), FDA's Office of Criminal Investigations' (OCI) Special Agents, local police, or United States Marshals to assist an inspection team if there is a reasonable fear of danger to the investigator.

If you are assaulted (either physically or put in fear by threats of physical violence), your supervisor can summon local police, the Federal Protective Service (1-877-437-7411), United States Marshals, FBI or contact OCI headquarters for assistance (301-294-4030). While OCI does not normally provide physical security in these cases, they will assist in threat evaluation based on specific facts and available criminal databases. OCI can also make contacts with local police and federal agencies based on previous established liaisons. If you have been assaulted or threatened and you are unable to reach your supervisor or other division management, you should contact the local police in the area where the assault or threat occurred. Be careful in any descriptions you give or write of such events, just as you are in recording other evidence that may result in a court case. Make sure that any inspected facility where weapons are observed, or where threats or assaults occur, is identified on that facility's Endorsement page of the inspection report for that facility and to your supervisor, so that Investigators or Agents who follow you into that facility will be alert to those possibilities. Your supervisor would also be responsible for checking the Personal Safety Alert box in FACTS and for beginning the notification process to alert other Federal or State agencies that also inspect the facility of the possible danger. For more information see IOM 5.2.1.3 Personal Safety Alert. For specific safety guidance related to inspections and interviews, see IOM 5.2.5.4.2 Hostile and Uncooperative Interviewees.

In addition, in any instance where you have perceived a threat to your personal safety during an inspection, investigation or sample collection, you should exit the situation immediately and report it to your supervisor. Potential threats may include geographic locations, concern about entering into a residence to conduct official business, or animals that are not caged or contained. You should then write a memorandum of the event in a factual manner including information pertaining to the who, what, when, where, and how of the event. Be careful in any descriptions you give or write of such events, just as you are in recording other evidence that may result in a court case. This memo will be filed in the official establishment file jacket and copies be sent to any and all resident posts and import program division offices who may interact with this firm. The memo will be filed on the opposite side of the folder from all other documents and will be a printed on eye-catching color paper in order for the document to be visible to the next Investigator. The memo should be retained and maintained within the division. A copy of the Memo documenting the personal safety situation should also be sent to the headquarter component via [orahqcsosafety@fda.hhs.gov](mailto:orahqcsosafety@fda.hhs.gov).

### **5.2.1.3 – eNSpect Personal Safety Alert**

In eNSpect, the person creating an assignment may add an "Active Personal Safety Alert" (PSA) on the "Firm" page. This field is editable any time after the assignment is created. The "Personal Safety Alert" tab on the "Firm Details" page in Management Services (FMS) should be checked for the existence of a PSA when assignments are

created and before inspections are conducted. Only the FACTS Supervisor Role will allow for updating the Maintain Firms screen. This personal safety alert may be selected when there is a potential hazard identified:

1. Where a previous threat/assault or physical resistance occurred
2. Where specific personal protective equipment is needed (respirators, etc.)
3. Where there are specific medical considerations for a population of investigators (e.g. the firm manufactures a drug hazardous to women of child-bearing years or those with allergies to peanuts, penicillin, or other products.)

In any example listed where there is a Personal Safety Alert, the specific safety alert should be documented both in the Endorsement and in a Memo to the File. The memo should be flagged "MEMO TO FILE - PERSONAL SAFETY ALERT" and should provide the factual information to support why the investigator should be alerted to the safety issue. Be careful in any descriptions you give or write of such events, just as you are in recording other factual evidence that may result in a court case. The memo should be filed in the official establishment file jacket and copies sent to any and all Resident Posts and import program divisions who may interact with the firm. The memo will be filed on the opposite side of the folder from all other documents and will be a printed on eye-catching color paper in order for the document to be visible to the next Investigator. The memo should be retained and maintained at the Program division office. A copy of the Memo documenting the personal safety situation should also be sent to [orahqcsosafety@fda.hhs.gov](mailto:orahqcsosafety@fda.hhs.gov). The supervisor and/or other program division management will be responsible for evaluating any corrective actions taken by the firm or individual to remove or stop the potentially dangerous situation or condition. Follow-up inspections at the facility should continue to document whether or not the safety situation continues exists. If the situation has been resolved (new management, dismissal of an employee, cessation of penicillin in a facility, etc.) the Personal Safety Alert should be removed from FACTS by the supervisor.

#### 5.2.1.4 – Personal Safety Plan

A Personal Safety Plan is an investigative tool developed to assist in managing and preparing for a potentially dangerous situation. Program division's should develop a Personal Safety Plan when the conditions surrounding the specific inspection, investigation or sample collection indicate a plan is needed. The plan allows all those involved to carefully evaluate the specific inspection in order to prepare for a successful conclusion. Utilizing Personal Safety concepts prior to a potentially dangerous situation is part of the training programs of many other Federal Agencies. The plan should document what specific roles and responsibilities are needed to conduct the inspection/investigation or sample collection. The plan should also answer the questions: Who, What, Why, When and Where concerning the potential danger.

There are seven principles to a Personal Safety Plan. These are:

1. **Summary of Potential Hazards:** This section of the personal safety plan includes all of the potential hazards, in a detailed description, that prompted the need for a personal safety plan. Be sure to answer the questions: Who, What, Where, When, and Why. Also include any specific hazards that require personal protective equipment or situations at the facility that may cause allergic reactions for investigators or analysts. Include in the section information from past inspection reports, discussions with previous FDA, State or local investigators, as well as any environmental or plant/facility specific information that would negatively impact a successful personal safety plan when initiated.
2. **Sources of Information:** This section of the personal safety plan includes all the sources from which your potential hazards were collected. For instance, document which FDA investigator or State inspector supplied factual statements; state the documents or databases from which you obtained information to assist in your hazard summary. This section is important, as it documents factual evidence, similar to all of your other FDA factual inspection gathering information.
3. **Response Alternatives:** This section will be the most important part of your plan because it includes all of the details of what will be done to mitigate the hazards. In this section, provide a list of factual, practical responses or options to consider. This will also allow your supervisor to see all the possible ways to handle the situation. The response plan should also outline all of the tools that you possess to assist you in handling the situation carefully, including training, experience, and other procedures you have at your disposal. Roles and responsibilities of all involved in the plan should be identified including those intended to be on-site, and those who will be off-site, and participating in the plan.
4. **Communication:** provide all information about how communication will occur between on-site and off-site participants; between those present on-site, and any emergency, law enforcement or medical responders. Also consider types of communication, e.g. code words for emergencies.
5. **Transportation:** Provide information in the plan as to how travel to the facility will happen. Is there a coordination point? Do you intend to use Government marked or unmarked cars? Who will ride in each car? What route will be taken going to and leaving the facility? Consider where you will park the car when you arrive at the facility. Consider what modes of communication will be used to communicate if multiple vehicles are used.
6. **Equipment:** Include in this section all equipment needed to initiate this plan. Is personal protective equipment needed? Is there any special sampling equipment or other equipment needed? Include in this section, equipment such as communication tools, FDA forms, etc. Assure that the equipment needed is in full functioning mode.

7. Emergency Exit Strategy: Describe in this section what the exit strategy will be in the event of an emergency. Consider emergency strategies for safety (issues), as well as any medical emergency. How will the emergency be communicated on-site and off-site? How do you exit the facility and return to your vehicle? Is there a scheduled meeting point to assure all are safe? The goal is to have no one left behind. Remember to contact your supervisor when you return to safety.

Once the plan has been completed, a debriefing of the situation should occur with all who were involved in the plan development. Evaluate what went well, what needed improvement, what would be done differently the next time. Evaluate whether the plan was successful and document lessons learned for the next time.

The Personal Safety Plan should be developed by the investigator, supervisor, other investigators who may be familiar with the facility, compliance officer, if needed, and any other individuals (Program Division or HQ experts, etc.) who may be able to assist in the depth, scope, and specifics of the firm in question. The decision of who should be involved in the development and approval of the plan is left to the program division's discretion.

Program division management and all involved in writing the personal safety plan should meet when necessary in order to assure a well-developed and understood personal safety plan. You and your supervisor should maintain contact during the execution of the personal safety plan. The supervisor should contact the employee during these personal safety situations at a predetermined frequency outlined in your plan. A debriefing session should be held following the execution of the plan. Discussions should include what actions worked well and where there are areas of improvement.

For foreign inspections where a Personal Safety Plan is warranted, headquarters POC will assist the inspection team. The inspection team's management may also wish to participate so that there is clear understanding of what actions will be taken for the foreign inspection.

The Personal Safety Plan should be placed in the official establishment file jacket separate from any EIRs in the same location as any Personal Safety Alert memos. A copy of completed and executed Personal Safety Plans must be sent to [orahqcsosafety@fda.hhs.gov](mailto:orahqcsosafety@fda.hhs.gov) in order to maintain a reference library of all Personal Safety Plans.

## 5.2.2 - NOTICE OF INSPECTION

Upon arrival at the firm locate the owner, operator or agent in charge of the establishment. This should be the top Management Official on site. Be certain of this individual's status. Introduce yourself by name, title and organization. Show your credentials to this person and present a properly signed, completed original of the FDA 482, Notice of Inspection or FDA 482d Request for FSVP Records. The

FDA-482 or FDA 482d should have the address of the home district of the firm. \*

If additional Agency personnel accompany you during the inspection, they must show their credentials to the top Management Official upon arrival at the site. A new FDA 482, Notice of Inspection or FDA 482d Request for FSVP Records must be issued. Submit a copy of the FDA 482(s) or FDA 482d with your EIR. Explain the purpose of your visit. Readily accept any management offer to have a representative accompany you on the inspection.

If non-FDA officials accompany you during your inspection and do not have authority to enter and inspect, you should obtain permission (preferably in advance) from the most responsible individual at the firm. Non-FDA officials and those who do not hold FDA credentials do not sign the FDA 482 or FDA 482d. See IOM 5.1.1 and 5.11.4.3.3.

For multiple occupancy inspections in drug establishments, refer to IOM 5.1.1.11. Inspections of multiple firms, which are separate legal entities, should be reported under separate EIRs.

If faced with a refusal, or partial refusal of inspection, proceed as outlined in IOM 5.2.5.4.

Any time an FDA 482 is issued, also issue an FDA 484 (at the conclusion of the inspection), Receipt for Samples, if you collect any samples at the firm. See IOM 5.2.4. See IOM 4.1.1.1 and 4.1.1.2 for instructions for issuance of the FDA 482 in certain sampling situations.

If you have concerns of when to or when not to issue the FDA 482, discuss with your supervisor.

\*: For all firms within the State of Arizona, the Home District is Denver District. Home District boundaries are identified in Appendix E.

### 5.2.2.1 - Multiple Date Inspections

If your inspection covers more than one day, advise management at the close of each day you have not finished the inspection and when you will return. Do this each day until you finish the inspection. An FDA 482 or FDA 482d is not required for each day of an inspection or when different individuals are interviewed. If there will be an extended period of time (i.e., a week or longer) before you can return to the firm to complete the inspection, be sure management is aware of the delay and discuss with your supervisor whether or not you need to issue another FDA 482 or FDA 482d.

### 5.2.2.2 - Inspection of Vehicles

If vehicles are present which are owned or leased by the firm being inspected and it is necessary to inspect the

vehicles, the inspection of these is covered by the FDA 482, Notice of Inspection, you issued to the firm.

If vehicles (trucks, trailers, RR cars, etc.) which are not owned or leased by the firm are present and inspection is necessary, a separate FDA 482, Notice of Inspection, is required:

1. Issue the FDA 482 to the driver of the vehicle.
2. If the driver is not present and if, after a diligent search, he cannot be located, issue a separate FDA 482 jointly to the firm being inspected and to the firm whose name appears on the cab. Enter the license number of the vehicle on the FDA 482. Give the original FDA 482 to the firm and leave a copy in the cab of the vehicle.
3. If there is no cab present, prepare a separate FDA 482 modified to read "\*\*\* to inspect unattended vehicle \*\*\*" and issue it to the firm being inspected as the "agent in charge" of the vehicle. Enter the license number of the vehicle, trailer or RR car number, etc., on the FDA 482. Should the firm being inspected refuse to accept the Notice, leave it in a conspicuous place in the vehicle. Describe the circumstances in your EIR.

### 5.2.2.3 - Follow-Up Inspections by Court Order

At times you may be instructed to conduct inspections of firms by authority of an injunction or other court order. This situation provides separate and distinct inspectional authority involving both the authority of the court order and the authority of [Section 704 of the FD&C Act](#) [21 U.S.C. 374], each providing independent courses of action.

When assigned to conduct inspections under these situations, obtain a copy of the injunction or other court order bearing the filing stamp and all relevant signatures. Prior to starting the inspection study, the order thoroughly for any special instructions of the court. Your supervisor will assist you in determining the depth of the inspection necessary to cover all of the court requirements.

Take a clearly legible copy of the court decree (not necessarily a certified copy) with you to the firm to be inspected.

Present your credentials in the same manner as for any other EI. Issue the FDA 482, Notice of Inspection, modified to read, "Notice of Inspection is hereby given under authority of injunction (provide here the injunction number and/or other identification) against the firm and pursuant to Section 704 \*\*\*". Show the person to whom the FDA 482 was issued a copy of the Order, and, read the following statement to that person.

"This inspection is being conducted under the authority of injunction (add the injunction number and/or other identification) (or other court order) granted by the United States District Court against this firm on (date). The inspection will cover all items specified in the decree. In addition to the inspection authority granted in the court decree, I am issuing you a Notice of Inspection under the authority of Section 704 of the Federal Food, Drug and

Cosmetic Act which authorizes inspections of firms subject to that Act."

If the firm refuses access to records, facilities, or information for which the decree provides inspectional authority, read the pertinent section(s) or portion of the order to the person refusing so there will be no misunderstanding as to the requirements of the decree. If the person still refuses, report the facts to your supervisor as soon as possible so the court can be promptly advised of the situation. See IOM 5.2.5 for information on handling refusals.

When you prepare your EIR, describe the sequence of events in detail including exactly what happened and how you handled the situation. This documentation will help support any charge of violating the court order and/or [Section 704 of the FD&C Act](#) [21 U.S.C. 374].

The court order may require a report to the court. Discuss this with your supervisor since the division will normally handle this part of the requirement.

### 5.2.2.4 - Conducting Regulatory Inspections When the Agency is Contemplating Taking, or is Taking, Criminal Action

You should not issue a Notice of Inspection if the agency is contemplating taking, or is taking, criminal action against a firm without first discussing the matter with your supervisor. Program division management will obtain advice from the Office of Chief Counsel and will allow or not allow, the inspection to proceed based on any considerations related to the criminal investigation. Decisions to inspect under such circumstances should be based on considerations of whether or not the request is consistent with FDA's responsibility to assure articles are not produced or distributed in violation of the Federal Food, Drug, and Cosmetic Act or other Federal law within FDA's jurisdiction. The program division should ensure these considerations are documented. In no circumstance should an inspection be conducted *solely* to obtain evidence to support a possible criminal case.

Inspections conducted in accord with this responsibility to protect the public and limited in scope to the authorizing statute are lawful even when criminal action is being considered or pursued. The Fourth Amendment to the United States Constitution prohibits searches without a warrant supported by probable cause. One exception to the warrant requirement includes the inspection of industries long subject to close supervision and inspection, which are conducted under a statute dispenses with the need for a probable cause warrant. Three criteria must be met under this exception from the warrant requirement. First, the regulatory scheme authorizing the regulatory inspection must be supported by a substantial government interest. Second, regulatory inspections must be necessary to further the regulatory scheme. Third, the statute's inspection program, in terms of the certainty and regularity

of its application, must provide a constitutionally adequate substitute for a warrant.

Section 704 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] is appropriately designed to allow regulatory inspections within appropriate limits. This provides the authority to inspect at reasonable times, within reasonable limits, and in a reasonable manner, establishments or vehicles being used to process, hold, or transport food, drugs, devices, or cosmetics. See IOM 2.2.1.1. FDA's normal inspection procedures provide guidance on what should be considered reasonable under Section 704.

Should the evidence obtained during an inspection become material to a criminal case, it is possible a defendant will claim the use of statutory authority to conduct the inspection was a pretext to conduct an unlawful warrantless search. As long as the limits of Section 704 and normal establishment inspection procedures are followed, the possibility a court will find the inspection to be pretextual should be minimal. Deviations from these limits make it more likely a court would find the use of statutory authority to be pretextual and render the evidence obtained to be inadmissible. Concerns related to the conduct of an inspection while a criminal investigation is being considered or pursued should be discussed with the Office of Chief Counsel.

It is the responsibility of the office generating the inspection assignment to inform the program division if a criminal action is ongoing or contemplated. There may be occasions when neither the office generating the inspection assignment nor the Program division conducting the inspection is aware the Office of Criminal Investigations (OCI) is conducting a criminal investigation of a firm which is subject to regulatory inspection. OCI may determine it is not in the interest of the agency to disclose to other components of FDA the existence of its investigation, as long as OCI is not involved in the agency decision to conduct a regulatory inspection. However, OCI and other components of FDA may also share information as set out below.

### **5.2.2.5 - When Evidence of a Criminal Violation is Discovered in the Course of a Regulatory Inspection**

There may also be occasions where you are conducting a regulatory inspection at a facility, and, in the course of the inspection, you discover evidence of a criminal violation. If this occurs, you should continue the regulatory inspection as you would under normal circumstances. See IOM 5.2.2.4. Document the observation and notify your supervisor. The program division should refer the observations to OCI for their consideration. Evidence of the observation could be used in a criminal investigation, and the evidence could legally be disclosed to criminal investigators.

If you become aware of an ongoing criminal investigation, notify your supervisor. The program division should follow the Regulatory Procedures Manual (RPM) and notify the

appropriate Center of any OCI involvement in a Center directed inspection.

The discovery of evidence of a criminal violation may also be relevant to FDA's responsibility to assure articles are being produced in conformity with the Food, Drug, and Cosmetic Act. Additional inspections may be warranted. Such inspections should be planned and documented in accordance with the preceding section, "Conducting Regulatory Inspections When the Agency is Contemplating Taking, or is Taking, Criminal Action."

### **5.2.2.6 - Use of Evidence Gathered in the Course of a Criminal Investigation**

The extent to which information gathered in the course of a criminal investigation may be shared with other components of FDA will vary with each case. Investigators should determine the extent of information sharing in accordance with the following guidelines.

Information and evidence gathered in the course of a criminal investigation may be shared with regulatory personnel, subject to two reservations:

1. Information obtained pursuant to grand jury subpoena or testimony may not be shared. Disclosure of such information to anyone other than individuals identified by the Department of Justice attorney involved could subject the individual making the improper disclosure to sanctions for contempt by the court. Only the court can authorize disclosure beyond these parameters. Information obtained by other means (search warrant, cooperative witnesses, surveillance, etc.) may be shared, subject to the following paragraph.
2. There may be a need to protect the confidentiality of the criminal investigation. For example, disclosure to regulatory investigators might prematurely disclose the existence of the criminal investigation or the identity of confidential informants. However, whenever you are calculating the need to protect the confidentiality of information gathered in the course of a criminal investigation through means other than the grand jury, you must consider whether it will be in the interest of public health to protect the confidentiality of that information.

Criminal investigators should consult their supervisors to determine whether disclosure should be made to regulatory investigators.

### **5.2.2.7 - Use of Evidence Voluntarily Provided to the Agency**

Criminal and regulatory investigators may share information and evidence voluntarily provided to FDA, without use of the regulatory inspection authority, search warrant, or subpoena. If criminal investigators decide not to share such information because of a need to protect the confidentiality of the criminal investigation, they should consider the potential impact on the public health of protecting the confidentiality of that information.

### 5.2.2.8 - Concurrent Administrative, Civil, and Criminal Actions

It may be appropriate to seek administrative and/or civil remedies against a firm or individual under investigation for criminal violations. There are many issues involved in determining whether such actions may proceed concurrently, or whether certain actions should proceed first. Each situation must be evaluated on an individual basis. If administrative and/or civil remedies are under consideration against a firm or individual also under investigation for criminal violations, representatives from the Center responsible for evaluating the administrative and/or regulatory action should meet with the Office of Criminal Investigations Headquarters staff to discuss issues related to the timing of administrative, civil, and criminal actions. The Office of Criminal Investigations and other components of FDA may share information subject to the reservations set out earlier.

### 5.2.2.9 - Working with a Grand Jury

Finally, if you are assigned to work with a grand jury, you should not participate in a regulatory inspection or other regulatory matter involving the same firm or individual(s). Such participation is contrary to long standing agency policy, might be unlawful, and could result in sanctions against the investigator and the agency. You should not participate in any regulatory matters that could result in improper disclosure of grand jury information, even after the grand jury investigation is closed. Grand jury proceedings remain secret even after they are concluded. Under no circumstances should you undertake such participation without first obtaining clearance from the Department of Justice attorney or the Office of Chief Counsel attorney assigned to the grand jury case. See IOM 2.2.7.3 for additional information on Grand Jury proceedings.

### 5.2.3 - REPORTS OF OBSERVATIONS

The FDA 483, Inspectional Observations (see Exhibit 5-5) and the FDA 4056 Produce Farm Inspection Observations (See Exhibit 5-18) is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts (see IOM 5.2.3.2) which were observed during the inspection. These observations are made when in the investigator's "**judgment**", conditions or practices observed, indicate that any food, drug, device, or cosmetic have been adulterated or are being prepared, packed, or held under conditions whereby they may become adulterated or rendered injurious to health. The issuance of written inspectional observations is mandated by law and ORA policy.

Be alert for specific guidance in assignments or Compliance Programs which may supplement the following general instructions.

All FDA-483s and FDA 4056s should adhere to the following general principles:

1. Observations which are listed should be significant and correlate to regulated products or processes being inspected.
2. Observations of questionable significance should not be listed on the FDA-483 and FDA 4056, but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation. This discussion will be detailed in the EIR.

All FDA-483s and FDA 4056s should have the following characteristics to be useful and credible documents:

1. Each observation should be clear and specific.
2. Each should be significant. Length is not necessarily synonymous with significance.
3. Observations should not be repetitious.
4. The observations should be ranked in order of significance.
5. All copies of the FDA-483 and FDA 4056 should be legible.

If an observation made during a prior inspection has not been corrected or is a recurring observation, it is appropriate to note this on the FDA 483 and FDA 4056.

Investigators and analysts should make every reasonable effort to discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when the FDA 483 or FDA 4056 is issued. This discussion should include those observations, which may be written on the FDA 483 or FDA 4056 and those that will only be discussed with management during the closeout meeting. Industry may use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made during the inspection process. Investigators are encouraged to verify the establishment's completed corrective actions as long as the verification does not unreasonably extend the duration of the inspection.

Corrective actions observed during a produce safety inspection are noted on the FDA 4056. Corrective actions not related to a significant observation are noted in the inspection notes and in the EIR. For annotations of the FDA 4056, refer to Section 5.2.3.4 - Annotation of the FDA 483 and the FDA 4056.

Include the results of confirmed positive environmental samples on the FDA-483 or the FDA 4056 if results are known prior to closeout for food inspections. The investigator should not prolong the inspection if the results are not known prior to close-out of the inspection.

There may be instances where same day discussion of observations may not be possible due to the volume of documents collected and document review reveals observations on a different day than the documents were collected or in other circumstances. When these instances occur immediately prior to the conclusion of the inspection the lack of a daily discussion of observations does not preclude listing of significant observations which were not previously discussed on the FDA 483 or the FDA 4056.



**eNSpect**

eNSpect is an automated FDA 483, FDA 4056 and EIR reporting system. Use eNSpect to generate the FDA 483 or FDA 4056 where applicable cite modules exist. eNSpect should not be used to create an FDA 483 or during an inspection of a firm involving multiple commodity areas when FDA 483 cites do not exist for ALL of the commodity areas for which observations need to be included on the FDA 483. You should be able to write the entire FDA 483 and FDA 4056 using eNSpect.

Use eNSpect for all EIRs whether or not your FDA 483 or FDA 4056 was generated using eNSpect and when no FDA 483 was issued. See IOM 5.11.4.

**5.2.3.1 - Preparation of Form FDA 483**

It is not necessary to complete all headings of the FDA 483, when multiple page 483s are issued. Complete all headings on the first page and, on subsequent pages, only those necessary to identify the firm and dates inspected. FDA 483s should be issued at the conclusion of the inspection and prior to leaving the premises. However, in preparing some complex FDA 483s, it may be necessary to leave the premises and return at a later time to issue and discuss your inspectional observations. In this case, you should advise the firm’s management your inspection has not been completed and you will return to issue the FDA 483 and discuss inspectional findings. There should be no unreasonable or unwarranted delays in issuing and discussing the FDA 483. During the inspection, do not show the firm’s management a draft, unsigned copy of the FDA 483 or an electronic copy of the FDA 483 on your computer screen. You should issue only a signed FDA 483 at the closeout discussion with management.

**5.2.3.1.1 - INDIVIDUAL HEADINGS**

**District Office Address and Phone Number** - Legibly print the District address where the firm is physically located, regardless of program area or investigator duty station.. Include the district office commercial telephone number and area code.

For example, if a firm is located in Little Rock, Arkansas, then the district office would be Dallas District Office. See Appendix E for boundary maps.

See IOM 1.6.5.1 – Professional Stature for situations where firms express a concern during routine enforcement activities where an FDA 483 was not issued, or the activity is not an inspection.

**Name and Title of individual to whom report is issued** - Enter legal first name, middle initial and last name and full title of the person to whom the form is issued.

**Firm or Farm name** - Enter full, legal name of the firm, including any abbreviations, quotation marks, dashes, commas, etc.

**Street address, city, state and Zip Code** - Enter street address, city, state and Zip Code. (Not P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

**Date(s) of inspection** - Enter actual or inclusive date(s) of inspection.

**FEI Number** - If the FDA Establishment Identifier is on the assignment, enter it here. If not readily available, leave blank.

**Type of establishment inspected** - Enter the types of the establishment, such as bakery, cannery, wholesale warehouse, drug repacker, salvage warehouse, etc.

**Employee(s) signature and Employee(s) name and title** - The names of everyone who participated in the inspection with the issuance of an FDA 482 should be listed on the FDA 483, FDA 483a, and FDA 4056 even if they are not available to sign the FDA 483, FDA 483a, and FDA 4056. Each member of an inspection team should sign the FDA 483, FDA 483a, and FDA 4056. However, absence of a team member at the conclusion of an inspection need not prevent issuance of the FDA 483, FDA 483a, or FDA 4056. See IOM 5.1.2.5.1. If you use an electronically generated FDA 483, FDA 483a, or FDA 4056, assure you have a copy for the program division files -- an unsigned photocopy or printed duplicate is unacceptable. See IOM 5.2.3.6.2.

Additional headings on the FDA 4056:

**Name of State and Department (if acting under the commission with FDA)** – if the FDA 4056 is used by a state acting under FDA commission, the name of the agency. For an FDA led inspection, place “N/A” in this box.

**Farm Mailing Address** – Address, city, state, and zip code at which the farm receives mail

**Farm Physical Location, If Different From Mailing Address – Location Identifiers Such As GPS Coordinates**

**Type of Inspection** -

- Initial – first inspection of the farm
- Routine – normal surveillance inspection
- Follow-up – follow-up to a violative inspection
- For-cause – inspection to follow-up on a specific issue, such as an outbreak or positive sample
- Other (please specify) – inspection that doesn’t meet one of the other categories (will be used very rarely)

For an initial inspection, you will check both the initial box and select an additional box (routine, for-cause or other box) as appropriate for the type of inspection conducted.

**Crops Observed** - List the crops for which some element of growing, harvesting, packing, and/or holding were observed during the inspection. If the farm grows or handles other crops but those crops were not observed during the inspection, do not list them.

### 5.2.3.1.2 - SIGNATURE POLICY

Everyone present at issuance signs the first and last pages of the FDA 483 and initials each intervening page in the signature block.

NOTE: if you are not using the official multi-part FDA 483 form and a copier is not available, insert carbon paper to reproduce a signed copy of the FDA 483.

NOTE: If issuing the FDA 483 using eNSpect, the lead CSO's signature will appear on all pages of the FDA 483 and the remaining team members' signature will appear on the last page.

On the FDA 4056, the signature is captured on one page in the FDA Representative Signature block. The preferred method of issuance of an FDA 4056 is an electronic copy, a paper copy should only be issued if there are circumstances which an electronic copy is not feasible.

When issuing an electronic FDA 4056, the lead FDA representatives should electronically sign the document. All FDA representatives present during the inspection, names are to be listed in the Representative(s) Name and Title box.

If an FDA 4056, paper copy is issued all FDA representatives present at the close out of the inspection are to sign the document. A copy of the 4056 will need to be obtained for inclusion in the EIR.

See IOM 5.2.3.6 -Distribution of the FDA 483 and FDA 4056.

### 5.2.3.1.3 - DATE ISSUED

Enter the date the form is actually issued to the firm's management.

### 5.2.3.1.4 - OBSERVATIONS

Where applicable, when formulating each FDA 483, FDA 483a, and FDA 4056 observation, answer Who (using titles or initials when necessary), What, When, Where, Why, How Much and How Often? Challenge each observation by asking "So What"? (regarding its significance)

Enter your reportable observations succinctly and clearly. Conditions listed should be significant and relate to an observed or potential problem with the facility, equipment, processes, controls, products, employee practices, or records. "Potential problems" should have a reasonable likelihood of occurring based upon observed conditions or events. Do not cite deviations from policy or guidance documents on your FDA 483, FDA 483a, and FDA 4056.

As appropriate, FDA 483, FDA 483a, and FDA 4056 observations should include relationship of observations to a given population, for example, "Two out of 50 records examined were \* \* \*" or "4 out of 12 bags examined were \*\*\*." When appropriate, an FDA 483, FDA 483a, and FDA

4056 observation may refer to inadequate situations as long as you provide supporting facts (examples) or explanation as to why the condition, practice or procedure observed is inadequate.

It is preferred not to identify individuals or firms by name i.e., suppliers and consignees within the FDA 483, FDA 483a, and FDA 4056. Where appropriate to support the FDA 483, FDA 483a, or FDA 4056 observation, identify the individual(s) or firm(s) by substituting other non-specific identifying information as below. Document your evidence in your EIR, fully explaining the relationship(s).

1. The lot number for a component received from or shipped to firm "A".
2. The invoice number for a shipment from or to firm "A".
3. A patient #, record #. See IOM 5.2.3.3 item 7.
4. The study number for a particular Clinical Investigator site.
5. Other necessary but non-specific identifying information to show the observation's relationship to a particular firm and/or individual.

Presently there are three ways to generate an FDA 483, FDA 483a, and FDA 4056.

1. eNSpect
2. Traditional hard copy
3. Electronic (non-eNSpect) version

When using a traditional hard copy FDA 483 or electronic (non-eNSpect) version of the FDA 483, the current version of the 483 must be used. As of the printing of the current IOM, the current version of the FDA 483 is dated 9/08.

### 5.2.3.1.5 - MEDICAL DEVICE INSPECTIONS

The following language should be inserted on the FDA 483 in addition to the above statement: "The observations noted in this form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

### 5.2.3.1.6 - CORRECTION OF FDA 483, FDA 483a, and FDA 4056 ERRORS

These procedures do not pertain to adverse conditions noted and then corrected during the inspection. Observations of this type stand and should remain on the FDA 483, FDA 483a, and FDA 4056.

The Inspectional Observations (FDA 483), Request for FSVP Records (FDA 483a) and Produce Farm Inspection Observations (FDA 4056) is of critical importance to both the Agency and regulated industry. Individual FDA 483s, FDA 483a, or FDA 4056 may become public through publishing in industry trade press, FOI inquiries, Headquarters postings and other means. Therefore, complete and accurate documentation of corrections to this official document is critical.

### 5.2.3.1.6.1 - Errors Discovered Prior to Leaving the Establishment

Non-eNSpect, FDA 483s, FDA 483a, and FDA 4056s:

1. Make handwritten changes to correct the error/s on the original FDA 483, FDA 483a, or FDA 4056 and initial the changes. Correct errors by striking through the erroneous text and entering the correct information (if any). When possible retrieve and destroy all uncorrected copies of the FDA 483, FDA 483a, or FDA 4056 either provided to or produced by the establishment.
2. If the establishment has photocopying equipment available and will provide you with a copy of the corrected original FDA 483, FDA 483a, or FDA 4056 then obtain a copy of the corrected original document from the establishment. If the establishment has no such equipment or refuses to provide you with a copy of the original corrected FDA 483, FDA 483a, or FDA 4056 then make the corrections, initial the changes and retain a copy of the corrected FDA 483, FDA 483a, or FDA 4056 for your Division's official establishment file.

eNSpect FDA 483s:

All corrections/deletions should be made in eNSpect. If there are technical difficulties which prevent you from issuing a modified eNSpect 483, you may handwrite the corrections on the original (maintain a copy for the EIR) and inform the firm representatives that you will make corrections and provide them with the corrected eNSpect 483.

1. Changes made to correct errors in the text of the observation will show on the face of the final printed FDA 483. Changed Text deletions will remain visible as strike through and correction made. For example, "lot ~~1234~~ **5678**" – (select text, right click, select font and select strike-through) or from "lot 1234" to "lots 1234 and 5678" and bold the changes "lots 1234 **and 5678**"
2. If an entire observation is removed or the underlying citation is changed, incidental text will be used to add the statement "An observation concerning \*\*\* was removed [or the underlying citation was changed] based on discussions with management."
3. Addition of a new observation or changes to the observation.

### 5.2.3.1.6.2 - Errors Discovered after Leaving the Establishment

Normally, you should not use the amendment process to issue additional FDA 483, FDA 483a, or FDA 4056 items after the inspection has been closed out and you have left the premises.

1. Non-eNSpect, FDA 483s, FDA 483a, FDA 4056s: Discuss any errors with your supervisor. If necessary, a revised FDA 483, FDA 483a, or FDA 4056 will be prepared.

2. eNSpect FDA 483s, FDA 483a, and FDA 4056s: Discuss any errors with your supervisor. Make all corrections/deletions in eNSpect per 5.2.3.1.6.1.
3. Issuing FDA 483s, FDA 483a, or FDA 4056s: Personally deliver the amended FDA 483, FDA 483a, or FDA 4056 to the firm for discussion. If personal delivery is not practical, mail the amendment to the firm with a full explanation cover letter. Include a copy of the original FDA 483, FDA 483a, or FDA 4056, amended FDA 483, FDA 483a, or FDA 4056, and cover letter in the EIR. In addition, you should call the person to whom the original FDA 483, FDA 483a, or FDA 4056 was issued to discuss the change(s). Document your discussion in your EIR.

**NOTE:** The issuance of an amended FDA 483, FDA 483a, or FDA 4056 in person or via mail does not change the inspectional end date. The inspectional end date remains as the date the original FDA 483, FDA 483a, or FDA 4056 was issued.

FDA 483s, FDA 483a, and FDA 4056s should be issued in eNSpect unless there are no commodity specific cites in eNSpect, technical difficulties, or certain multiple commodity situations (See IOM 5.2.3) Other options are:

1. Electronic (non-eNSpect) version of the FDA-483, FDA 483a, or FDA 4056.
2. Handwritten FDA 483, FDA 483a, or FDA 4056.

When using a handwritten or electronic (non-eNSpect) version of the FDA 483, FDA 483a, or FDA 4056, the current version must be used.

### 5.2.3.2 - Reportable Observations

You should cite factual observations of significant deviations from the [FD&C Act](#) [21 U.S.C. 301], [PHS Act](#), [21 CFR](#), and other acts where FDA has enforcement authority unless these cites require concurrence or are specifically prohibited – see IOM 5.2.3.3 Non-Reportable Observations. Examples of these observations generally fall into two categories.

#### 5.2.3.2.1 – Adulteration Observations

Review Sections [402](#), [501](#), [505\(k\)](#), [601](#), and [704](#) of the FD&C Act [21 U.S.C. 342, 351, 355(k), 361, and 374]. Include specific factual observations of:

1. Foods, drugs, devices, or cosmetics consisting in whole or in part of filthy, putrid, or decomposed substances.
2. Undesirable conditions or practices, bearing on filth or decomposition, which may reasonably result in the food, drug, device, or cosmetic becoming contaminated with filth.
3. Insanitary conditions or practices which may reasonably render the food, drug, device, or cosmetic injurious to health.
4. Careless handling of rodenticides or pesticides.

5. Results of field tests (organoleptic examination of fish, crackout of nuts, etc.) if the results revealed adulteration.
6. Observations of faulty manufacturing, processing, packaging, or holding, of food, drug, or device products as related to current good manufacturing practice regulations including inadequate or faulty record keeping.
7. Observations of faulty can closures and/or deviations from recommended processing times and temperatures.
8. Deviations from the animal proteins prohibited in ruminant feeds requirements ([21 CFR 589.2000](#)).
9. Results of analytical laboratory findings which reveal adulteration.

### 5.2.3.2.2 - OTHER OBSERVATIONS

You may include other factual observations of significant deviations from the [FD&C Act](#) [21 U.S.C. 301], [21 CFR](#), Government Wide Quality Assurance Program (GWQAP) requirements, and other Acts as directed by CPs and other agency directives. In some cases, you may cite labeling deviations as directed below. This list is not all inclusive.

1. Observations indicating non-conformity with commitments made in a New Drug Application, New Animal Drug Application, or in an antibiotic certification or certification exemption form. See [Section 505 FD&C Act](#), [21 U.S.C. 355].
2. Observations, forming the basis for product non-acceptance under the Government Wide Quality Assurance Program (GWQAP). See IOM 5.2.3.5.
3. Deviations from blood and blood products labeling requirements as specified in [21 CFR 606.121](#) and [21 CFR 640](#).
4. Animal protein products, and feeds containing such products, that are not in compliance with the labeling requirements of paragraphs (c) through (f) of [21 CFR 589.2000](#). See [Section 403\(a\)\(1\) or 403\(f\) of the FD&C Act](#) [21 U.S.C. 343(a)(1) or 343(f)].
5. Deviations from the applicable labeling regulations for human cells, tissue, and cellular and tissue-based products (HCT/PS) as specified in [21 CFR 1271](#) and [CP 7341.002](#).
6. Observations indicating drug misuse, failure to maintain proper drug use records, and/or poor animal husbandry practices during drug residue investigations. See the applicable Compliance Program(s) for guidance.
7. Observations indicating non-conformity with the post marketing adverse drug experience reporting requirements as specified in [21 CFR 310.305](#), [314.80](#), [314.98](#), [314.540](#), or [600.80](#) or other post marketing requirements as specified in [21 CFR 314.81](#) or [600.14](#). See Sections [505](#) and [760](#) of the FD&C Act [21 U.S.C. 355(k) and 379aa].
8. Observations indicating non-conformity with the Medical Device Reporting requirements as specified in [21 CFR 803](#) {See [Section 519\(a\) of the FD&C Act](#) [21 U.S.C. 360i]}; the Medical Devices Reports of Corrections and

- Removals requirements as specified in [21 CFR 806](#) {See Section 519(f) of the FD&C Act [21 U.S.C. 360i(f)]}; the Medical Device Tracking requirements as specified in [21 CFR 821](#) {See Section 519(e) of the FD&C Act [21 U.S.C. 360i(e)]} and the Unique Device Identification (UDI) requirements of 21 CFR 801 Subpart B and 21 CFR 830.
9. Observations indicating noncompliance with medical device pre-market notification requirements and pre-market approval requirement under [FD&C Act sections 510\(k\)](#) and [515](#) [21 U.S.C. 360 (k) and 360e] respectively, should only be made with the prior confirmation of CDRH and/or CBER.
10. [21 CFR PART 200.10](#) does allow reporting observations noted at a contract facility to the contracting facility. Before doing this, check with your supervisor to determine if this is appropriate.
11. Observations indicating non-compliance with LACF/ Acidified food registration and failure to file scheduled processes. Before doing this, verify lack of such, as covered in CP 7303.803A.
12. Deviations from the applicable labeling requirements for outsourcing facilities as specified in Section 503(B)(a)(10) of the FD&C Act.

13. Observations at animal food facilities that are not subject to animal food regulations (e.g., not required to register as a food facility) indicating food safety noncompliance with the FD&C Act adulteration or misbranding provisions in FD&C Act section 402 and 403. See [Compliance Program 7371.000: COMPREHENSIVE ANIMAL FOOD INSPECTION](#) for more details.

### 5.2.3.3 - Non-Reportable Observations

Do not report opinions, conclusions, or characterize conditions as "violative." The determination of whether any condition is violative is an agency decision made after considering all circumstances, facts and evidence. See IOM 5.2.7 involving discussions with management at which time opinions may be discussed.

Do not quote Regulations (e.g., specific CFR sections) when listing items.

Do not report observations pertaining to:

1. Label and labeling content, except per IOM 5.2.3.2.2, items 2, 3, 4, 5, and 12 above.
2. Promotional materials.
3. The classification of a cosmetic or device as a drug.
4. The classification of a drug as a new drug.
5. Non-conformance with the New Drug Regulations, [21 CFR 312.1](#) (New Drugs for Investigational Use in Human Beings: Exemptions from Section 505(a)) unless instructed by the particular program or assignment.
6. The lack of registration required by [Section 415](#) and [510 of the FD&C Act](#). The lack of registration per [21 CFR 1271 Subpart B](#) Procedures for Registration and Listing,

- promulgated under Section 361 of the PHS Act.
7. Patient names, donor names, etc. If such identification is necessary, use initials, code numbers, record numbers, etc.
  8. The use of an unsafe food additive or color additive in a food product.

The FDA 483 or FDA 483a should not include specific corrective actions taken by the firm in response to observations noted on the FDA 483, FDA 483a, or during the inspection except as described in IOM 5.2.3.4. These actions should be reported in the EIR.

Use eNSpect to document in the “Summary” and “General Discussion with Management” section Non-Reportable Observations, which you discussed with management. These objection-able conditions fall into three basic categories:

1. Observations of significant deviations from specific Laws and/or regulations, non-reportable items 1-9 above.
2. Observations of deviations from specific Laws and/or regulations, which in your judgment, are of “questionable significance” and “deemed not to merit inclusion on the FDA 483, FDA 483a, or FDA 4056,” but do warrant discussion with management.
3. Observations which in your judgment deviate from official published guidance, not regulations, but warrant discussion with management.

The reporting of observations for an FDA 483 or FDA 483a in these 3 categories is as follows:

Category 1: You should select the appropriate eNSpect cite, verify or set the “Print type” to “Do Not Print,” and save the observation in the eNSpect database. This should be done even if there are no other reportable observations. For example, Lack of Food Registration as covered in IOM 5.4.1.5.2 is not reportable.

Category 2 or 3: You should always report these two categories of observations which were discussed with management under the “General Discussion with Management” heading in the EIR as specified by IOM 5.11.4.3.15. You have options in choosing how observations in category 2 are reported. You may select the appropriate cite in eNSpect, enter the “specifically” text regarding the observation, and discussion with management, set it to “Do not print”, save, and it will be automatically entered into the eNSpect when it is generated.

The second option which is also true for category 3 (i.e., there are no eNSpect cites for official guidance, only regulations) is the observation/s discussed with management may be entered directly into the eNSpect EIR under the “General Discussion with Management.”

Do not report opinions, conclusions, or characterize conditions as “violative.” The determination of whether any condition is violative is an agency decision made after considering all circumstances, facts and evidence. ...

Observations, which you discussed with management. These objection-able conditions fall into three basic categories: 1. Observations of significant deviations from specific Laws and/or regulations, non-reportable items 1-9 above. 2. Observations of deviations from specific Laws and/or regulations, which in your judgment, are of “questionable significance” and “deemed not to merit inclusion on the FDA 483, FDA 483a, or FDA 4056,” but do warrant discussion with management. 3. Observations which in your judgement deviate from official published guidance, not regulations, but warrant discussion with management.

### 5.2.3.4 - Annotation of the FDA 483 and FDA 4056

Offer to annotate the FDA 483 for all medical device inspections. The program division has discretion to annotate the FDA 483s in other program areas. BIMO inspections are generally excluded from annotations. Annotations of FDA 483s for inspections in other program areas may be done if both the establishment and the investigator/team believe annotation will facilitate the inspection process. When an FDA 483 is annotated it should be done in accordance with the guidance that follows.

Inform the establishment of the annotation program at some point prior to the final discussion with management. Determine from management whether they wish to have their FDA 483 observations annotated. It is voluntary on the part of the establishment. If the establishment does not want one or more observations annotated, you must honor the request.

The actual annotation of the FDA 483 should occur during the final discussion with management. The annotations are succinct comments about the status of the FDA 483 item. The annotations can be made after each observation, at the end of each page of the FDA 483 or at the bottom of the last page of the FDA 483 prior to the investigator's signature. See IOM 5.2.3 for discussions of FDA 483 observations with management.

If the establishment has promised and/or completed a corrective action to an FDA 483 observation prior to the completion of the inspection, the FDA 483 should be annotated with one or more of the following comments, as appropriate:

1. Reported corrected, not verified.
2. Corrected and verified.
3. Promised to correct.
4. Under consideration.

On the FDA 4056, if the produce farm has corrected the item or has committed to correct it, the Description section should include one of the following annotations:

1. Reported corrected, not verified.
2. Corrected and verified.
3. Promised to correct.

The term "verified" means "to confirm; to establish the truth or accuracy". In this case, you must do the verification. In some situations, you will not be able to verify the corrective action unless there is further program division or Center review or until there is another inspection of the establishment.

The establishment's stated objections to any given observation or to the FDA 483 or FDA 4056, as a whole should not be annotated on the FDA 483 or FDA 4056. If firm does not wish to annotate and FDA 483, then select no annotation in eNSpect, or if issued outside eNSpect, do not annotate. The EIR should include the establishment's objections to the observation and the fact the establishment declined to have the observation annotated.

When an establishment has promised corrections and furnishes a date or timeframe (without a specific date) for completion, then you may add "by xxx date" or "within xxxx days or months" in the annotation. Where the investigator and the establishment have "agreed to disagree" about the validity of an observation on the FDA 483, you may annotate this observation with "Under consideration" or with no annotation based on the establishment's desire.

All corrective actions taken by the establishment and verified by FDA should be discussed in detail in the EIR.

### 5.2.3.5 - Government Wide Quality Assurance Program (GWQAP)

When performing product acceptance examinations under the GWQAP, you must discuss all deficiencies with management and report these deficiencies in writing on the FDA 483. This includes all deficiencies related to the FD&C Act as well as deficiencies in complying with contract requirements, which result in non-acceptance. There must be a clear differentiation on the FDA 483 between these two types of deficiencies.

Enter the FD&C type deficiencies (GMP deviations, etc.) first on the FDA 483. If there are deficiencies in contract provisions, draw a line across the sheet and add a heading "The Following Additional Contract Non-Conformances Were Observed." Enter each deficiency, which forms a basis for non-acceptance, followed by the reference to the applicable contract requirement or specification.

### 5.2.3.6 - of the FDA 483, FDA 483a, and FDA 4056

The FDA 483, FDA 483a and FDA 4056 should be issued to the most responsible person available at the close of the inspection.

Per 5.2.3.1., FDA 483s should be issued at the conclusion of the inspection and prior to leaving the premises.

The signed FDA 483, FDA 483a or FDA 4056 can be issued in the following ways:

1. Physical paper copy. Be sure printed versions of the signed FDA 483s, FDA 483a, and FDA 4056s are legible.
2. Electronically by email as a PDF attachment (on site prior to leaving the premises).
3. Electronic Media transfer to the firm (e.g., USB, CD/DVD...). Follow all IT security policies and procedures when using electronic media, including FDA policy with portable media devices available here [http://inside.fda.gov:9003/it/ITAcquisitions/lro\\_nKeyRollout/default.htm](http://inside.fda.gov:9003/it/ITAcquisitions/lro_nKeyRollout/default.htm) and IOM 5.3.8.3.1 - ELECTRONIC RECORDS and IOM 5.3.8.3.3.1 - IDENTIFYING AND SECURING ELECTRONIC STORAGE MEDIA

If the FDA 483, FDA 483a or FDA 4056 is issued electronically, document your method of issuance and FDA-483 discussions with management in your regulatory notes per IOM 5.2.7 – Discussions with Management.

### 5.2.3.6.1 – Non-eNSpect generated FDA 483, FDA 483a, and FDA 4056

Before leaving the premises at the end of the EI, print and present the issued FDA 483, FDA 483a, or FDA 4056 to the most responsible individual. Upload into eNSpect one copy of any signed, modified, and/or amended FDA 483, FDA 483a or FDA 4056, issued to the firm.

### 5.2.3.6.2 – eNSpect generated FDA 483, FDA 483a, and FDA 4056

Before leaving the premises at the end of the EI, present the printed signed FDA 483, FDA 483a, or FDA 4056 to the most responsible person available.

## 5.2.4 - RECEIPT - FACTORY SAMPLES

You must issue an FDA 484, Receipt for Samples, if you collect any physical sample during an inspection. At the end of the EI and prior to leaving the premises, issue the original FDA 484 to the same individual who received the FDA 482.

(See IOM 4.2.5) If this person is not available, give it to someone else who meets the definition of owner, operator, or agent in charge. Submit an exact copy with the EIR. Do not comment on type of examination expected or promise a report of analysis.

### 5.2.4.1 - Items Requiring Receipt

Issue an FDA 484 for any item of food, drug, device, or cosmetic actually removed from the establishment.

NOTE: A receipt must always be issued to anyone from whom you obtain Rx drugs. This includes individuals as well as firms. See IOM 4.2.5.4 and IOM 4.4.10.3.44.

The following are examples of exhibit materials also requiring a Receipt for Samples:

1. Air filter pads,
2. Rodent pellets, nesting material, package cuttings, insects, insect frass and
3. Any other physical evidence actually removed from the plant, including in-line and environmental swabs.

### 5.2.4.2 - Items Not Requiring Receipt

Do not issue an FDA 484 for:

1. Items or materials examined during the inspection but not removed from the establishment (report adverse results of analysis of materials on FDA 483 and FDA 4056 as indicated in IOM 5.2.3.2),
2. Labels and labeling, including promotional material,
3. Photographs taken during the inspection, or
4. Record(s): including production, quality control, shipping and interstate records.

Firm management may request copies of documents or records you obtain from their firm. There is no objection to supplying them.

See IOM 5.3.8.5 for procedures when a firm requests a receipt for records copied during an inspection or investigation.

## 5.2.5 - INSPECTION REFUSAL

A refusal is refusal to permit an inspection or prohibiting you from obtaining information to which FDA is entitled under the law. Discuss all refusals with the most responsible official present at the firm at the time the refusal was made. See IOM 4.2.3 for information regarding refusal to permit sampling.

In the case of a refusal you must show your inspection was attempted to conduct in reasonable time, reasonable manner, and reasonable limit to show you exercised prudence to avoid refusal. You must have presented your credentials and given the responsible individual a properly prepared and signed Notice of Inspection, FDA 482 or FDA 482d Request for FSVP Records.

Inspection refusals may take several forms. All refusals to permit inspection must be reported in your EIR under the "Refusals" heading.

In the case of drug inspections, inspection refusals, as well as delaying, denying, or limiting your ability to conduct the inspection, may cause a drug to be deemed adulterated under Section 501(j) of the FD&C Act [21 U.S.C. 351(j)]. See subsection 5.5.5.8 in Subchapter 5.5 (Drugs) for further guidance on responding to these situations.

### 5.2.5.1 - Refusal to Permit Inspection

When you are faced with a refusal of entry, call the person's attention to the pertinent sections of the Acts ([Sections 301\(f\) and 704 of the FD&C Act](#) [21 U.S.C. 331 (f) and 374] and [Section 351\(c\)](#), 360A(a), (b) and (f); 360B(a); and [361\(a\) of the Public Health Service Act](#). Portions of these are listed on the front and back of the FDA 482. If entry is still refused, leave the completed FDA 482, leave the premises and telephone your supervisor immediately for instructions.

Note: [CPG Sec. 130.100 Inspectional Authority; Refusal to Permit Inspection](#)

In the case of drug inspections, if the person refuses entry or delays, denies, or limits your ability to conduct the inspection, also call the person's attention to Section 501(j) of the FD&C Act [21 U.S.C. 351(j)] (an adulterated drug could lead to further prohibited acts under 301(a), (b), (c) [21 U.S.C. 331(a), (b), (c)]). See subsection 5.5.5.8 in Subchapter 5.5 (Drugs) for further guidance on responding to these situations.

In the case of international inspections, a refusal to permit inspection may result in a recommendation for regulatory action, e.g., Import Alert and cancellation of Food Facility Registration. Refusal to permit an international inspection should be reported in a memo uploaded into an Operation 15 – Foreign Investigation and not reported as a "Washout" in eNSpect.

### 5.2.5.2 - Refusal to Permit Access to or Copying of Records

If management objects to the manner of the inspection or coverage of specific areas or processes, do not argue the matter but proceed with the inspection. However, if management refuses to permit access to or copying of any record to which you are entitled under law, call attention to [Section 301\(e\) of the FD&C Act](#) [21 U.S.C. 331] or applicable sections of the PHS Act. If management still refuses, proceed with the inspection until finished.

In the case of drug inspections, if management refuses access to or copying of any record to which you are entitled under law, in addition to Section 301(e) noted above, call attention to Section 501(j) of the FD&C Act [21 U.S.C. 351(j)] (an adulterated drug could lead to prohibited acts under 301(a), (b), (c) [21 U.S.C. 331(a), (b), (c)]).

Furthermore, if during a drug inspection management delays producing records you request to which you are entitled under law, without giving a reasonable explanation such as requiring sufficient time to compile a large volume of records or translate the records into English, you may call their attention to 501(j) of the FD&C Act. Similarly, if management limits your access to or ability to copy any record to which you are entitled under law, you may call their attention to Section 501(j) of the FD&C Act. See subsection 5.5.5.8 in Subchapter 5.5 (Drugs) for further guidance on responding to these situations.

It is not an inspection "refusal" when management refuses to provide information e.g., formulation, lists of shipments and manufacturing codes, unless it is specifically required by law or regulation. If the refusal is such that you cannot conduct a satisfactory inspection, discuss with your supervisor if a Warrant for Inspection should be requested.

### 5.2.5.3 - Refusal after Serving Warrant

If you have been refused entry, obtained a warrant, tried to serve or execute it and are refused entry under the warrant, inform the person, the warrant is a court order and such refusal may constitute contempt of court. If the warrant is not then immediately honored (entry and inspection permitted), leave the premises and promptly telephone the facts to your supervisor.

If you have served the warrant and during the inspection you encounter partial refusal or resistance in obtaining access to anything FDA is authorized to inspect by the warrant, inform the firm that aspect of the inspection is part of a court order and refusal may constitute contempt of court. If the warrant is not then immediately honored, leave the premises and promptly telephone the facts to your supervisor.

### 5.2.5.4 - Hostile and Uncooperative Interviewees

More often than not, investigations or inspections are conducted in a reasonable atmosphere. Nonetheless, there will be times you are confronted by unfriendly or hostile persons.

Your activities must always be conducted with tact, honesty, diplomacy, and persuasiveness. Even though you must at times adopt a firm posture, do not resort to threats, intimidation, or strong-arm tactics.

Many times, a hostile or uncooperative attitude on the part of individuals being interviewed results from fear, timidity, or previously distasteful encounters with law enforcement personnel. In most cases a calm, patient, understanding and persuasive attitude on your part will overcome the person's reluctance or hostility. Often the mere fact you patiently listen while individuals share their views will make them receptive to your quest.

### 5.2.5.4.1 - INDICATORS

Normally you have no way to predict the nature of the individuals you meet. However, there are often indicators, which can alert you, such as:

1. Establishment inspection reports, endorsements or memorandums may show situations where investigators encountered belligerent or hostile individuals. These reports may be FDA reports and/or State contract reports, if available.
2. Discussions and conversations with FDA, federal, state and local inspectors and investigators may reveal instances where uncooperative individuals and problem situations were encountered.
3. The nature of the assignment, program or information requested may indicate some degree of caution is needed.
4. A firm located in an area with a reputation for unfriendliness to law enforcement personnel should alert you some employees of the firm may be less than cooperative during the investigation.

If you find yourself in a situation which, in your judgment, indicates violence is imminent, stop the operation and make an exit as soon as possible. Immediately report the facts to your supervisor.

### 5.2.5.4.2 - SAFETY PRECAUTIONS

The FDA recognizes there are situations where it is advisable to take precautions for your personal safety. In those, consult your supervisor. Some procedures, which may be utilized to minimize the danger, include:

1. Inspections or investigations carried out by a team of two or more persons.
2. Consider whether or not the use of an unmarked government car would be more beneficial to assist you in your inspection in lieu of a marked government car.
3. Request additional information from your State and/or Local Agencies who also regulate and inspect the facilities in question. In many instances, your State counterparts may have more information regarding the facility. This may be especially helpful for those firms that FDA has not yet inspected but were inspected by your State counterparts.
4. Each inspection team should be assigned one FDA cell phone or alternate communication device. While we recognize that some Investigators carry a personal cell phone, FDA strongly suggests that your personal cell phone not be utilized to contact the firm or firm's management. In some instances, such uses in the past have resulted in later inappropriate contacts from the firm to the individual FDA Investigator.
5. Request assistance from local law enforcement agencies prior to or during investigations. This assistance may include information about the facility you are to inspect, assistance with communication devices, or police protection, if the police jurisdiction allows for such an action.
6. In potentially hazardous investigations such as methadone or schedule II Class Drugs, two



investigators may be used and personnel from the U.S. Drug Enforcement Administration, State, or local law enforcement agencies may be requested to accompany you.

### 5.2.5.4.3 - PROCEDURES WHEN THREATENED OR ASSAULTED

In instances when you are actually assaulted or threatened, you should immediately notify your supervisor. Your supervisor can summon local police, United States Marshals, or contact OCI headquarters for assistance (301-294-4030). OCI can make contacts with local police and federal agencies based on previous liaison. Also, the program division should notify [orahqcsosafety@fda.hhs.gov](mailto:orahqcsosafety@fda.hhs.gov).

If you are physically attacked, you have the same recourse as any other citizen as well as the benefit of federal laws protecting government officials while in the performance of their official duties. If you are physically attacked, you should get to safety, call your supervisor, report the incident and seek medical attention if needed. Remember that the medical attention you receive may be used as documentation for the Agency in support of any legal action taken against the firm or the individual.

### 5.2.5.4.4 - NOTIFICATION OF FBI AND US ATTORNEY

It is a federal crime for anyone to kill, assault, resist, oppose, impede, intimidate, or interfere with, a federal official in the performance of their official duties.

In case of assault or threat against you, notify your supervisor immediately, so the facts can be submitted to the Federal Bureau of Investigations and the U.S. Attorney's office for immediate action.

The referenced sections in Title 18 of the U.S. Code are:

1. [Title 18 U.S.C.A. Section 111](#), which provides:
 

"111. Assaulting, resisting, or impeding certain officers or employees.  
Whoever forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person designated in Section 1114 of this title while engaged in or on account of the performance of his official duties, shall be fined not more than \$5,000 or imprisoned not more than three years, or both.  
Whoever, in the commission of any such acts uses a deadly or dangerous weapon, shall be fined not more than \$10,000 or imprisoned not more than ten years, or both. \*\*\*\* "
2. [Title 18 U.S.C.A. Section 1114](#), which provides:
 

"1114. Protection of officers and employees of the United States.  
Whoever kills \*\*\*\*\* or any officer or employee of the Department of Health and Human Services or of the Department of Labor assigned to perform investigative, inspection, or law enforcement functions while engaged in the performance of his official duties, shall be punished as provided under sections [1111](#) and [1112](#) of this title. \*\*\*\*\* "

See Title 18 of the US Code Sections 111 and 1114 for the complete text. See also IOM 1.5.

## 5.2.6 - INSPECTION WARRANT

A refusal to permit inspection or a refusal to permit access to or copying of records may invoke criminal provisions of sections 301(e) and 301(f) of the FD&C Act [21 U.S.C. 331(e), (f)]. Furthermore, in the case of drug inspections, delaying, denying, limiting, or refusing an inspection may invoke criminal provisions of sections 301(e) and 301(f) [21 U.S.C. 331(e), (f)]. Depending on the individual situation, instances of refusal may be met by judicious use of inspection warrants.

Instructions for obtaining warrants are contained in the [Regulatory Procedures Manual, Chapter 6-3](#). See your supervisor for information and instructions.

You are operating as an agent of the court when you serve an inspection warrant and it must be executed expeditiously once served. See IOM 5.2.5.3 for guidance on how to handle any refusal after obtaining a warrant.

In situations where a potential problem is anticipated with the service of a warrant, the Program division should consider sending a Supervisory Consumer Safety Officer or Compliance Officer and a U.S. Marshal with the Investigator to assist and supervise the serving of the warrant.

After obtaining an Inspection Warrant, return to the firm and:

1. Show your credentials to the owner, operator, or agent in charge,
2. Issue the person a written Notice of Inspection (FDA 482),
3. Show that individual the original signed Inspection Warrant,
4. Give him/her a copy (not the original) of the warrant.

The copy you provide need not be signed by the issuing judge, but the judge's name should be typed on the copy.

Follow the procedures of the court or U.S. Attorney involved, if their methods differ from the above.

When an inspection is made pursuant to a warrant, a Return showing the inspection was completed must be made to the Judge (or U.S. Commissioner or Magistrate) who issued the warrant. The Return, executed on the original warrant, should be made promptly and usually no later than 10 days following its execution.

## 5.2.7 - DISCUSSIONS WITH MANAGEMENT

After completion of the inspection, meet with the most responsible person available to discuss the objectionable conditions observed. Objectionable conditions may be identified as reportable (See IOM 5.2.3.2) or non-reportable (See IOM 5.2.3.3). During the discussion, be direct, courteous, and responsive with management.

Explain the significance of each item and relate to the applicable sections of the laws and regulations administered by the FDA.

If significant deviations are observed during the inspection, you should inform management during the closeout discussion, the conditions observed may, after further review by the Agency, be considered to be violations of the FD & C Act or other statutes. Legal sanctions available to FDA may include seizure, injunction, civil money penalties and prosecution.

Significant deviations observed during a foreign inspection could result in a facility's product(s) being refused or detained upon entry into the United States.

Do not be overbearing or arbitrary in your attitude or actions. Do not argue if management voices a different view of the FDA 483 observations. Explain, in your judgment the conditions you observed may be determined by the FDA, after review of all the facts, to be violations. Make clear the prime purpose of the discussion is to call attention to objectionable practices or conditions, which should be corrected.

Determine management's intentions regarding correcting objectionable conditions, including time frames. They may propose corrections or procedural changes and ask you if this is satisfactory. If this involves areas where your knowledge, skill, and experience are such that you know it will be satisfactory, you can so advise management. Do not assume the role of an authoritative consultant. Do not recommend the product or services of a particular establishment. If asked to suggest a product or consulting laboratory, refer the inquirer to a classified directory or trade publications and or organizations. Advise management if FDA receives an adequate response to the FDA 483 or FDA 4056, or other objectionable conditions, within 15 business days of the end date of the inspection, it may impact FDA's determination of the need for subsequent action.

Report in your EIR all significant conversations with management or management representatives. In most instances it is not necessary to quote management's response verbatim. Paraphrasing the replies is sufficient. However, if the situation is such that quoting the reply or replies is necessary, enclose them in quotation marks.

### 5.2.7.1 - Protection of Privileged Information

You have certain responsibilities under the FD&C Act, [Section 301\(j\)](#); Sections 359(d) and 306(e) of the Public Health Service Act; and Section 1905 of the Federal Confidential Statute ([18 U.S.C. 1905](#)) regarding protection of confidential material obtained during your official duties. See IOM 1.4.

Do not volunteer information about other firms or their practices. Ignore casual exploratory questions or remarks from management about competitors or their processes. Your casual and seemingly innocuous remarks may reveal

privileged information. Therefore, be alert and avoid voluntarily or unknowingly divulging information, which may be privileged or confidential and possibly compromise FDA's and your own integrity.

Management often request copies of any documents or records you obtain from their firm. There is no objection to your supplying these. When management requests copies of photos taken by you in a plant, follow IOM 5.3.4.5.

You may encounter situations when management invites outside individuals to observe the inspectional process (e.g., representatives from the press, trade associations, congressional staff, other company officials). As discussed in Section 5.1.4.3 of the IOM, the presence of representatives invited by the firm should not disrupt the inspectional process. You are to continue the inspection in a reasonable manner.

If the firm allows invited individuals to photograph, videotape, or prepare audio recordings during the inspection, you should make every effort to protect privileged information in your possession. However, it is the Agency's position that it is the firm's responsibility to protect confidential and/or proprietary information observed or recorded by those individuals invited by the firm. Where applicable, refer to IOM 5.3.5 for additional procedures on how to prepare your own recording in parallel with the firm's recording.

### 5.2.7.2 - Refusals of Requested Information

Should management refuse to provide any reasonable request for information, which is not specifically required by the law, determine the reasons for the denial and report the details in the EIR. Types of refusals of interest to FDA and refusal codes to be entered in FACTS are listed in the FDA Data Codes Manual. Refusal codes' data are used when reporting to Congress. See IOM 5.2.5.4 for instructions in dealing with hostile and/or uncooperative interviewees.

## 5.2.8 - CONSUMER COMPLAINTS

Prior to conducting any inspection, you should review the FACTS system, OSAR 360, and the factory jacket becoming familiar with all FDA Complaint/Injury forms. You may want to request additional information to consumer compliant coordinator based on the program area to fulfill additional information if available related to establishment to be inspected. Be especially alert for ones marked "Surveillance Information for Next EIR" and make sure you investigate these during your inspection. If reviewing complaints in OSAR, the "more detail" link needs to be opened to determine if the complaint was previously followed up, or if it stills requires follow-up.

During the inspection, discuss these complaints with management without revealing the complainant's name(s). Determine if the firm has had similar complaints on the same product. Determine what action the firm has taken to identify the root cause of the problem and to prevent a

recurrence in the future. See IOM 5.11.4.3.11 for reporting instructions.

## 5.2.9 - INTERVIEWING CONFIDENTIAL INFORMANTS

When you are faced with a situation involving sources of information who want to remain anonymous, please contact your supervisor and follow the procedures here. In addition, refer to IOM 5.2.1.2 regarding your personal safety. If your management concurs with the decision to utilize a confidential source, it is particularly important you take the necessary steps to keep the identity of the source, and any information which could lead to the identity, confidential. For purposes of this subchapter, a confidential source is a person who provides information that may be of assistance to FDA without necessarily becoming a party to the actual FDA investigation. If you believe the information provided by the source could lead to a criminal investigation, please contact the Office of Criminal Investigations (OCI).

### 5.2.9.1 - How to handle the first contact

When you interview a person, who may become a confidential source use the following procedures:

1. Type of meeting. Try to schedule a personal interview with the person rather than a telephone interview. At a face-to-face interview you can assess the person's demeanor, body language, overall presentation, and truthfulness.
2. Meeting location. The place and time of the interview should be the choice of the person, unless there is a concern with personal safety. If the person's suggested location is unsuitable, the investigator should suggest the location. When you conduct the interview off FDA premises, notify your supervisor of your destination, purpose, and estimated time of return. When an off-site interview has been completed, check-in with your supervisor.

#### 5.2.9.1.1 - INTERVIEWING METHODS/TECHNIQUES

It is strongly recommended you have two investigators conduct interviews of a confidential source. The lead investigator conducts the interview, while the second investigator takes notes and acts as a witness to the interview. You should:

1. Prepare carefully for the interview. The investigators should develop the questions they intend to ask the person during the interview, e.g., "establish motivation," and record and number the questions to be asked in their diaries prior to the interview. This preparation assists in documenting the interview process and reduces the amount of note taking needed during the interview. The investigators also should discuss their interviewing strategy, and determine the method by which they will consult with each other during the interview and (during extensive interviews) share the interviewing and note-taking responsibilities;

2. Have the person tell the story chronologically, placing complex situations into logical order; and
3. If the person makes allegations, ask him or her how he or she knows the allegations are true.
  - a. How were they in a position to know?
  - b. Did they personally see, hear, or write about the information/incident?
  - c. Can they provide proof of the allegations?

#### 5.2.9.1.2 - ESTABLISH MOTIVATION

At the end of the interview ask the person why he or she is divulging this information. This may reveal their motive(s):

1. Is the person a disgruntled current or former employee who harbors a grudge?
2. Is the person looking for some type of whistle-blower reward or notoriety?
3. Does the person just want to do the right thing?
4. Is the person involved in actual or prospective litigation about or related to the information?

#### 5.2.9.1.3 - ANONYMITY

If the person is requesting anonymity, inform him or her FDA:

1. Will not divulge his or her identity, the occurrence of the interview, or the sensitive information provided to FDA if the information could lead to the identity of the person, unless FDA is required to disclose the information by law, e.g., the investigation leads to a hearing or trial and he or she is required to testify, and
2. Will try to corroborate all information provided by the person, minimizing the chances he or she must later testify. However, testifying remains a possibility.

Ask the person for names of other persons who might be willing to speak with you about the allegations and corroborate their story.

### 5.2.9.2 - Protect the Identity of the Source

Obtain sufficient personal information necessary to enable you to contact the person for follow up if needed. However, to maintain the confidentiality of the person, do not include the person's identifier information such as gender, name, address, and phone number in the memorandum of interview. You should assign the confidential source a code name or number and use the identifier in memoranda and other communications relating to the confidential source (see IOM 5.2.9.2.2 item 2).

#### 5.2.9.2.1 - ACCESS

Know who is authorized by program division procedure to access the information and restrict access by others accordingly. Share the minimum amount of information necessary to meet the purpose of the disclosure.

#### 5.2.9.2.2 - STORAGE REQUIREMENTS

Each program division should establish procedures, in addition to those listed below, to properly store confidential

information. The following list contains information related to storage procedures.

1. Use security measures necessary to protect the confidentiality of personal information, whether it is in hard copy or electronic form, on FDA premises, in an FDA home-based computer, or in any other form. Use whatever means necessary and appropriate to physically safeguard the information, such as storing in a safe, or locked file cabinets, or password-coded computers, etc.
2. When referring to the source in any manner (orally, in writing, electronically, etc.), consider using code to identify the source. For example, use a number rather than the individual's name, to identify the source. Personal privacy information should be safeguarded to the extent allowed by law. Use discreet subject headers in the file labels as appropriate.
3. Remove personal information from a file only after you have noted in the file your name, date, etc. Promptly return that information to the file.

### 5.2.9.2.3 - DISCLOSURE

Do not disclose information from or about the source, unless the disclosure complies with the law and FDA's procedures. Do not share non-public information outside of the Freedom of Information (FOI) process, unless the sharing is done according to our regulations and procedures. Refer FOI requests to FDA's Division of Freedom of Information (see item 3 below). See also IOM Subchapter 1.4. The following information relates to disclosures of information from or about a confidential source.

1. Make duplicates of the personal information only to the extent necessary for authorized disclosure (inside or outside of FDA). Do not leave the copy machine unattended.
2. Make only authorized disclosures of the information, regardless of the manner of disclosing (oral, written, etc.). Do not use mobile telephones or leave voice mails with the information. Avoid transmitting the non-public information by facsimile or e-mail.
3. If you receive a FOI request for information from or about a source consult with your supervisor immediately. Disclosure to a non-FDA government official of information from or about a source may be disclosed only if permitted by law and FDA procedures, and after consulting your supervisor, OSPOP/DIDP and, if needed, OCI.
4. Immediately retrieve information from or about a source if inadvertently disclosed. Follow FDA's Inadvertent Disclosure SOP.

### 5.2.9.2.4 - DESTRUCTION

Destroy personal information by shredding or similar means which physically destroys the record and/or, if the information is in electronic form, makes it unreadable.

After a matter has been referred to the Office of Chief Counsel (OCC) for litigation or enforcement action, consult with OCC if you are interested in contacting the source.

## 5.2.10 - ROUTINE BIOSECURITY PROCEDURES FOR VISITS TO FACILITIES HOUSING OR TRANSPORTING DOMESTIC OR WILD ANIMALS

This section is FDA's guidance when you visit any type of facility where any domestic or wild animals are housed or transported. If a firm has more restrictive controls, follow those in addition to the controls cited below as long as they do not interfere with your assignment needs. The controls and procedures are intended to prevent you from becoming a vector or carrier of animal diseases, to prevent the spread of animal disease, and to set a good example for stockmen, growers and industry servicemen. A number of chronic diseases, such as Johne's Disease, bovine virus diarrhea (BVD) and others exist in domestic animals which you can unknowingly spread. Any inspectional contact with herds of livestock (including poultry) or non-domesticated animals exposes you to potential claims of introducing or spreading disease. This could occur between sections of a single site, such as poultry houses, or between different sites or farms. The potential also exists for the introduction of disease from an animal processing plant, such as a slaughterhouse or renderer to a live animal facility. You can prevent this by following appropriate cleaning and disinfection steps between facilities. Generally, a break of 5 days or more between sites is sufficient to eliminate concern about transmission of infectious agents.

These precautions, biosecurity measures, are necessary in two types of situations. The first is when there is no known disease present and your actions are precautionary. This section primarily addresses those kinds of activities. The other situation involves known or suspected disease outbreaks or more notorious disease conditions such as salmonella in eggs, infectious Laryngotracheitis, foot and mouth disease, vesicular stomatitis, and blackhead which can be highly contagious and spread from one group of animals to another by movement of people and objects between infected and non-infected groups. In these cases, special precautions must be taken to make sure you are not an unknowing vector for the spread of disease. See IOM 5.2.10.3.

Biosecurity on a produce farm is a set of preventive measures designed to protect the farm, including crops and livestock, from bacterial, fungal and viral diseases and agricultural pests. When conducting a produce safety inspection, you should abide by the farm's policies. During the pre-inspection call and prior to entering the growing area, you should ask if the farm has implemented biosecurity practices. You should follow these animal and phytosanitary practices and procedures requirements.

If you will only be inspecting an office or house away from areas where animals are housed or kept, clean and suitable street attire may be sufficient. Be aware if you visit any area of a facility where animals have been, you should always sanitize, clean or change footwear and it may be necessary to change outerwear before visiting another animal site to prevent any possibility of transmission of disease.

Your vehicle may also transport infection if you drive through contaminated areas and may require frequent cleaning between sites.

### 5.2.10.1 - Pre-Inspection Activities

When you know you are going to visit or inspect any animal production or holding facility, consider contacting the State Veterinarian and/or the Regional APHIS office to determine if there are any areas in the state under quarantine or special measures to control animal diseases. APHIS office locations can be found on their website. The State Veterinarian will be listed under Government Listings in your phone book and is listed at this website. Milk Specialists frequently working with State counterparts in the Interstate Milk Shippers program should contact these sources at least quarterly for updates. Ask for any special controls or procedures they recommend. Follow any guidance they offer in addition to the precautions in this section. You should also consider pre-notification of the facility following guidance in IOM 5.2.1.1, Pre-Announcement, unless your assignment does not allow pre-notification. If you elect to pre-announce the inspection, in addition to the normal contact, ask to speak with the person at the facility responsible for their biosecurity measures and find out what they require of employees and visitors. If their requests do not interfere with your ability to do your job, follow their requests as we do when inspecting sterile manufacturing facilities.

Make sure your vehicle is clean and has been recently washed. Commercial car washes are adequate as long as you check to make sure any dirt, manure or other debris, which may be present from a previous site, has been removed. Some facilities may require additional disinfection of tires upon entry to the premises. Ensure tires and floor mats are clean. Consider designating places in your vehicle for storage of clean, unused supplies and dirty or used supplies.

In addition to your normal inspectional tools, obtain the following equipment and supplies from your program division:

1. Laundered or disposable coveralls or smocks (coveralls are suggested because they give better coverage). If you are going to visit multiple facilities in one day or trip, obtain sufficient quantities so you can change into clean or unused clothing between each site.
2. Disposable plastic gloves, rubber boots, which can be sanitized, and disposable shoe/boot covers. Rubber boots over which you place disposable shoe/boot covers are preferred.
3. Reusable cloth or plastic laundry bag(s) for clothing to be laundered. (Disposable bags can be used.)
4. Soap, water and disposable or freshly laundered individual hand (or paper) towels.
5. Sanitizing solution(s) and equipment (brushes, bucket, tray, measuring devices, etc.) to permit you to properly sanitizing hands, boots, equipment and your vehicle. Most disinfectants will require removing organic matter before use and good brushes are essential to remove dirt from boots and other objects.

Make sure any equipment you take with you has been thoroughly cleaned and sanitized as necessary. Clip boards, briefcases, flashlights, inspectional sampling tools, coolers, brushes, buckets and other objects should be cleaned between uses as necessary and between visits to any suspected infected facilities. Disposable equipment should be used to the fullest extent possible.

Additional information for produce safety inspection staff to follow is in the Standardized Approach to Produce Farm Inspections document.

Maintain copies of any applicable Material Safety Data Sheets (MSDS) for disinfectants with you in your vehicle. If the firm's management requests information on the disinfectants you are using, they may read or copy these MSDS. Be familiar with the instructions and precautions concerning use of disinfectants. Any disinfectant should be effective against known or suspected microbiological agents.

In the event of a foreign animal disease, contact the USDA, APHIS Veterinary Services area Veterinarian in Charge for additional precautions and procedures to follow. (See 5.2.10.3)

### 5.2.10.2 - General Inspection Procedures

Always begin each day with a clean vehicle free from any visible dirt or debris. During the day, take precautions to minimize contamination of your vehicle. If your vehicle becomes obviously dirty with adhering mud or manure, clean it before visiting another animal facility. When you arrive at a facility where animals are located, check to see if there are designated parking spots or pads for visitors. If so, park your vehicle there unless directed otherwise by the firm. If there is no guidance, park well away from all areas housing animals. When you arrive, inquire about or reconfirm any biosecurity measures the firm employs. Confirm your actions are suitable and follow expectations of the facility when this does not interfere with your inspection ability. Follow steps requested by the firm to remove contamination from vehicles, which may include troughs or pools of disinfectants for tires or other control measures. Avoid driving through manure, mud or wastewater at these sites.

In general, entry to animal housing or feeding areas, corrals, calf pens, hospital pens or special treatment facilities should be avoided unless the assignment requires their inspection or there are specific reasons requiring entry. If you must visit the feeding area occupied by livestock or birds, first determine if any groups are infected with disease. Arrange to visit the known non-disease areas first. Do not handle any animals unless official duty requires such contact. Before leaving the area where you parked your car, put on protective clothing as described and proceed with the purpose of your visit; sanitizing hands (and gloves if worn) and boots as necessary during the visit or inspection.

General procedures:

1. Wear rubber boots or other suitable footwear, which you disinfect upon arriving at the site and prior to departure. It is preferable to also place disposable foot coverings over your footwear, regardless of the type, after you have disinfected them. If the firm has footbaths, use them. Boots and footwear should be disinfected with any of the agents identified at the end of this subsection using a good brush. Clean and disinfect the brush(es) and bucket you use for these activities.
2. Wash your hands with soap and water. If you are visiting a facility where a known animal disease is present or the firm's biosecurity protocol requires, wear disposable gloves.
3. Wear disposable or freshly laundered coveralls, when appropriate. Some facilities may provide disposable coveralls and require visitors to shower in and shower out at their facilities. If requested by the firm and facilities are provided, you should follow those requests.
4. Wear appropriate head coverings, as necessary. If you wear a head covering, clean and disinfect between facilities or use disposable head coverings.
5. Minimize any materials you carry with you such as notebooks, flashlights, etc. to what is required. Consider keeping these things in clean plastic bags or containers between uses. Disinfect any of these types of items as best you can between visits to facilities or between different animal-housing areas.
6. If you are visiting production units with animals of multiple ages, always try to work from the youngest to the oldest.
7. Avoid direct contact with livestock or wild animals, bodily fluids or animal byproducts when visiting facilities.
8. Milk Specialists, Milk Safety Branch and State Training Team staff frequently working with State counterparts in the Interstate Milk Shippers program shall follow any biosecurity measures the firm employs, any biosecurity measures the State employs, and as a minimum shall follow the coded memoranda issued by CFSAN Milk Safety Branch on this subject.

Upon completing your assignment in a given animal area, return to the same area where you donned protective clothing. Remove disposable shoe/boot covers and gloves, if applicable, and place them in a disposable paper or plastic bag. Clean and sanitize boots/footwear. Remove the protective clothing, if applicable, by peeling it off inside out. (This keeps the surfaces exposed to contamination on the inside.) Unless the firm's biosecurity plan prohibits removal of waste from their premises, all waste should be disposed of by the investigator as follows: Place all disposable items in a disposable, nonporous bag for appropriate disposal according to State and/or local regulations. Place reusable coveralls or other reusable protective clothing in a separate bag for disposition at the office.

Follow guidance on biosecurity provided in the applicable Compliance Program or "Guide to the Inspection of \*\*\*\*\*" in addition to precautions in this Section.

Repeat these procedures for each separate location visited or inspected.

Purchase commercially available solutions for disinfecting objects or consult with your servicing laboratory. Commercial products such as Nolvosan, Efersan, One Stroke Environ or Virkon-S may be used as long as they are registered by EPA for the intended purpose. Lye or chlorine based cleaners and disinfectants may also be used.

The following formula for household bleach may be used. Mix 3/4 cup (6 oz) of liquid bleach (5.25%) in one gallon of water (128 oz). This solution will be approximately 1:20 dilution. Formulations of household bleach, which are more concentrated than 5.25% are commercially available. Dilute accordingly to these directions. A more concentrated 1:10 solution (1-oz bleach to 9-oz water) may be used with decreased contact time required. Dilutions should be prepared fresh daily and protected from light.

You should read the label and be familiar with directions and precautions, such as removing any organic matter from objects to be disinfected, for any disinfectant you use. In the absence of directions or for chlorine solutions you prepare: 1. Remove visible dirt from the object (boots, tools, tires, etc.). 2. Wipe, brush or scrub surfaces with the solution and keep wet for 2 minutes. 3. Allow to air dry or dry with previously sterilized toweling.

### 5.2.10.3 - Special Situation Precautions

If you are required to inspect or visit a facility known or suspected to be involved in a contagious animal disease outbreak or otherwise identified as having diseased animals, contact the Center for Veterinary Medicine and/or Center for Food Safety and Applied Nutrition for additional precautions which may be necessary before you visit these sites. Your activities may be limited to visiting a single site in a day, taking extra-ordinary decontamination steps, ensuring you do not visit or inspect another facility for 5 or more days following the visit to the contaminated site or other steps. APHIS may have special restrictions or precautions for you to follow. The State Veterinarian may also request you follow additional requirements. During inspections of poultry operations where salmonella contamination is known or suspected, you should make sure you contact CFSAN directly for specific procedures to follow. Additional decontamination steps will be required.

### 5.2.10.3 – Standard Operating Biosecurity Procedures for Egg Farm Inspections/ commercial Poultry Operations

#### Classification of Farms

Program divisions should categorize inspections according to risk with farms providing out-door access being considered the highest risk to HPAI. Large farms (those with ≥ 50,000 layers should be inspected first, followed by small farms (those with between 3,000-49,999 layers) and farms with outdoor access (regardless of the number of birds at the farm) should be inspected last. For example, if a program division is assigned 15 inspections as part of an Egg Assignment, and 5 of those farms

provide outdoor access, the 10 farms that do not provide outdoor access should be inspected first and the 5 with outdoor access should be inspected last. Of the first 10 of these inspections the largest farms (from a number of layers at the farm perspective) should be inspected first and then in descending order as the number of layers decreases (a farm with 1 million layers would be inspected before a farm with 750,000 layers, even though both are classified as large farms).

### Biosecurity Practices

These practices should be followed on every egg farm inspection. It is the responsibility of the lead investigator to brief his/her inspectional team on these practices prior to arrival at the farm.

### Pre-Inspection Measures

1. Contact the State Veterinarian to check for quarantines. No egg inspections should be initiated without first contacting the state veterinary office and checking for quarantines. Investigators should ask if there is any type of quarantine and follow that up with a question specifically about HPAI-related quarantines. If quarantines are in place, investigators should ask how long they are expected to continue. If the state veterinarian or official designated by the state indicates that inspections should not continue, those instructions should be followed, and no inspections should be conducted until state clearance is given. If an extended quarantine is expected (longer than 2 weeks), the program division should organize a follow up meeting to include the program division, State Veterinary Office or designated state official, ORA-OFFO, CFSAN-OFS, and CFSAN-OC (see contacts at the end of this document). The purpose of these meetings will be to establish a channel of communication between FDA and the State to ensure state concerns are addressed while ensuring FDA's inspectional obligations are met.

2. Following clearance from the state veterinarian's office, the lead investigator should conduct a cross reference check of the inspection location against the HPAI Current Avian Influenza findings on the USDA/APHIS web page. The Current Avian Influenza findings can be found at the following web address:

<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Poultry/Avian-Influenza>

During the cross check, investigators should check the state and county from the USDA/APHIS webpage against the location of the farm to be inspected. If the farm is in the same county as a confirmed HPAI occurrence, the program division should cancel the inspection and set up a follow up meeting to include the program division, ORA-OFFO, CFSAN-OC and CFSAN-OFS (see contacts at the end of this document). During this meeting, the following information will be considered: the confirmation date of the occurrence (how far removed from the time HPAI was detected to when the current inspection is scheduled), the relative locations of the HPAI infected site and the farm to

be inspected (the infected, buffer, and surveillance zone criteria established by APHIS will be considered), and other pertinent information. After all pertinent information is considered, a decision will be made to either cancel the inspection or reschedule it for a more appropriate time.

3. The mandatory minimum wait time between different farms is 72 hrs. However, many farms have increased the wait period to longer than 72 hrs. in response to lessons learned from the 2015 HPAI outbreak. If the wait time established by the producer is longer than 72 hrs., that specified wait time should be adhered to. In situations where the farm to be inspected includes outdoor access for the birds (this information should be established during the pre-inspection call) the minimum wait time between farms increases to 1 week. Contact with specific bird populations could also result into mandatory one week minimum wait times. Bird populations should be categorized into two broad categories. Population 1 includes birds that are under a biosecurity plan as specified in 21 CFR 110.118.4(b)(1) through (5) (this populations most often will refer to only those birds at commercial farms, i.e. those to be inspected). Population 2 includes all other birds, including but not limited to backyard flocks, duck or geese or other bird populations at municipal parks, avian species at zoological gardens, chicks or ducklings at feed stores, etc. If an investigator only has contact with Population 1 AND if the farm to be inspected has an established wait time of less than 1 week, that time requirement should be followed. If an investigator has contact with Population 2, they MUST wait 1 week before conducting an inspection.

4. When possible, program divisions should send separate inspectional teams on egg farm inspections such that the time between separate farm visits for any one inspectional team is maximized. For example, rather than sending Inspectional Team A to conduct inspections at Farm 1, Farm 2 and Farm 3, every attempt should be made to instead send Inspectional Team A to conduct the inspection at Farm 1, Inspectional Team B to conduct the inspection at Farm 2 and Inspectional Team C to conduct the inspection at Farm 3. The goal being to increase the length of time that any of the three inspectional teams have to visit the next farm up for inspection.

5. Vehicles to be used during inspections should be washed a maximum of 24 hours before and after each egg inspection. Given that HPAI is highly susceptible to detergents, high temperatures and desiccation, car washes where hand held nozzles are available should be used when possible. Initially, a cycle should be conducted where a high-pressure rinse is used to remove all organic matter (e.g. mud, dirt and debris) with specific care taken to address the wheel wells, tires, vehicle undercarriage, and vehicle body. This should be followed by a cycle where a scrub brush with a detergent is used on the whole vehicle including the wheel wells, tires, and vehicle body. Subsequently, a high-pressure rinse that includes the wheel wells, tires, vehicle undercarriage and vehicle body

should be completed. The interior of the vehicle should then be vacuumed thoroughly to remove organic matter and floor mats sprayed with a disinfectant aerosol spray. The vehicle should then be allowed to dry thoroughly in a sunny area (as opposed to a shaded garage). After the vehicle has dried, disinfectant should be applied to the wheel wells, tires and undercarriage (See item #11 below for appropriate disinfectant selection). The vehicle body does not have to be disinfected.

When necessary or during inclement weather, drive-through car washes may be substituted for manual car washes provided that the cycle includes an undercarriage wash, application of a detergent and a high-pressure rinse. The interior should still be vacuumed and disinfected following the car wash. After the vehicle dries, the tires, wheel wells and undercarriage should be disinfected as described above.

#### During-Inspection Measures

6. Follow the farm's own biosecurity program to the extent that it does not interfere with investigators conducting the inspection.

7. Do not enter or inspect houses where birds are known to have disease, including but not limited to, SE.

8. FDA personnel participating in the inspection cannot be bird owners. Ownership of birds disqualifies that investigator from participation in all egg farm inspections.

9. Always change all Personal Protective Equipment (PPE) between houses. PPE includes disposable body coverings, boot covers, hair bonnets, sterile gloves, respirators, eye and hearing (in areas where loud machinery is in use) protection. The use of disposable PPE and respirators is preferred to eliminate the need for disinfection between poultry houses. In situations where permanent eyewear is worn it must be cleaned and disinfected between each poultry house.

10. Investigators should wash hands thoroughly before donning gloves for entry into the house. Where available, use soap and water; if not available, use hand sanitizing gels. It is the responsibility of the team lead to ensure that all members of the team are adhering to protocol. This should be done at both the clean and dirty areas established at the farm, prior to entry into any poultry house.

#### 11. Selection of disinfectants:

Ethanol should be used to disinfect the lids of evaporated milk cans, scissors and can openers used during sampling within a poultry house.

Phenolic or quaternary ammonium-based sanitizers should be used on wheel wells, tires and vehicle under carriage. The vehicle body should not be disinfected, as the detergent from the car wash is sufficient and some sanitizing compounds can damage the vehicles finish.

Lysol or equivalent based aerosol spray should be used on floor mats and soles of shoes.

Purell or equivalent hand gel should be used for hand disinfection.

In situations where reusable respirators are used they must be cleaned and disinfected in accordance with manufacturer's recommendations

Selection of the appropriate disinfectant is critical; for questions or assistance with disinfectant selection please contact ORA-OO-ORS (see contacts at the end of this document).

12. No item which has been in a layer house may be brought into a different house without a complete cleaning and disinfection or replacement with a new one. This includes all items, e.g., pens, supply tubs, scissors. Replacement of items is more effective than disinfection and lessens the workload on site; therefore, all efforts should be made to replace items rather than transfer between houses. Investigators should plan carefully prior to inspections and pack inspection kits on a per house basis so as to eliminate the need to share equipment between houses. Aside from permanent eyewear and "egg pad" tablets, there should not be a need to share equipment/items between houses.

13. Use disposable cameras, when possible. Otherwise, digital cameras are to be placed within plastic bags prior to entry into the house.

14. Double bag all garbage; specifically, one bag is to be left at the vehicle and the other taken into the house to be inspected. When the garbage is removed, it is placed into the bag left at the vehicle, so as to assure that the bag which went into the layer house never touches the vehicle interior.

15. Houses should be inspected from the cleanest areas to the dirtiest areas and from the youngest to oldest birds.

16. No jewelry is allowed to be worn into poultry houses.

17. Where possible, wear clothing that has not been on another egg farm and ensure the clothing is laundered. If possible use the hot water cycle to launder clothing that will be used during an egg inspection.

18. If possible, inspectors should park their car at the beginning of the driveway or outside the farm and carry all of their equipment onto the farm. Investigators should coordinate with farm management to determine the best parking spot for the vehicle.

19. Eyeglasses should be cleaned and disinfected with disposable decontamination wipes.

Items 20-32 listed below represent either direct or indirect contact with Population 2 as described in item #3 of the pre-inspection measures above. A minimum of 1 week, preferably longer, prior to participating in an FDA egg farm



inspection, all investigators involved in the inspections should:

20. Not come in contact with bird feeders or bird baths for a minimum of 1 week prior to participating in an egg farm inspection.

21. Stay away from family members, friends or acquaintances that are pet bird owners or have backyard poultry flocks of any type.

22. Not visit fairs where poultry or birds are shown or exhibited.

23. Not visit live bird markets of any type, or gatherings where live birds may be present.

24. Not visit flea markets, trade shows, or swap meets where live poultry or birds of any type may be present.

25. Not visit zoos, theme or amusement parks where live birds may be present.

26. Not visit known nesting grounds or resting place for wild birds, such as natural preserves or refuges, known breeding grounds or bird sanctuaries.

27. Not attend birthday parties or functions where a petting zoo that includes poultry is part of the event, e.g., baby chicks, pet ducks or geese, are present.

28. Not come in contact with birds, such as ducks or geese, at municipal, state or other types of parks. e.g., where ducks, geese or pigeons and other birds are local inhabitants and people congregate to feed them.

29. Not visit an ocean side town where you may come in contact with shorebirds, e.g., gulls.

30. Not visit feed stores or other retail establishments where live poultry may be sold, e.g., baby chicks, turkey poults, ducklings, etc.

31. Not go hunting for wild fowl or handle wild fowl. If you have family members or friends who hunt fowl, do not come in contact with them for a least the week prior to the inspection.

32. Not meet with other known bird owners either as part of your work (e.g., meeting another producer at a location away from their farm) or meet with other known bird owners in your social circle.

#### Post-Inspection Measures

33. Wash the vehicle used during the inspection as specified in item #5 in the pre-inspection procedures of this directive.

34. Clean and disinfect the sampling kit(s), e.g. tubs, scissors, can openers

35. Clean and disinfect respirators in accordance with manufacturer's recommendations

#### Contacts

##### CFSAN-OC:

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## SUBCHAPTER 5.3 - EVIDENCE DEVELOPMENT

### 5.3.1 - TECHNIQUES

The recognition, collection, and effective presentation of admissible evidence is essential to successful litigation. Evidence is required to support your observations and reports of violative conditions.

Although the inspectional procedures to detect adulteration and contamination, etc., are described under specific headings in the IOM, the same procedures and/or techniques may also apply to other areas. For instance, the procedures to detect contamination from filth, insects, rodents, birds, etc., described in IOM section 5.4.7 may also apply to drugs or other products. Your experience and training assists you in making this transition and enables you to detect possible violative conditions.

Keep in mind the policy announced in the 4/23/1991 memorandum from the Director, Office of Compliance: The lack of a violative physical sample is not a bar to pursuing regulatory and/or administrative action providing the CGMP deficiencies have been well documented. Likewise, physical samples found to be in compliance are not a bar to pursuing action under CGMP charges.

### 5.3.2 - SAMPLES

Samples, including "Factory Food Samples" (in-lines) and packaged finished products collected during inspections provide the necessary key to establish routes of contamination and/or actual product adulteration. They also

document the character of products packed prior to the inspection. Collect samples for laboratory examination only when they contribute to confirming the suspected violation. Be selective since negative reports of analysis of food samples are required under [Section 704\(d\) of the FD&C Act](#) [21 U.S.C. 374 (d)] to be furnished to the firm and might give management a false picture of the firm's operation.

When possible collect duplicate subsamples to provide for the 702(b) portion of the sample. See IOM 4.3.2.1 and 4.3.7.4.1 for additional guidance and [21 CFR 2.10](#) for exemptions regarding the collection of duplicate portions.

### 5.3.3 - EXHIBITS

Impressive exhibits are extremely effective and important forms of evidence to establish existence of violative conditions or products. They should relate to insanitary conditions contributing or likely to contribute, filth to the finished product, or to practices likely to render the product injurious or otherwise violative. Diagrams of the establishment, floor plans, flow charts, and schematics are useful in preparing a clear concise report and in later presentation of testimony. A small compass is useful in describing exact locations of objectionable conditions in the plant, in your diagrams, and locations from which samples were taken, etc.

Submit as an INV sample exhibits (except photographs) collected during an inspection or investigation. Describe each subsample and assign a unique subsample number to each exhibit. Group similar subsamples on one collection report. Examples of exhibits include:

1. Live and dead insects, insect frass, webbing, and insect chewed materials; nesting material of rodents and/or other animals; and other behavioral evidence of the presence of insects, rodents and other animals. ("INV Samples of Filth Exhibits.")
2. Components and finished dosage forms.
3. Samples of in-process ingredients, in-process materials and unpackaged finished products. ("Factory Food Samples" or "in-lines.") Note: Samples of packaged finished products and ingredients are official samples.
4. Manufacturing and control devices or aids.
5. Physical samples if possible and practical or, photographs with descriptions of scoops, stop-gap expediences, other unorthodox manufacturing equipment or makeshift procedures. If photos are taken, follow the procedures described in IOM 5.3.4.
6. Evidence showing the presence of prohibited pesticide residues. A method of swabbing for prohibited pesticide residues was published in Laboratory Information Bulletin # 1622. Excerpts are quoted as follows:
  - a. Apparatus - Four dram size glass vials, 95% ethanol, and cotton swabs preformed on 6" long wooden handles. Keep uncontaminated in a clean plastic bag.
  - b. Procedure - Blow away loose dirt or debris from approximately a 3" x 3" selected area. Measure approximately 2 cm of 95% ethanol in vial, dip swab into ethanol, press out excess on inside of vial and roll moist swab back and forth firmly across the

selected area. Return swab to vial, swirl in alcohol, press out excess on inside of vial and again roll moist swab across the same area 90° to the previous swabbing. Re-insert swab into vial, break off swab handle and cap the vial with the swab inside.

- c. When swab subsamples are submitted, also submit a blank control sub consisting of an unused swab placed in a capped vial containing 2 cm of the same alcohol that was used for the other swabs.
- d. Describe the type of material swabbed (cardboard carton, metal table top, rubber inspection belt, etc.) and the area covered. A reasonable area is approximately 10 sq. inches. Always try to establish a definite link in the chain of subsamples leading towards the highest level of contamination. If possible, identify the pesticide suspected. Be sure to include a floor plan with the areas sampled identified.

Do not remove the firm's only copy of records. Whenever possible, scan, photograph or photocopy, if duplicates are not available. Reproductions should be reviewed to ensure all relevant information is readable. Records should not be accepted by email from outside USFDA.

### 5.3.4 - PHOTOGRAPHS

Photos taken during inspections are not investigational samples. They are exhibits. Photos are not attached to collection reports unless the photos are part of an Official Sample. See IOM 4.1.4 Official Samples and IOM 4.5.2.4 Photographs. Only use a Government issued camera to take photographs.

Since photographs are one of the most effective and useful forms of evidence, every photo should be taken with a purpose. Photographs should only be taken for evidentiary purposes, e.g., to document violations and environmental surface subsample sites. Photographs should be related to insanitary conditions contributing or likely to contribute filth to the finished product, or to practices likely to render it injurious or otherwise violative.

**CAUTION:** Evaluate the area where flash photography is contemplated. Do not use flash where there is a potentially explosive condition; e.g. very dusty areas or possible presence of explosive or flammable vapors. In these situations, use extremely fast film and/or long exposure time instead of flash.

Examples of conditions or practices effectively documented by photographs include:

1. Evidence of rodents or insect infestation and faulty construction or maintenance, which contributes to these conditions.
2. Routes of, as well as, actual contamination of raw materials or finished products.
3. Condition of raw materials or finished products.
4. Employee practices contributing to contamination or to violative conditions.
5. Manufacturing processes.
6. Manufacturing and various control records showing errors, substitutions, penciled changes in procedure, faulty practices, deviations from GMP's, NDA's, or other

protocols, altered or inadequate assays or other control procedures and any variation from stated procedure. See IOM 5.3.8.2 for identification of records.

7. Effluent contamination of water systems. See IOM 5.4.3 for techniques in photographing this type of contamination.

When photographing labels, make sure your picture will result in a legible label with printing large enough to be read by an unaided eye. Photograph whited out documents by holding a flashlight against the whited outer side and taking a close-up photo of the reverse using high-speed film. This will produce a photo with a mirror image of the whited outer side.

If you use a Polaroid camera or color slide film, explain the facts in your EIR or on the C/R to alert reviewers that there are no negatives.

### 5.3.4.1 - In-Firm Photographs

Take your camera into the firm and use it as necessary just as you use other inspectional equipment. Only FDA issued cameras are to be used in official business. Don't request permission from firm management to take photographs during an inspection because taking photographs is part of the Agency's authority to conduct inspections as part of Section 704(a)(1) of the FD&C Act [21 USC 374(a)(1)].

If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of firm conditions. Advise management the U. S. Courts have held that photographs may lawfully be taken as part of an inspection. If management continues to refuse, provide them with the following references:

1. "Dow Chemical v. United States", 476 U.S. 227 (1986) This Supreme Court Decision dealt with aerial photographs by EPA, but the Court's language seems to address the right to take photographs by any regulatory agency. The decision reads in part, "\*\*\* When Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission. \*\*\*\*"
2. "United States of America v. Acri Wholesale Grocery Company, A Corporation, and JOSEPH D. ACRI and ANTHONY ACRI, Individuals", U.S. Division Court for Southern Division of Iowa. 409 F. Supp. 529. Decided February 24, 1976.

If management refuses, obtain name and contact information for the firm's legal counsel, and advise your program division management immediately. If the firm does not have legal counsel on retainer, collect the name and contact information for the most responsible individual. Program division management will inform their ORA Regional Counselor in the Office of Chief Counsel (OCC) of the situation, and OCC will then contact the firm's legal counsel or most responsible individual to discuss FDA's legal right to take pictures during inspections. OCC will relay the results of this conversation to program division

management. If you have already taken some photos do not surrender film to management. Advise the firm it can obtain copies of the photos under the Freedom of Information Act. See IOM 5.3.4.5.

If management of a drug or device firm does not give a reasonable explanation for its objection, such as a showing that the chemical properties of products manufactured at the facility are such that taking photographs would adversely affect product quality, you may advise management that the refusal may constitute a limiting of the inspection under Section 501(j) [21 U.S.C. 551(j)] of the FD&C.

### 5.3.4.2 - Photo Identification and Submission

One of the most critical aspects about photographs or videotapes is the ability for the agency to provide testimony clearly verifying the authenticity of the conditions depicted in the photograph or video. It makes no difference if the photo is a 35 mm print from acetate negatives, a Polaroid photo, a digital photo or video taken with a video recorder. You must create a trail, starting with the taking of the photo, confirming its original accuracy and establishing a record describing the chain of custody. To do this, you must make sure each photograph is described in your regulatory notes in sufficient detail to assure positive correlation of the photo or video with your inspection findings. One way you can do this is to photograph a card with your name, program division address and phone number as the first frame or picture on a roll of film or in the digital record. This will help identify the film or file and assist in tracking if it is lost or becomes separated from its identification envelope during processing or storage. Proper procedures will also allow the agency to provide evidence confirming the authenticity of the photographs or video recording in the event you are not able to testify personally.

#### 5.3.4.2.1 – FILM BASED PRINTS

Identify each print on the margin with exhibit number, firm name (or DOC Sample Nos., if DOC Sample), date taken or inclusive dates of inspection, and your initials. Do not place any identifying marks on the picture area of the print. (Some photo developing firms are supplying borderless prints. For this type print, place identification along the back bottom edge of the print and mount the print so the identification can be read without removing the print from the mounting paper. A narrative description may be placed on the mounting paper next to the print. If part of an EIR, include as exhibits. If part of a DOC sample, attach to the collection report with other records associated with a DOC Sample.)

#### 5.3.4.2.2 - COLOR SLIDE IDENTIFICATION

If color slides are used, identify each slide, in the same manner as for prints. Program divisions may have special mounting frames for color slides, so the narrative description of each slide must be in the body of the report with proper reference to exhibits, or, each description may

be placed on sheets of paper following the mounting frames and properly referenced.

### 5.3.4.2.3 - NEGATIVE IDENTIFICATION

Identify the edge of at least two negative strips, with the same information as for prints using a 3/16" strip of pressure sensitive tape. Place all negatives in an FDA-525 envelope. Complete blocks 2, 3, (4 if DOC Sample), 5, 7, and 12 and seal with an Official Seal, FDA-415a. If negatives are not part of a DOC Sample, enter firm name in the Sample Number block.

As applicable, submit the sealed FDA-525 or envelope as an exhibit to the EIR, with the Investigative Report as an attachment, or with the other associated records/documents with a DOC Sample.

### 5.3.4.2.4 - VIDEO RECORDINGS

Handle and protect the original video record just as if it were a photograph negative. Unused videotapes should generally be used to capture the video and, for subsequent copies of the original recording. Write-protect and identify the original videotape with a label with the firm name (or Sample number if it is being submitted as part of an official sample), date taken, and your initials. Seal the original copy of the electronic media in an FDA-525 or similar envelope. Complete blocks 2, 3, 5, 7, and 12 of the FDA 525 and seal with an Official Seal, FDA-415a. If you use a larger envelope, identify the envelope with your name, title, home program division, date, firm name, firm address (include zip code), and description of the contents of the envelope.

Seal the original videotape in an FDA-525 envelope or similar envelope. If you use a larger envelope, identify the envelope with your name, title, home program division, date, firm name, firm address (include zip code), description of the contents of the envelope, and marked in large, bolded letters "STORE AWAY AND PROTECT FROM MAGNETIC FIELDS."

As applicable, submit the sealed FDA-525 or similar envelope as an exhibit to the EIR, with the Investigation Memorandum as an attachment, or with the other associated records and documents with a DOC sample.

If you perform any editing of the recording, you should only perform this on a copy of the original video recording to prevent possible damage to the original. Document in your regulatory notes you made a copy of the original and verified the copy is an accurate copy of the original video you took. This "original copy" should be treated just as if it is the original. When you sign the report, memorandum or other agency document, your signature certifies you are saying the content of the document, including any video recordings, is true and accurate to the best of your ability

### 5.3.4.2.5 – DIGITAL PHOTOGRAPHS OR VIDEO RECORDINGS

Prior to the year 2000, FDA investigators traditionally worked with silver acetate photographic film or used analog video tapes. Early digital cameras recorded photographic images directly to floppy disks or mini-CDs in which the evidence could be handled like photographic negatives.

The important difference today is digital cameras are capable of recording high resolution images on the order of twenty to thirty megapixels. The corresponding image file sizes can be over fifteen megabytes when using uncompressed file formats. To cope with the increased file sizes, digital camera manufacturers have introduced non-volatile flash memory cards which can record digital images, delete images, and be recorded over and over again. This presents a new issue since the original digital images, which are captured at the moment when the images are recorded on the memory card, will be copied at a later time to a CD-R or other permanent storage media. Due to the cost of flash memory cards and the large file sizes, it is not feasible to purchase new memory cards for each inspection/investigation as you did using photographic film. You will be working with an "original copy" of the images which have to be copied in the exact format to a CD-R or DVD-R as they were originally recorded on the flash memory card to preserve the chain of custody. The term "other permanent storage media" includes the hard-drive on the work computer/laptop of the investigator, and not a shared or personal computer. In order to preserve the chain of custody, it is acceptable to transfer the images from the flash memory card onto the hard-drive and then burn the images onto a CD-R or DVD-R, so long as the images have not been altered in any way before being burned onto the CD-R or DVD-R.

In the same manner, digital video recordings may involve the use of different media types such as tapes, CD-Rs or DVD-Rs, or built-in hard drives. If you cannot handle the original video recording as in IOM 5.3.4.2.4, you will need to create an "original copy" of the video recording.

Despite the differences in photographic film and digital technology, you are responsible for collection, handling, documenting the chain of custody, storage, and submission of your evidence in a manner where you can testify to its authenticity in a court of law. See IOM 5.3.4.2 and 5.3.4.3.

### 5.3.4.2.6 – GLOSSARY OF DIGITAL TERMINOLOGY

Some basic terminology is used when referring to digital devices in IOM 5.3.4.2.4, 5.3.4.2.5, 5.3.4.3.

#### 5.3.4.2.6.1 – Digital Data

Electronic data in binary form consisting in its simplest form as "1"s and "0"s. A computer interprets data by whether the state is on ("1") or off ("0").

### 5.3.4.2.6.2 – Analog Data

Information captured in a directly measurable signal versus an analog signal converted and stored in binary.

### 5.3.4.2.6.3 – Memory Card

Any non-volatile memory media that can be removed and which retains data without the need for electrical power. Examples of current memory cards are: Compact Flash (CF), Secure Digital (SD), Memory Stick (Sony), and Extreme Digital (xD).

### 5.3.4.2.6.4 - Original

The file recorded by a digital device on digital storage media at the moment in time when the user takes a picture or makes a recording. This concept is similar to a film camera where the photographic film records the image when exposed by light. The film image negatives produced when the film is developed are considered the originals and prints are considered copies. See IOM 5.3.4.2.1 and 5.3.4.2.3.

### 5.3.4.2.6.5 – Original Copy

An exact copy of the original file recorded by the digital device (camera, video recorder, etc.). The original copy will retain all the characteristics of the original and is indistinguishable from the original.

### 5.3.4.2.6.6 - Permanent Storage Media

A media format in which the digital files cannot be altered once written. Examples are CD-Rs, DVD-Rs and other approved media.

### 5.3.4.2.6.7 - Time/Date Stamp

The internal clock within the camera which records the time/date information on the image file. Set the time/date stamp for the location where the photographs or videos are being taken. In this usage, the time/date stamp does not refer to imprinting the time/date stamp within the photographic image although the time/date stamp can also be imprinted on the photograph as some film cameras could do.

### 5.3.4.2.6.8 - Working Copy

A copy of the original copy used when you need to make additional copies for your report, sample C/R. Creating a working copy decreases the chance the original copy is damaged.

## 5.3.4.3 - Preparing and Maintaining Digital Photographs as Regulatory Evidence

Assure and protect a digital photo's chain of custody (and authenticity) following this procedure:

1. Prior to using the digital camera, verify the date and time stamp is correct and there are no images stored on the memory card. Reformat the memory card using your camera's reformat command to delete any images not related to your current assignment. Depending on your inspection/investigation, camera, and memory card capacity you should consider bringing more than one memory card if possible.
2. Handle your camera and the memory cards in a manner to protect your evidence and maintain the trail of the "chain of custody" for the evidence you have collected. For example, keep the camera and memory cards in your personal possession at all times or hold under lock and key in a secure storage area. Also, keep any additional memory cards containing images in your personal possession until transferred to permanent storage media. When necessary, document these facts in your regulatory notes or written report (EIR, CR etc.).
3. As soon as practical, create an original copy of the digital photos. Some older FDA cameras will capture images directly to a (Write-once Compact Disk Recordable (CD-R)); in this case, the CD-R from these cameras becomes the original CD-R. Identify, date and initial the CD-R as an original image record. If a CD-R/W was used, copy the images to a CD-R to create an original copy with files that cannot be altered. Follow additional instructions for creating and finishing a CD-R in step 4 below.
4. If the camera requires downloading of images to a CD-R or other media, download all the images from the digital camera to an unused CD-R or other electronic storage media to create an original copy. If there was more than one memory card used, use a separate CD-R for each memory card. The storage capacity of a CD-R is about 650 MB; thus, more than one CD-R may be needed to create an original copy of your memory card depending on your camera's resolution, the storage capacity of your memory card, and the number of pictures taken. The images should be transferred in a file format maintaining the image resolution at the time the image was captured. If possible, avoid the use of any file compression in transferring the images to the CD-R. Prior to preparing the CD-R or transferring image files, verify that the computer you are using is set to the correct date and time. Make the CD-R permanent in a format readable by any CD-R reader. Prior to making the working copy from the original copy, identify the original copy. For EIRs identify with the firm name, FEI, date taken or inclusive dates of inspection, and your initials. For sample collections identify with sample number, collection date, and your initials. It is important to identify the original copy as soon as possible to prevent possible mix up of the original copy with any working copies.
5. Use a permanent CD safe marker to identify the original copy CD-R. Do not use ball point pens or similar tipped markers since the CD-R may be damaged. See the NIST document, ["Care and Handling of CDs and DVDs - A Guide for Librarians and Archivists"](#). Figure 12, page 23 shows where to identify the CD-R.

6. Where applicable, document in your regulatory notes the verification and identification of each photographic image comparing them to your regulatory notes, which were recorded at the time the photographs were taken.
- 7.

Make only one working copy from each original copy. Make any additional working copies using the initial working copy. No more than one copy should be made from the original copy to preserve the original copy. After making the initial working copy, seal the original copy of the electronic media in an FDA-525 or similar envelope until submitted with the written report (e.g., EIR, C/R.). Complete blocks 2, 3, 5, 7, and 12 of the FDA 525 and seal with an Official Seal, FDA-415a. If you use a larger envelope, identify the envelope with your name, title, home program division, date, firm name, firm address (include zip code), description of the contents of the envelope and seal with an Official Seal, FDA- 415a. If the images are captured or transferred to electronic storage media, refer to IOM 5.3.8.3 for the handling of electronic storage media. If possible, the investigator (who took the photos and will authenticate them at trial) should store the sealed electronic storage media until it is submitted with the written report. If you break the seal for any reason, see IOM 4.5.4.5 – Broken Official Seals and “Temporary Seals.”

8. Working copies should be used to print photos, insertion into an EIR, cropped, otherwise edited or to be included in a referral.
9. Document in your regulatory notes or written report (EIR, CR, etc.) any steps taken for any unusual editing of original photo images. For example: Superimposing over an important area of the image, image enhancement, composite images, etc.
10. Do not scan the FDA 525 or envelopes containing the photo discs and upload as exhibits. The actual photographs included and described in the EIR are the official exhibit and are maintained in the eNSpect system. The original officially sealed disc(s) and unsealed working copy disc(s) should be included with the unlabeled hard copy exhibits and attachments filed in accordance with applicable procedures. The following statement should be included section 5.11.4.3.16 - Additional Information, “The officially sealed original copy and unsealed working copy discs containing the photographs taken during the inspection are filed with the unlabeled exhibits and attachments.”

#### **5.3.4.4 - Preparing Digital Photos for Insertion in an eNSpect Establishment Inspection Report (EIR)**

Digital photos taken during an inspection can be inserted into the body of a report in eNSpect or can be printed and attached to the EIR as an exhibit. Inserting digital photos can dramatically increase the file size of the eNSpect document. To maintain a minimum eNSpect document file size, the following is recommended: Do not open a digital

picture/photo and use copy and paste to insert the picture/photo into the eNSpect document. Instead, save pictures/photos in a JPEG image format (.jpg file name extension) in a separate folder in preparation for inserting into eNSpect. Then resize all the JPEG pictures to a reasonable image file size. Ensure you are not using the original picture file as the file will be overwritten using this procedure. To do this:

1. Open Microsoft Office Picture Manager, select “Add a new picture shortcut.” After the window opens, select the folder containing the pictures you want to edit. The window will close and the photographs contained in the folder will be available.
2. Hold the control key down and left click to select each image file(s) to be resized.
3. Right click and select “Edit Pictures.” After the sidebar appears, select “Resize.”
4. In the “Resize Settings” sidebar, select the button for “Predefines with X height” and select “Document – Small (800 x 600px). Click OK.
5. New resized pictures will be created in Microsoft Office Picture Manager and are denoted by an asterisk in the picture name. The files must be saved for the change to take effect. Select “File” and select “Save.” The resized picture files will replace the files in the original source folder. If you want to keep the source picture files you must rename the resized files by selecting each file individually by selecting “File,” then “Save As,” and entering a new name.
6. The resized photograph files are now ready for insertion into the eNSpect EIR document. Remember to maintain the original image files, not the resized digital image files, for filing with the hard copy exhibits and attachments in accordance with applicable procedures

To insert a picture into the eNSpect EIR document:

1. Open the eNSpect EIR document. Position cursor to where you want to insert the picture.
2. From the menu bar, click on Insert, choose Picture, click on From File, find and select folder with resized pictures to be inserted. See Exhibit 5-7.
3. Double click on the resized picture to be inserted.
4. Picture inserted into the eNSpect EIR document can be made larger or smaller by clicking on the picture and grabbing the corner of the picture frame and dragging to achieve the desired size.
5. Include the following information in the EIR narrative: the photo number; the date the photo was taken and by whom; and a brief narrative description of what the photo depicts.

Alternative method: Digital photographs can also be submitted as Exhibits to the EIR. A narrative description may be placed below the digital photograph. Include the photo number, the date photo was taken and by whom, and a brief description of what the photo depicts.

See also 5.3.8.2 - Identification of Records Collected. Photographs can be resized using Microsoft Office Picture

Manager. See Exhibit 5-8 which shows the "resize" menu option.

**NOTE:** When any digital photos are used in an EIR, submit the original or original copy of the camera images following procedures as outlined in IOM 5.3.4.3 – Preparing and Maintaining Digital Photographs as Regulatory Evidence.

### 5.3.4.5 - Photograph Requests

Do not routinely advise firms they may have copies of photos. However, if management of the firm initiates the request, advise them it is possible to obtain copies of photographs taken in their plant under the Freedom of Information Act. Any request should be sent to The Food and Drug Administration, at the address listed on the FDA 482 or FDA 483 or FDA 4056. The firm must bear the cost of duplicating the photographs.

Since photographs are records in an investigative file, they are not available under the Freedom of Information Act until the file is closed.

Do not discourage firms from taking their own photographs at the same time and of the same scenes as you.

### 5.3.5 - RECORDINGS

Under normal circumstances recording devices will not be used while conducting inspections and investigations. However, some firms are now recording and/or video-taping, the inspection and/or the discussion with management portion of the inspection. These firms should be advised we do not object to this procedure, but we will also record the discussion to assure the accuracy of our records. Occasionally a firm's management may record the serving of an inspection warrant or, in a hostile situation, may want to record everything. In such cases, depending on the circumstances, you may prepare your own recording in parallel with the firm's recording. Do not depend on the firm to provide a duplicate of their recordings.

Use a clear tape cassette and identify the tape verbally as follows:

"This is Investigator \_\_\_\_\_ of the U.S. Food and Drug Administration speaking in the (state location) of (firm name), (address), (city), (state), and (zip code). It is now a.m./p.m. on (date). Present are (list individuals present with title). This discussion is being recorded by both the representative of (firm name) and by me. We are going to discuss the inspectional findings of an inspection conducted at this firm on (inclusive dates)."

At the close of the discussion and prior to leaving the firm, the recording will be verbally identified as follows:

"This is Investigator \_\_\_\_\_ speaking. It is now \_\_\_\_\_ a.m./p.m. on (date). This was a recording of the discussion with management at the conclusion of an inspection of (firm name and address) conducted on (dates)."

If the recording covers a different situation, the identification should be modified accordingly. If the representative of the firm refuses permission to record the discussion, continue with your discussion and report the facts in your EIR.

The tape cassette must be identified with the firm name, date of the inspection, and investigator's name. Program divisions have the option of transcribing the tape and making the transcription an exhibit for the EIR. However, the tape itself must be made a permanent part of the EIR as an exhibit.

### 5.3.6 - RESPONSIBLE INDIVIDUALS

The identification of those responsible for violations is a critical part of the inspection, and as important as determining and documenting the violations themselves. Responsibility must be determined to identify those persons to hold accountable for violations, and with whom the agency must deal to seek lasting corrections.

Document and fully report individual responsibility whenever;

1. It is required by the assignment,
2. Inspectional findings suggest the possibility of regulatory action, or
3. Background information suggests the possibility of regulatory action.

Under the Medical Device Quality System regulation ([21 CFR 820.20](#)), if the management at the firm is not exercising the controls required by the regulation, the deviations may be cited on your FDA 483.

#### 5.3.6.1 - Discussion on Duty, Power, Responsibility

**Duty** - An obligation required by one's position; a moral or legal obligation.

**Power** - Possession of the right or ability to wield force or influence to produce an effect.

**Responsibility** - An individual who has the duty and power to act is a responsible person.

Three key points to consider are:

1. Who had the duty and power to detect the violation?
2. Who had the duty and power to prevent the violation?
3. Who had the duty and power to correct the violation?

#### 5.3.6.2 - Inspection Techniques How to Document Responsibility

Always determine and report the full legal name and title of persons interviewed, who supplied relevant facts and the name/title/address/email address of top management officials to whom FDA correspondence should be directed. If an email address does not exist, this should be noted.

Obtain the correct name and correct title of all corporate officers or company officials. Obtain pertinent educational and experience backgrounds, and the duties and powers of the officers and employees in key managerial, production, control, and sanitation positions. Ascertain the experience and training of supervisory personnel, in terms that will describe their qualifications to carry out their responsibilities.

There are numerous ways to establish and document responsibility. Evidence may be obtained during interviews and record review specifically intended to determine responsibility. Cover and report items such as:

1. Organizational charts,
2. Statements by individuals admitting their responsibility or attributing responsibility to others,
3. Company publications, letters, memos and instructions to employees, and
4. The presence or absence of individuals in specific areas at specific, significant times, and their observed activities directing, approving, etc.

In order to establish relationships between violative conditions and responsible individuals, the following types of information, would be useful:

1. Who knew of conditions?
2. Who should have known of the conditions because of their specific or overall duties and positions?
3. Who had the duty and power to prevent or detect the conditions, or to see they were prevented or detected?
4. Who had the duty and power to correct the conditions, or to see they were corrected? What was done after person(s) learned of the conditions? Upon whose authority and instructions (be specific)?
5. What orders were issued (When, by whom, to whom, on whose authority and instructions)?
6. What follow-up was done to see if orders were carried out (when; by whom; on whose authority and instructions)?
7. Who decided corrections were or were not complete and satisfactory?
8. What funding, new equipment, new procedures were requested, authorized or denied in relation to the conditions; who made the requests, authorizations, or denials.

Duties and power related to general operations should be established to supplement the specific relationships to violations. Examples of operational decisions that indicate responsibility are:

1. What processing equipment to buy.
2. What raw materials to purchase.
3. What products to produce and what procedures to follow in production?
4. Production schedules - how much to produce, what to make, when to stop or alter production?
5. What production controls to be used?
6. What standards are set for products, raw materials, processes?

7. How to correct or prevent adverse conditions; how much to spend and whom to hire to correct or prevent adverse conditions; when to clean up?
8. How products will be labeled; what products to ship; label approval?
9. When to reject raw materials or products; when to initiate a recall; acceptable quality levels for products?
10. When to hire or fire personnel?
11. Who will accept FDA 482, Notice of Inspection; refuses inspection; accept Inspectional Observations, FDA 483?
12. Who designed and implemented the quality assurance plan; who receives reports of Q.A.; who acts or should act upon the reports?
13. Who is responsible for auditing other facilities, contractors, vendors, GLP sites, etc.?
14. In the firm's business relationships, who signs major contracts, purchase orders, etc.?

In some circumstances, documenting of individual responsibility requires investigative techniques that lead to sources outside the firm. These sources may include contractors, consultants, pest control or sanitation services, local health officials and others. Copies of documents between the firm and outside parties may help establish responsibilities. Do not overlook state officials as another possible source of information in selected cases.

During the course of the inspection you may observe persons who hold responsible positions and/or influence in the firm whose abilities or judgment may be affected by an obvious infirmity, handicap, or disability. If it is obvious the infirmity adversely affects the person's responsibilities or duties that are under FDA oversight, describe in your EIR the extent of the infirmity and how it relates to the purported problem or adverse condition.

### 5.3.7 - GUARANTEES AND LABELING AGREEMENTS

Review the Code of Federal Regulations, [21 CFR 7.12](#), [7.13](#), [101.100\(d\)](#), [201.150](#), and [701.9](#), for information concerning guarantees and labeling agreements.

#### 5.3.7.1 - Guarantee

Certain exemptions from the criminal provisions of the FD&C Act are provided where a valid guarantee exists as specified in [Section 303\(c\) of the FD&C Act](#) [21 U.S.C. 333 (c)]. Obtain a copy of any Food and Drug guarantee, which the firm claims to use relating to a violation noted during your inspection. No person may rely upon any guaranty unless he has acted merely as a conduit through which the merchandise reached the consumer.

#### 5.3.7.2 - Labeling Agreement

Products regulated by FDA are normally expected to be completely labeled when introduced into or while in interstate commerce. Under certain conditions exemptions are allowed when such articles are, in accordance with



trade practices, to be processed, labeled, or repacked in substantial quantity at an establishment other than where originally processed or packed. Sections 405, 503(a) and 603 of the FD&C Act [21 U.S.C. 345, 353(a), and 363] also provide exemptions from complete labeling for products.

### 5.3.7.3 - Exemption Requirements

To qualify for this exemption, the shipment must meet one of the following:

1. The shipper must operate the establishment where the article is to be processed, labeled or repacked; or
2. If the shipper is not the operator of the establishment, he must first obtain from the owner a written agreement signed by and containing the post office addresses of such persons and such operator and containing such specifications for the processing, labeling or repacking of such articles as will insure that such article will not be adulterated or misbranded within the meaning of the Act, upon completion of the processing, labeling or repacking.

Submit copies and dates of written agreements where unlabeled articles are shipped in interstate commerce.

## 5.3.8 - RECORDS OBTAINED

Many types of inspections and investigations require collection of copies of records to document evidence of deviations. In some cases, this may involve voluminous copies of Good Manufacturing Practice (GMP) records, commitments made in the Pre-Approval process, adherence to the requirements of the Low Acid Canned Food regulations or other areas. Copies of records are also obtained to document interstate commerce, product labeling and promotion, and to identify the party or parties responsible for a variety of actions. Copies of records can be obtained in paper format or electronic format. All records become part of the government's case should it go to litigation.

Normally, during litigation proceedings, the best evidence rule prevails in court, whereby the copy of the record in the custody of the government can be authenticated, if the original record is not produced by the custodian of the record.

It is imperative the government witness [usually the collector of the record(s)] be able to testify where, when and from whom the copies were obtained, and that the copy is a true copy of the source record, based on their review of the source record.

### 5.3.8.1 - Verification of Source Records

You must verify the copy of the record(s) you received is an accurate representation of the original or source record(s) so you are able to testify your copy is an exact duplicate of the original or source record. Record in your regulatory notes you authenticated copies of records and when, where, and from whom copies were obtained.

Do not write on, highlight, or otherwise alter copies of original records obtained from the firm as they will no longer be an accurate representation of the source record. The Investigator may write on a second copy of records, provided they include both a copy of the original or source record and their altered copy as exhibits to the EIR.

### 5.3.8.2 - Identification of Records Collected

Articles used as evidence in court cases must be identified so you can later testify the records entered as evidence are the very ones you obtained. This includes all records as noted in IOM 5.3.8, and any others for evidence in administrative or judiciary proceedings. When identifying and filing records, you must ensure the record is complete and no identification method or filing mechanism covers, defaces or obliterates any data on the record.

You must identify records submitted in support of an inspection or investigation, including records provided in an Establishment Inspection Report (EIR) or narrative memorandum. The identification must positively identify the specific copies you received during your inspection or investigation and to avoid any filing mix-up. If labels are used to identify records, they must be permanently applied so any removal will be obvious.

Electronic labeling should be used to identify records collected. Identification should include at least the firm name, FEI Number, date(s) of the inspection, the initials of all FDA participants, exhibit number and page number(s). Refer to ORA-OO.004, "Using eNSpect to Create, Store, and Preserve Electronic Records Associated with an Establishment Inspection Report," When you collect a sample, each page of the copied records will become part of the collection report and should be identified as noted in IOM 4.4.5. Examples include records of interstate commerce, manufacturing deviations, label and labeling violations. Records submitted with a memorandum of investigation will be identified with the firm or subject name, the date(s) of the investigation, the initials of all FDA participants, and page number.

There are occasions when a single record may include hundreds of sheets of bound paper. Abbreviated methods of identification may be used for bound records by fully identifying the first and last few pages. In some cases, firm's clearly mark each page with the sequential and total pages number (e.g., page 6 of 10, 7 of 10, etc.) and this allows you to fully mark only a few pages in the beginning and end of the exhibit.

All pages must be identifiable if not in bound records. One example of a shortened method of identifying individual exhibits containing a large number of pages (usually more than 25) is to fully identify the first few and last few pages with at least the exhibit number, date and the initials of all FDA participants. Then identify the remaining pages with the page number of the total page numbers, and your

initials, e.g., "5 of 95 SHR". This may not be acceptable if you have more than one exhibit consisting of exactly 95 pages.

Whatever method is used, you must assure the record is complete and is always identifiable. This is so you can testify as to the "where", "when" and "from whom" the copies were obtained, and that the copy is a true copy of the source record based on your review of the source record. The identification method should allow any reviewer to determine if the record is complete or pages or parts are missing.

### **5.3.8.3 – Electronic Records, Microfilm and Microfiche**

When attempting to obtain records, you may find they are stored on microfilm, microfiche, or some form of a computerized management information system as electronic records. Records obtained during the course of the inspection in these forms are handled the same as any records following procedures outlined in IOM 5.3.8.1 and 5.3.8.2.

#### **5.3.8.3.1 - ELECTRONIC RECORDS**

Electronic records are defined in 21 CFR 11.3(b)(6) as any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by an electronic system. This term applies specifically to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. In both instances, these records will be maintained and handled as identified in 5.3.8.3.3.

Electronic data obtained from a firm provides an investigator with a wealth of information which can be used to assess their compliance with the FD&C act and promulgated regulations. If there are no mechanisms available for a firm to securely transmit the data electronically to the investigator, the data may be provided to FDA on a CD, DVD or a USB. Data received on movable media presents a challenge with IT security as well as physical security of the media. The information obtained from the firm is commercial confidential information (CCI) and as such must be protected to the greatest extent possible. It is the responsibility of the investigator to make sure the physical data source remains secure. Likewise, data obtained from extra-governmental sources may contain viruses or malware that may be included with the information provided to the investigator either on purpose or accidentally. The transfer of electronic data must be evaluated along with concerns related to safeguarding the security of both FDA and firm information. ORA investigators must be very cognizant of issues that may

arise with the use of electronic media and be vigilant while using it.

Electronic data can be obtained by receiving electronic media from the firm or by providing a clean, preformatted media (CD, DVD or USB). ORA procedures for the use of electronic media will be identical for both domestic and foreign inspections/investigations. Those foreign locations which may present a security challenge will be handled on a case-by-case basis through the foreign trip planning process and will be discussed with the investigator prior to departing the United States.

The Device Control Data Loss Prevention (DLP) tool at FDA blocks most FDA users from using unauthorized USBs, as this is against FDA security policy as described in FDA Staff Manual Guide 3251.12, Appendix Z. Certain ORA Investigators have an exception and are permitted read access to firm-provided USBs in order to transfer data onto their machines. However, they are not permitted write access, as FDA data should not be written to a device that is not FIPS 140-2 compliant and/or approved on the FDA Master Approved Technologies (MAT) list. If you are an investigator and are having problems accessing content on a firm-provided USB, please contact your ISSO.

#### **5.3.8.3.1.1 ORIGINAL COPY**

An original copy is an unaltered copy of a source electronic record. Original copies collected to support observations of potential violations or used as evidence in administrative or judiciary proceedings, including any original copy included in an EIR, memorandum, or C/R, must be stored as to maintain the chain of custody and assure the records may be verified any time after collection.

#### **5.3.8.3.1.2 WORKING COPY**

A copy of an electronic record which is created from the original copy and is used to review and analyze the records, so as to not alter the original copy. This is an exact copy of the original copy electronic records.

#### **5.3.8.3.2 - ELECTRONIC DATABASES AND QUERIES**

Firms may use proprietary programs developed in-house or off the shelf programs to generate and/or store records used to show regulatory compliance, such as blood bank databases, drug production records, medical device complaints, and/or service records. These programs can often times be queried to generate electronic databases or summary data in a commonly used file format, such as Microsoft Excel. During an establishment inspection you may request and receive electronic databases or summary data generated by the firm from their databases. The methods used must maintain the integrity of the electronic data and prevent unauthorized changes. Do not personally access a firm's electronic records, databases, or source data during the course of an inspection, unless it is a bioresearch monitoring inspection which meets the criteria outlined in section 5.10.2.1. For all other inspections, follow the instructions below.

When it is necessary to access a firm's data during an inspection:

1. Oversee the firm's personnel accessing their system and have them answer your questions.
2. Request the firm run queries specific to the information of interest.
3. Request the firm provide the parameters used to generate the data.
4. Request the firm to copy the data to electronic storage media.

Firm electronic data can be dynamic with real time updating. Your request may require the firm to develop one or more custom queries to provide the requested information. A custom report query is the method of using the reporting software to pull the specific data requested during the inspection (i.e., all complaints from the last 12 months with specific data fields). You must assume the query logic is not validated and take appropriate action to ensure the data is accurate and no data has been accidentally omitted due to a programming logic error occurring at the firm.

Reviewing data contained in electronic databases is generally most effectively accomplished with the use of a computer. Reviewing electronic data may require the transfer of electronic data to electronic storage media for you to use in your computer; see section 5.3.8.3.3 below for information on how to handle electronic storage media. Do not use the firm's equipment or personnel to perform computerized data manipulation for the purposes of review and analysis.

#### **5.3.8.3.2.1 - REQUESTING Electronic RECORDS from databases**

Before requesting a copy of computerized data, you should determine several things including information about the size and contents of the database, the program used by the firm, and the program you will use, among others. The following steps are useful in preparing for an electronic database request.

1. Determine the firm's application program used to maintain the data of interest. It is best to obtain data files in a format compatible with application programs currently used by the agency. Check the program you plan to use to ensure it can handle the file size you will be using.
2. You should determine what fields of information are routinely captured by the firm. This can be accomplished by requesting a printout of the data structure of the data file or observing the inputting of data at a computer terminal or workstation. It is common for databases to contain numbers or other coded information requiring translations from look up tables to give meaningful text. You should determine if information fields contain coded

data, and if so, a code breakdown should be obtained. Information about code breakdowns should be located in the SOPs for that computerized system. Also, be aware in relational databases, there may be linking data fields that exist in other tables that should also be considered in the overall data request.

3. If the files are too large to fit on electronic storage media, file compression can be used. If possible, ask that the firm prepare the data in a compression format that is self-extracting. Self-extracting files are executable files and should be virus scanned before and after executing. All electronic storage media should be scanned prior to being used on any FDA computer. Whatever compression utility is used, make sure you have the software to manipulate the files as needed.

#### **5.3.8.3.2.2 - ELECTRONIC RECORDS RECEIVED ON ELECTRONIC STORAGE MEDIA**

If you provide the electronic storage media to the firm, use only clean and preformatted media. An additional safeguard is to request the firm reformat the media on their own computer to assure it is usable and "clean".

Any request for electronic records on electronic storage media should be made with a computer application in mind and the information obtained should be useful. The electronic records should be in a format compatible with software applications knowledgeable to you and available from the Agency. Certain types of file conversion are difficult and should not be attempted without the necessary knowledge and availability of conversion type programs where applicable. Other file conversions are simple and have standard, built in conversion programs, such as converting a Microsoft Word document to an Adobe PDF. If help is needed for file conversion, assistance may be available within the program division.

Any electronic storage media containing electronic records received during the course of an inspection should be considered and handled as the original copy. The original copy (USB, CD, DVD, etc.) of electronic records should be secured to assure the integrity of the data when used to support observations of potential violations or used as evidence in administrative or judicial proceedings. Seal with an FDA-415a in an FDA-525 or similar envelope. Complete blocks 2, 3, 5, 7, and 12 of the FDA-525 and seal with an Official Seal, FDA-415a. If you use a larger envelope, identify the envelope with your name, title, Home District and Program Division, date, firm name, firm address (include zip code), and description of the contents of the envelope. Mark the FDA-525 or similar envelope as containing electronic storage media or other media and document the software type and version(s) required to open the included software, e.g. Microsoft Word 2016, Microsoft Excel 2016, or Windows Photo Viewer. The electronic storage media or other media should be stored as part of

the hardcopy exhibits in the designated file room. See IOM 5.11.5.1.

There are no guarantees the files provided on electronic storage media will be usable data. It is your responsibility to make a working copy from each electronic storage media prior to closing the inspection. You will need to view the copied files and verify the files contain the information requested and the information is useable to you.

If you perform analysis of the data, including sorts, pivot tables, or other reviews, on the working copy of an electronic database to develop or support observations, you should request the firm conduct the same analysis and provide a copy of this analysis (the firm is under no obligation to do so.) This can be done by requesting an electronic database that includes only the information of interest (e.g. an Excel spreadsheet of failures of a certain type for a specific time period), or requesting a paper copy of the information of interest.

### 5.3.8.3.3.1 - IDENTIFYING AND SECURING ELECTRONIC STORAGE MEDIA

You should follow these steps to ensure proper identification and security of electronic storage media:

1. Label each original copy of electronic storage media
  - a. Firm name
  - b. Date and your initials
  - c. If you provide the disk(s)/USB to be used, use only new and preformatted disk(s)/USB.
  - d. The name of the appropriate software and version to ensure readability of the information.
2. Make a working copy of the electronic storage media
  - a. Virus scan the original storage media
    - i. Disconnect your machine from the FDA network, the VPN, and the internet.
    - ii. Insert the Media into your computer (USB into USB port or CD/DVD into drive).
    - iii. Do NOT click ok on or accept any Windows prompts for driver installations.
    - iv. Right Click on the drive of interest.
    - v. Select "Scan for threats..."
    - vi. When the window identified in Figure XX appears, select "Continue."
      - (1) We do not want to "Clean" the data as it may be used as evidence if a virus or malware was detected.
    - vii. If the scan is clean, proceed forward. If the scan detects a problem, the security scanning tool should quarantine the file(s). At this point, the file(s) will not be accessible, and you should put in an ERIC ticket to report the incident (which should be assigned to the FDA Incident Response team). If the scan reveals malware or a virus, maintain chain of custody on the electronic media. Alert the SCSO of the issue and the steps taken.
  - b. Check the security on the storage media by viewing the "Security" tab under the "Properties" window

(right click). This will ensure you have the ability to view and analyze the data.

- c. Copy the original information from the electronic storage media onto a working copy.
  - d. Verify the data is useable.
3. Identify and place the original copy of electronic storage media as identified in 5.11.5.1.
  4. Prepare electronic record(s) for inclusion in the EIR, Memorandum, or C/R.

### 5.3.8.5 - Listing of Records

If management requests a list of the copies of records you obtain, prepare it in duplicate and leave the original with the firm. Many firms prepare duplicate copies of documents requested during our inspections. In the interests of conserving inspectional time, you may ask the firm to prepare the list of copies concurrently with the photocopying and you then verify the accuracy. Do not use form FDA-484, Receipt for Samples. Describe the circumstances in your report including the name and title of the individual to whom you gave the list. Submit the duplicate list with your report as an exhibit.

### 5.3.8.6 - Patient and/or Consumer Identification on Records

During the course of many types of inspections and investigations you will review and collect records which specifically identify (by name) patients or consumers. Under most state Privacy Laws this information is confidential. Some firms we inspect may mistakenly believe this information is not releasable to the federal government. However, Federal laws preempt State laws; with few exceptions we are entitled to review and copy the complete record, including the identifying patient/ consumer names. The Agency is then required to maintain the confidentiality of the records/files, as with any confidential record you collect. See IOM 5.10.5. Any disclosure of the information contained in the record(s) can only be by Law, i.e., judge's order, disclosure, Congressional order, etc. If you encounter resistance from the firm in providing patient records, you may refer them to 45 CFR 164.512(b) which explains the exemptions allowing FDA access to the patient records.

General, routine guidance is as follows:

1. For records copied as a result of injury or complaint investigation, where you obtain patient identification, the identification should remain intact and stored in the official FDA files. Frequently, medical releases must be obtained from a complainant, consumer or "next-of-kin". At least one or two extra should be obtained and stored in the files.
2. For any inspection/investigation involving a regulation required Informed Consent, such as clinical investigations, IRBs, bioequivalence testing, etc., patient identification should remain intact and stored in the official FDA files.

- For most others, such as MQSA, plasmapheresis, blood donations, etc., only the patient initials and unique identifier supplied by the firm (such as donor number, donation number, etc.) need be routinely retained in the FDA files.

It is not uncommon for a firm to voluntarily purge the documents of the pertinent identifiers as they are copied. You must verify (by direct comparison to the original document) you received an accurate reproduction of the original, minus the agreed to purging, prior to accepting the copy.

As with any inspection there are times when the specific identifiers must be obtained, copied and retained, such as if/when further interview of the patient/consumer could be necessary. If in doubt, obtain the data. It is always easier to delete later than to return to obtain the information, especially in the few cases where questionable practices may result in the loss of the information.

All documents obtained containing confidential identifiers will be maintained as all documents obtained by FDA containing confidential information, i.e., in the official FDA files. Confidential identifiers may be flagged in the official FDA files for reference by reviewers to assure no confidential data are released under FOIA.

**5.3.9 - REQUEST FOR SAMPLE COLLECTION**

There are times one program division will request another program division to collect surveillance or compliance samples for it. The requesting program division should provide as much of the following information as is available on specific shipments, using the FACTS Create Sample Assignment Screen. See IOM Exhibit 5-9.

The following fields must be completed in order to save the assignment: Requesting Organization, Priority, Subject, POC Name, Op Code, Accom Org, Num of Ops, and PAC. When you create a sample collection assignment, which will require laboratory analysis, you should also create an assignment for the laboratory, using operation 41.

The screen is organized in sections.

**5.3.10 - POST-INSPECTION NOTIFICATION LETTERS**

Issuance of Post-inspection notification letters have been discontinued in all program areas. See [FMD 145](#).

**SUBCHAPTER 5.4 – FOOD AND COSMETICS INSPECTIONS**

**5.4.1 - FOOD and COSMETIC INSPECTIONS**

Food inspections are conducted to evaluate the methods, facilities, and controls used in manufacturing, storage and distribution of foods.

Cosmetic Inspections are conducted to determine whether cosmetics are being manufactured in a manner that ensures products adequately meet all statutory and regulatory requirements so as to be safe for consumers to use.

See CFSAN Office of Compliance's intranet website for the most current guidance (e.g., compliance programs, field assignments, field guidance).

**5.4.1.1 - Preparation and References**

Before undertaking an inspection of food see items 1-11 below. For inspection of cosmetics see items 1,2,3,5,6,7, and 8 below:

- Review the program division files of the firm to be inspected and acquaint yourself with the firm's history, related firms, trademarks, practices and products. The review will identify products difficult to manufacture, require special handling, special processes or techniques, and hours of operation, which is especially important in bacteriological inspections. Remove, for subsequent investigations and discussion with management, Complaint/Injury Reports, which are marked for follow-up during the next inspection. See IOM 5.2.8.
- Become familiar with current programs relating to the particular industry involved and relevant DDHAFO Inspection Guides. Become familiar with any applicable Compliance Policy Guide .
- Understand the nature of the assignment and whether it entails certain problems, e.g., *Salmonella* or other bacteriological aspects.
- Review the [FD&C Act Chapter IV](#) - Food.
- Review and become familiar with the appropriate parts of 21 CFR pertaining to foods and cosmetics. All CFRs can be found [here](#).

Food	21 CFR 101-190
Cosmetics	21 CFR 700-740
Control of Communicable Disease	21 CFR 1240
Interstate Conveyance	21 CFR 1250

- Determine the type operation to be inspected to ensure application of the appropriate regulations.
- Ensure that you have received all necessary training that may be required. Consult your supervisor with questions.
- Review implementation dates of regulations to ensure application of the appropriate regulations.
- Review reference materials on food technology and other subjects.
- If you are assigned to inspect food-service establishments under the FDA - Secret Service Agreement, you should use the most current copy of the

"Food Code" and be standardized in its use. All Food Service Specialists and most Interstate Travel Sanitation Specialists are standardized in use of the code.

11. Be familiar with the "Food Chemicals Codex". See IOM 5.4.4.3.

### 5.4.1.2 - Inspectional Authority

See IOM subchapter 2.2 for broader information on this topic.

Authority to Obtain Records and Information in LACF and Acidified Foods Plants:

FDA's regulation in [21 CFR 113](#) requires commercial processors of low-acid foods packaged in hermetically sealed containers to maintain complete records of processing, production and initial distribution. [21 CFR 114](#) requires the same of commercial processors of acidified foods. [21 CFR 108.25\(g\)](#) and [21 CFR 108.35\(h\)](#) provide that a commercial processor shall permit the inspection and copying of the records required by 21 CFR 113 and 21 CFR 114 by duly authorized employees of FDA. The demand for these records must be in writing on an FDA 482a, Demand for Records, signed by you and must identify the records demanded.

#### 5.4.1.2.1 - WRITTEN DEMAND FOR RECORDS

To obtain the records:

1. Prepare an FDA 482a, "Demand for Records", listing the records demanded. Describe the processing records to be reviewed and/or copied as accurately as you can, e.g., "All thermal process, production, and quality control records, including analytical records and maintenance records which may document any changes to the equipment or the thermal process that are mandated by 21 CFR 108, 113 and 114 for all Low Acid Canned Food (LACF) or Acidified Food (AF) produced at this facility."

If only a specific record is desired list it specifically as follows: e.g., "Fill Weight Records for #2 Filling Machine for the period of 4-15-17 through 6-7-17."

2. Sign the form.
3. Issue the original to the same person to whom the FDA 482, "Notice of Inspection", was issued.
4. Submit an exact copy with your EIR.

#### 5.4.1.2.2 - WRITTEN REQUEST FOR INFORMATION

[21 CFR 108.35\(c\)\(3\)\(ii\)](#) states commercial processors engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall provide FDA with any information concerning processes and procedures necessary by FDA to determine the adequacy of the process. [21 CFR 108.25\(c\)\(3\)\(ii\)](#) requires the same of commercial processors of acidified foods. The information

in this regulation is the data on which the processes are based. Many processors will not have this information and in fact [21 CFR 113.83](#) requires only that the person or organization establishing the process permanently retain all records covering all aspects of establishing the process. The processor should, however, have in his files a letter or other written documentation from a processing authority delineating the recommended scheduled process and associated critical factors.

You may encounter situations where you believe control of certain factors is critical to the process and there is no evidence to document these factors were considered when the process was established (e.g., a change in formulation which could affect consistency). It is appropriate to issue a written request for a letter or other written documentation from a processing authority, which delineates the recommended scheduled process and associated critical factors. This represents the processing authority's conclusions and should correlate with the filed process.

If you believe control of certain factors are critical to the process and are not delineated in the process authority's recommendation or the filed process, obtain all available information about the situation. Include the name of the person or organization who established the process and the specific practices of the firm. This information should be included in your report and forwarded by your program division to the Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS-605) for review, as soon as possible. If the process establishment data and information is deemed necessary by the center, they will either request it directly from the processor or will direct the program division to request it. If requested to obtain the information:

1. Prepare an FDA 482(b) - Request for Information listing the specific information requested. Specify each product involved by food product name and form, container size and processing method. For example, "All documents and records mandated by 21 CFR 108, 21 CFR 114.83 and 21 CFR 113.83 relating to or having a bearing on the adequacy of processes for all Low Acid Canned Food (LACF) or Acidified Food (AF) products that are manufactured, processed or packed by this firm.
2. Sign the form.
3. Issue the original to the same person to whom the FDA 482, "Notice of Inspection", was issued.
4. Submit the carbon copy or exact copy with your EIR.

#### 5.4.1.3 - Records Access Under Sections 414 and 704 of the FD&C Act

The Food Safety Modernization Act amended Section 414 of the Act to provide FDA with access and the ability to copy records under the following circumstances:

1. FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner:
  - a. Is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and

- b. The records are needed to assist FDA in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.
2. FDA believes that there is a reasonable probability that use of or exposure to an article of food, and any other article of food that the FDA reasonably believes is likely to be affected in a similar manner:
- a. Will cause serious adverse health consequences or death to humans or animals, and
  - b. The records are needed to assist FDA in determining whether there is a reasonable probability that the use of exposure to the food will cause serious adverse health consequences or death to human or animals.

If, during an inspection, you believe the above conditions exist, and:

- 1. The firm refuses to provide access to the records, or
- 2. Based on past experience, the program division anticipates that the firm may refuse to provide access to records, or
- 3. The firm requests FDA to provide a separate written request for records,

Notify your supervisor and consult with your program division Compliance Branch.

Program division management will obtain DE concurrence before you issue the Form FDA 482c Notice of Inspection - Request for Records See Exhibit 5-10. Program division management will notify FDA's Office of Emergency Operations (OEO) of any situation requiring issuance of Form FDA 482c. (OEO contact number: 1-866-300-4374 or 301-796-8240 - 24 hours/day.) OEO will notify CFSAN or CVM, as appropriate, OHAFO, DE and OCC according to standard operating procedures to obtain a determination that the situation warrants issuance of Form FDA 482c. DE, in consultation with CFSAN or CVM OEO, OHAFO and the Program division, will determine if the standards for records inspection in paragraphs (1) or (2) of section 414(a) have been met and identify the scope of the records to request. Issue an FDA 482c, Notice of Inspection – Request for Records. See Exhibit 5-10 according to their instructions.

FDA may at a later time, request additional records related to the same article of food, or other article of food that is likely to be affected in a similar manner, as long as the criteria in 414(a)(1) or (a)(2) continue to be met. The request for additional records may be verbal or written as necessary to facilitate access to the records.

Investigators should document in the EIR a firm's refusal to allow access to records or a firm's request for a written request for records and issuance of Form FDA 482c.

**5.4.1.4 - Food and Cosmetic Defense Inspectional Activities**

Food and cosmetics security inspectional activities should be conducted during all routine food and cosmetics safety

inspections. During the normal course of the inspection be alert to opportunities for improvement or enhancement of the firm's food and cosmetics security preventive measures, as compared to those recommended in the guidance documents described below. You should not perform a comprehensive food and cosmetics security audit of the firm or conduct an extensive interview of management or employees in an attempt to determine the level of adoption of preventive measures listed in the guidance. The goal is to facilitate an exchange of information to heighten awareness on the subject of food and cosmetics security.

**5.4.1.4.1 - FOOD AND COSMETIC SECURITY**

Inspectional activities relative to food and cosmetic security for routine food and cosmetic establishment inspections should include:

- 1. Discussion with firm management of relevant FDA guidance documents including:
  - a. FDA Firm Resources
  - b. Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration.
  - c. Retail Food Stores and Food Service Establishments: FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

These documents should be used as references during inspections, as appropriate. If firm management does not already have a copy of the relevant guidance documents provide them with hard copies or information on how to obtain the guidance from [FDA's web site](#).

- 2. Identification of opportunities for improvement or enhancement of the firm's food and cosmetic security preventive measures, as compared to those recommended in the guidance documents, and encouragement of management to make such improvements or enhancements to their security system.

Keep in mind that guidance does not represent mandatory conditions or practices; some of the recommended food and cosmetics security preventive measures may not be appropriate or practical to the specific operation; and other means of achieving the goals of the preventive measures listed in the guidance may be more suitable for the specific operation than those cited as examples. The important message for management is to consider the goals of the food and cosmetics security preventive measures; evaluate the goals relative to the specifics of their operation; and address those that are relevant to the extent practical.

Food and cosmetics security observations should not be listed on form FDA-483, Inspectional Observations, unless they likewise constitute deviations from Current Good Manufacturing Practice. Security discussions should be handled discretely and should only involve management of the firm.

The fact that the discussion took place and, if applicable, that a copy of the guidance document(s) was provided should be recorded in the summary section of the EIR. For example, under a section heading titled "Food and Cosmetics Security" you should only state, "A copy of the **FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration** documents were provided to and food and cosmetics security issues were discussed with (name of firm official)." The details of inspectional findings regarding security should **NOT** be recorded. You should also minimize the quantity and detail of notes taken relative to the firm's food and cosmetics security program, **recording only items** needed to serve as a "memory jog" during the discussion with management.

#### 5.4.1.4.2 - RECONCILIATION EXAMINATIONS

During routine food and cosmetic inspections, conduct one reconciliation examination during each food and cosmetic establishment inspection. The examinations are to be conducted on raw materials used in the manufacture of foods or cosmetics, or finished products received by the firm for further distribution. Preference should be given to products of foreign origin. Where possible, these examinations should be performed on products as they are received by the firm.

Consult the factory jacket for any information on special conditions in the facility that may affect selection of personal protective equipment; consult your supervisor for any recommendations on personal protective equipment; and have available all necessary personal protective equipment to conduct the activity.

As Part of an Import Field Examination and Entry Review - See IOM 6.3.1 and 6.4.3. For imported food and cosmetics, a reconciliation examination should be conducted:

1. Per Part A [IOM 5.4.1.4.3] during all routine import field exams. You should only report time under the Counter Terrorism PAC at the direction of your supervisor or if there is a for cause assignment.
2. In instances where review of entry information raises suspicion (resulting in a detailed reconciliation exam per Part B [IOM 5.4.1.4.4]).

A detailed reconciliation exam should be conducted when there are anomalies in entry declaration information. These may include new, unusual, or unfamiliar commodities, manufacturers, importers; suspicious trans-shipments; or credibility issues such as those between the product and declared country of origin.

If anomalies are found, entry documents should be requested and reviewed for discrepancies between the information declared through electronic filer submissions and that found in entry documents. Entry documents may include invoices, bills of lading, export certifications, and other relevant documents obtained from the importer, filer, or manufacturer/processor of the product. Fields in which discrepancies are found that may raise concern include country of origin, manufacturer, product description, product code, and quantity.

Avoid duplication of examination of the same foreign manufacturer, unless a prior reconciliation examination disclosed an unexplained discrepancy.

Follow guidance in IOM 5.4.1.4.3 to IOM 5.4.1.4.4 below for domestic and import reconciliation exams.

#### 5.4.1.4.3 - RECONCILIATION EXAMINATION GUIDANCE PART A

Reconciliation examinations are performed to ensure that:

1. The food or cosmetic is what it purports to be
2. There are not unexplained differences in the quantity of product ordered, shipped, and received, and
3. There are no signs of tampering or counterfeiting.

Before initiating the exam make a general assessment of the appearance of the lot. Look for packaging that: appears to have been opened and resealed; appears wet, stained, punctured, or powdered. Also, be alert to abnormal chemical odors. If any of these conditions are detected stop the exam and contact your supervisor for guidance. If the lot appears normal proceed with the examination. To the extent possible the exam should be performed in a well-ventilated, well-lit area.

Determine, to the extent possible, whether:

1. The actual goods in a lot are the same as those that are declared in the shipping documents
2. There is consistency in the manufacturer declared on the product labeling, bulk product packaging, and shipping documents; and
3. There is no (unexplainable) inconsistency in actual quantity of goods in the lot, and the quantity ordered and declared in the shipping documents.

**If no unexplained inconsistencies are detected, no further action is indicated.**

If unexplainable inconsistencies are detected, document the occurrence, including photographs of the labeling and packaging, and an accurate count of the lot. Contact your supervisor, who should, in the case of imported products, contact the U.S. Customs and Border Protection for appropriate action. If the examination discloses evidence that inaccurate product identification data was submitted to the OASIS entry screening system, the program division should evaluate the need for follow-up with a compliance filer evaluation and consider providing the information to the U.S. Customs and Border Protection for appropriate action.

**In addition, if unexplained inconsistencies are detected, follow part B [IOM 5.4.1.4.4] of this guidance while conducting a detailed reconciliation exam.**

#### 5.4.1.4.4 - RECONCILIATION EXAMINATION GUIDANCE PART B

Open the shipping packaging of a quantity of product approximating the square root of the number of shipping cartons/packages in the lot and examine the contents. Look for the following:



1. Product identity on the package that does not match the identity declared on the shipping documents
2. Mixed product sizes within a carton or within the lot;
3. Product sizes that do not match the sizes declared on the shipping documents
4. Differences in product configuration or package type (e.g. plastic containers mixed with glass jars or aluminum or steel cans)
5. Easily apparent variations in weight
6. Product labels that display crude, unprofessional, or inconsistent styles of print, color or use of language
7. Unusual placement of labels (e.g. off-center)
8. Variations in lot coding ink color, appearance of embossing, or format (e.g., two line vs. three line, use of letters, numbers and symbols). unusually excessive use of a single code in a very large lot
9. Differences between the actual can codes in the lot and those listed on the shipping documents
10. The existence of a tamper-evident notice on the labeling when the packaging does not contain a tamper-evident feature
11. Product that is beyond its expiration date
12. Inconsistencies in expiration dates within a lot

If no unexplainable discrepancies are noted select at least 1 package at random from the entire shipment and examine their contents. For those products that the contents are visible through the package it is not necessary to open the package. For other products, open the package and examine and field destroy the contents. Look for the following:

1. Differences between the product and that which is declared on the label
2. Color differences in the product between containers of the same lot
3. Style differences in the product between containers of the same lot or between the actual product and the label and document declaration (e.g., sliced vs. whole, colorless noodles vs. egg noodles)
4. Readily detectable abnormal odors (e.g. strong decomposition, bitter almond, petroleum odor, garlic, chlorine, sulfur). Note: specific sensory examination is not expected.

Verification that the product is consistent with the product ordered may require that you obtain information from the owner of the goods, importer, filer, or custom house broker. Review of the following types of documentation may be necessary to accomplish the above instructions, to the extent that they are available: authentic label supplied by the owner of the goods, importer, filer, or custom house broker; purchase order; invoice; shipping records (bill of lading, weigh bill, manifest). Depending on the findings of the exam and record review, you may wish to request that the importer assist in an evaluation of the authenticity of the product, based on the importer's experience with the product.

Every effort should be made to document any discrepancies through use of photographs, and additional records that may be available from the filer, importer, owner, or customs house broker.

#### 5.4.1.4.5 - SPECIAL SAFETY PRECAUTIONS

See IOM Subchapters 1.5 Safety, subsections including 1.5.1.1 thru 1.5.1.4, and Section 1.5.3 on sampling hazards.

When performing an establishment inspection or reconciliation examination, follow these instructions:

1. If there are no signs of tampering or counterfeiting, use level I protection, which consists of: work gloves; coveralls; work boots; and in a dusty situation, a dust mask.
2. If there are signs of tampering or counterfeiting, use level II protection and consult your supervisor for any additional safety precautions needed. Level II protection consists of: work gloves worn over surgical gloves; full face respirator with appropriate cartridges; disposable coveralls; and work boots.

#### 5.4.1.5 - Food Registration

Section 415 of the FD&C Act (21 U.S.C. 350d) requires most domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA before operations commence. Section 415 also requires food facilities to renew their registration biennially. FDA requires renewals to be submitted between October 1 and December 31 of each even-numbered year. Facilities may register electronically at <http://www.access.fda.gov>, by mail, or by CD-ROM for multiple submissions, to Food and Drug Administration, Food Facility Registration, HFS-651, 5100 Paint Branch Parkway, College Park, MD, 209932, or by fax to 301-436-2804. FDA maintains the registration information in the Food Facility Registration Module (FFRM) within the FDA Unified Registration and Listing System (FURLS) database. A facility is not registered until all required fields have been completed in FFRM. Upon completion, the registrant is issued a system generated 11-digit registration number.

For food facilities that are required to register, the owner, operator, or agent in charge of a facility must provide the following:

1. Facility name, address, phone number, and emergency contact phone number;
2. Parent company name, address, and phone number (if applicable);
3. Name, address, and phone number of the owner, operator, or agent in charge;
4. Email address for the contact person of the facility or, in the case of a foreign facility, the U.S. agent for the facility;
5. All trade names the facility uses;
6. Applicable food product categories, as listed on the registration form;
7. Name, address, and phone number of a foreign facility's U.S. agent and phone number of the facility's emergency contact if it is someone other than the U.S. agent;

8. Certification that the information submitted is true and accurate and that the person submitting the registration is authorized to do so; and
9. Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act (section 415(a)(2)).

Section 415(b) of the FD&C Act also provides FDA with authority to suspend the registration of a facility when:

1. FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals (SAHCODHA); and
2. That facility:
  - a. Created, caused, or was otherwise responsible for that reasonable probability of SAHCODHA; or
  - b. Knew of, or had reason to know of, the reasonable probability of SAHCODHA, and packed, received, or held such food.

The purpose of registration is to provide FDA with sufficient and reliable information about food facilities. Registration will help provide information on the origin and distribution of food that may be associated with a real and potential threat to public health. In the event of a foodborne outbreak of illness, registration information will enable FDA to notify the food facility representatives and to investigate the source and cause of the outbreak. It will also enable FDA to identify and contact other facilities that might be associated with the food causing the outbreak.

Under section 301(dd) of the FD&C Act (21 U.S.C. 331(dd)), the failure to register a food facility is a prohibited act. Food from a foreign facility that is not registered may be held at the port of entry (section 301(l) of the FD&C Act (21 U.S.C. 381(l))).

#### Low Acid and Acidified Food Registration

21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1) require all commercial processors, when first engaging in the manufacture, processing, or packing of acidified foods (AF) or low-acid canned Foods (LACF) to register their facility with FDA and file information including the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method, and a list of foods so processed in each establishment by using form FDA 2541.

In addition to registering the facility, AF processors must provide FDA with information, using Form FDA 2541e, on the scheduled processes for each acidified food in each container size (21 CFR 108.25(c)(2)). LACF processors must file processes using either Form FDA 2541d, 2541f or Form FDA 2541g.

Both registration and filing can either be done electronically (<https://www.access.fda.gov/>) or by mail by using the appropriate forms.

#### 5.4.1.5.1 - FACILITIES EXEMPTED FROM REGISTRATION

The following food facilities do not have to register (21 CFR 1.226):

1. A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the U.S. A foreign facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature. The facility conducting the *de minimis* activity also must register.
2. Farms that are devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes:
  - a. Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and
  - b. Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.
3. Retail food establishments whose sales to consumers exceed their sales to non-consumers (businesses are considered non-consumers).
4. Restaurants that prepare and serve food directly to consumers for immediate consumption.
5. Nonprofit food establishments in which food is prepared for, or served directly to, the consumer.
6. Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels that otherwise engage in processing fish are required to register. For the purposes of this section, "processing" means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.
7. Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products

Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

8. Other exemptions from registration in the final rule are based on the definition of food included within the scope of the registration regulation. Facilities that manufacture/process, pack, or hold food contact substances (including packaging materials) (21 CFR 1.227(b)(4)(i)(A)) or pesticides (21 CFR 1.227(b)(4)(i)(B)) are exempt from registration.

#### 5.4.1.5.2 - FOOD FACILITY REGISTRATION RESOURCES

Additional information relating to food facility registration is available at the following website: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>.

See the guidance in [Compliance Policy Guide Sec. 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#). During inspection of a domestic or foreign facility that is required to register, make sure that firm's management is aware of the food facility registration requirements. Inform the firm's management that information regarding food facility registration and penalties for failure to register is available at the following website: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>. For facilities that are required to register, but have not done so, encourage electronic registration and provide them with the web site address for electronic registration <http://www.access.fda.gov>. If the firm needs to submit the hard copy registration form, inform them that they may obtain a registration form to complete and submit by mail at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf>). Also encourage the firm to submit the optional information on the registration form to assist and facilitate FDA's future communications with the firm.

If the registration information obtained during the inspection (foreign and domestic) is different from the information in FFRM, send an email to [CFSANFoodFacilityRegistration@fda.hhs.gov](mailto:CFSANFoodFacilityRegistration@fda.hhs.gov) with the facility name, FEI or registration number, and a description of the specific registration information that is inaccurate (e.g., type of activity, facility name, address, emergency contact information). If the facility is operating with no registration, a suspended registration, an invalid registration, or a cancelled registration, send an email to [CFSANFoodFacilityRegistration@fda.hhs.gov](mailto:CFSANFoodFacilityRegistration@fda.hhs.gov) with the facility name and FEI with a description of the situation. Report what you noticed with the Food Facility Registration (FFR) in your EIR.

## 5.4.2 - PERSONNEL

### 5.4.2.1 - Management

Follow the guidance described in IOM 5.3.6 when documenting individual responsibility including obtaining the full name and titles of the following individuals:

1. Owners, partners, or officers.
2. Other management officials or individuals supplying information.
3. Individuals to whom credentials were shown and FDA 482 Notice of Inspection, FDA 482d Request for FSVP Records and other inspectional forms issued.
4. Individuals refusing to supply information or permit inspection.
5. Individuals with whom inspectional findings were discussed or recommendations made.

Regulations require plant management take all reasonable measures and precautions to assure control of communicable disease, employee cleanliness, appropriate training of key personnel, and compliance by all personnel with all requirements of [21 CFR 110.10](#), [112 Subpart C](#), [113.10](#), and [114.10](#).

Determine if adequate supervision is provided for critical operations where violations are likely to occur if tasks are improperly performed.

### 5.4.2.2 - Employees

Improper employee habits may contribute to violative practices in an otherwise satisfactory plant. Observe the actions of employees during all phases of the inspection. Observe employees at their work stations and determine their duties or work functions.

Note whether employees are following food hygiene and food safety practices, including wearing outer garments suitable to the operation in a manner that protects against allergen cross contact and contamination, maintaining adequate personal cleanliness, and store personal items properly. Note whether employees eat while on duty. Determine if hand washing and sanitizing, if necessary, is adequate, and performed at the appropriate times and intervals. Unsecured jewelry and other objects should be removed, covered or sanitized as appropriate. Gloves, if they are used in food handling, shall be maintained in an intact, clean, and sanitary condition. Hair nets, headbands, caps, beard covers, or other effective hair restraints should be worn, where appropriate, in an effective manner. Determine disease control practices, if there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated. For example, if employees have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, they should be excluded from any operations which may be expected to result in contamination.

Under no circumstance should you swab a sore, touch or remove a bandage from an employee in an attempt to

obtain bacteriological data. To do so is a violation of personal privacy, possibly hazardous to you and/or the employee, and usually provides little useful data.

Observe employee traffic patterns to determine how it affects possible routes of contamination. During inspections of produce farms evaluate practices for growing, harvesting, packing, and holding practices of covered produce to prevent contamination of covered produce and food contact surfaces.

Observe and record insanitary employee practices or actions showing employees handling or touching insanitary or dirty surfaces and then contacting food products or direct food contact surfaces. Such practices might include employees spitting, handling garbage, placing their hands in or near their mouths, cleaning drains, handling dirty containers, etc. and then handling food product without washing and sanitizing their hands. Observe whether employees comply with plant rules such as, "No smoking", "Keep doors closed", "Wash hands before returning to work", etc. See IOM 5.4.7.2.2.

Be alert to employees handling insanitary objects, then quickly dipping their hands in sanitizing solutions without first washing them. Depending upon the amount and type of filth deposited on the hands during the handling of insanitary objects, such attempts at sanitizing are questionable at best. Sanitizers work most effectively on hands, which have been first cleaned by washing with soap and water.

Conversations with employees doing the work may provide information on both current and past objectionable practices, conditions and circumstances. These should be recorded in your notes.

Where appropriate, determine employee education and training. Also determine type, duration, and adequacy of firm's training programs, if any, to prepare employees for their positions and to maintain their skills.

### 5.4.3 - PLANTS AND GROUNDS

Grounds must be kept in a condition that will protect against the contamination of food. Building structures at produce farms may include fully or partially enclosed structures and fields. If the plant grounds are bordered by grounds not under the operator's control care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination. Environmental factors such as proximity to swamps, rivers, wharves, city dumps, drain fields, runoff, concentrated animal feeding operation (CAFO), compost operations, manure operations, etc., may contribute to rodent, bird, insect or other sanitation problems.

#### 5.4.3.1 - Plant Construction, Design and Maintenance

The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-

production purposes. Determine the approximate size and construction (e.g., brick and concrete block) of building housing the firm and if suitable in size, construction, and design to facilitate maintenance and sanitary operations.

Buildings, fixtures, and other physical facilities must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Check placement of equipment, storage of materials, lighting, ventilation, and placement of partitions and screening to eliminate product contamination by bacteria, birds, vermin, etc. Determine any construction defects or other conditions such as broken windows, cracked floor boards, sagging doors, etc. which may permit animal entry or harborage.

Determine who is responsible for buildings and grounds maintenance. Many facilities such as docks, wharves, or other premises are owned and maintained by other firms, municipalities, or individuals for lease for manufacturing operations. Determine who is legally responsible for repairs, maintenance, rodent proofing, screening, etc. Evaluate the firm's attitude toward maintenance and cleaning operations.

#### 5.4.3.2 - Waste Disposal

Waste and garbage disposal poses a problem in all food operations depending upon plant location and municipal facilities available.

Check the effectiveness of waste disposal on the premises and ensure it does not cause violative conditions or contribute toward contamination of the finished products. Check for in-plant contamination of equipment and/or product, if its water is supplied from nearby streams, springs, lakes or wells.

Suspected dumping of sewage effluent into nearby streams, lakes, or bay waters near water intakes can be documented by color photographs and water-soluble fluorescein sodium dye. Place approximately two ounces dye, which yields a yellowish red color, into the firm's waste system and/or toilets, as applicable, and flush the system. The discharge area of the effluent becomes readily visible by a yellowish-red color on the surface of the water as the dye reaches it. Color photographs should be taken.

Determine collecting or flushing methods used to remove waste from operating areas. If water is used, determine if it is recirculated and thus may contaminate equipment or materials.

Determine the disposition of waste materials that should not be used as human food such as rancid nuts, juice from decomposed tomatoes, etc.

Determine the disposition of waste, garbage, etc., which contain pesticide residues. Determine how this is segregated from waste material which contains no residues, and which may be used for animal feed.

### 5.4.3.3 - Plant Services

If applicable, check steam generators for capacity and demand. Demand may reach or exceed the rated capacity, which could affect adequacy of the process. Check boiler water additives if steam comes in direct contact with foods. Boiler additives for steam that comes into contact with food must be approved as direct food additives under 21 CFR 173.310

Check central compressed air supply for effective removal of moisture (condensate) and oil. Determine if any undrained loops in the supply line exist where condensate can accumulate and become contaminated with foreign material or microorganisms.

### 5.4.4 - RAW MATERIALS

Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food. Raw materials must be stored under conditions that will protect against allergen cross-contact as well as microbial, chemical or physical contamination and stored in a manner to minimize deterioration.

List in a general way the nature of raw materials on hand. Itemize and describe those, which are unusual to you, or involved in a suspected violation (copy quantity of contents and ingredient statements, codes, name of manufacturer or distributor, etc.). Be alert for additives and preservatives. Evaluate the storage of materials. Determine the general storage pattern, stock rotation and general housekeeping. Materials should be stored so they are accessible for inspection. Thoroughly check ceilings, walls, ledges, and floors in raw material storage areas for evidence of rodent or insect infestation, water dripping or other adverse conditions.

#### 5.4.4.1 - Handling Procedure

Determine if growing conditions relative to disease, insects, and weather are affecting the raw material. Check measures taken for protection against insect or rodent damage. Raw materials may be susceptible to decomposition, bruising or damage, e.g., soft vegetables and fruits delivered in truckload lots. Determine the holding times of materials subject to progressive decomposition. Review storage practices for ingredients that require time / temperature control such as bulk silos or in-process batters and slurries.

#### 5.4.4.2 - Condition

Evaluate the firm's acceptance examination and inspection practices including washing and disposition of rejected lots. Examine rejected lots and if you encounter a raw material that is potentially adulterated or misbranded, consider collecting a sample and ensure the information is reported to the appropriate HAF Division. If the documentation shows the product was imported, contact your

corresponding [import division](#) to determine if the product is subject to Import Alert and to determine appropriate follow-up.

Determine the general acceptability of raw materials for their intended use and their effect on the finished product. Raw stocks of fruits or vegetables may contribute decomposed or filthy material to the finished product. Be alert for use of low quality or salvage raw materials. Check bags, bales, cases and other types of raw material containers to determine signs of abnormal conditions, indicating presence of filthy, putrid or decomposed items. Check any indication of gnawed or otherwise damaged containers, to ascertain if material is violative. Be alert to contamination of raw materials by infested or contaminated railroad cars or other carriers.

Document by photographs, exhibits or sketches any instances where insanitary storage or handling conditions exist.

#### 5.4.4.3 - Food Chemicals Codex

Any substance used in foods must be food-grade quality. FDA regards the applicable specifications in the current edition of the publication "Food Chemicals Codex" as establishing food-grade unless FDA publishes other specifications in the Federal Register.

Determine whether firm is aware of this publication and whether or not they comply.

### 5.4.5 - EQUIPMENT AND UTENSILS

By arriving before processing begins, you are able to evaluate conditions and practices not otherwise observable before plant start-up. This includes adequacy of clean-up, where and how equipment is stored while not in use, how hand sanitizing solutions and food batches are prepared and if personnel sanitize their hands and equipment before beginning work.

Dirty or improperly cleaned equipment and utensils may be the focal point for filth or bacterial contamination of the finished product. Examine all equipment and utensils to determine the following: design, materials, workmanship, materials, maintenance, suitability, and ease of cleaning and sanitization. Determine if equipment is constructed or covered to protect contents from dust and environmental contamination. Open inspection ports to check inside only when this can be done safely. Notice whether inspection ports have been painted over or permanently sealed.

Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food.

### 5.4.5.1 - Filtering Systems

Observe the firm's filtering systems and evaluate the cleaning methods (or replacement intervals of disposable filters) and schedules. Check types of filters used. There have been instances where firms have relied on household furnace type filters.

### 5.4.5.2 – Cleaning and Sanitization of Equipment and Utensils

Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination. Utensils and equipment must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

Check the sanitary condition of all machinery. Determine if equipment is cleaned prior to each use and the method of cleaning. Observe how cleaning occurs and if there is a possibility of aerosol contamination of food contact surfaces. For example, the use of high-pressure hoses on one system that is idle may contaminate an adjacent system that is operational. If the firm rents or leases equipment on a short-term basis, report prior cleaning procedures. Equipment may have been used for pesticides, chemicals, drugs, etc., prior to being installed and could therefore be a source of cross-contamination.

### 5.4.5.3 - Conveyor Belt Conditions

Equipment used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

Inspect conveyor belts for build-up of residual materials and pockets of residue in corners and under belts. Look in inspection ports and hard-to-reach places inside, around, underneath, and behind equipment and machinery for evidence of filth, insects, and/or rodent contamination. Chutes and conveyor ducts may appear satisfactory, but a rap on them with the heel of your hand or a rubber mallet may dislodge static material, which can be examined. See IOM 4.3.7.7.3 for procedure on taking In-line Sample Subs.

### 5.4.5.4 - Utensils

Determine how brushes, scrapers, brooms, and other items used during processing or on product contact surfaces are cleaned, sanitized and stored. Evaluate the effectiveness of the practices observed.

### 5.4.5.5 - Mercury and Glass Contamination

Be alert for improper placement or inadequately protected mercury switches, mercury thermometers, or electric bulbs.

Breakage of these could spray mercury and glass particles onto materials or into processing machinery.

### 5.4.5.6 - UV Lamps

If firm is using ultra violet (UV) lamps for bacteria control, check if it has and uses any method or meters to check the strength of UV emissions. If so, obtain methods, procedures, type equipment used, and schedule for replacement of weak UV bulbs.

### 5.4.5.7 - Chlorine Solution Pipes

In plants where chlorine solution is piped, check on type of pipe used. Fiberglass reinforced epoxy pipe has been observed to erode inside through the action of the chlorine solution. This poses a threat of contamination from exposed glass fibers. Pipes made with polyester resin do not deteriorate from this solution.

### 5.4.5.8 - Sanitation Practices

Overall sanitation must be under the supervision of one or more competent individuals assigned responsibility for this function. Observe sanitizing practices throughout the plant and evaluate their effectiveness, degree of supervision exercised, strength, time, and methods of use of sanitizing agents. Determine the use, or absence of, sanitizing solutions both for sanitizing equipment and utensils as well as for hand dipping. If chlorine is used, 50 ppm - 200 ppm free chlorine should be used for equipment and utensils, while a 100-ppm free chlorine will suffice for hand dipping solutions. Sanitizing solutions rapidly lose strength with the addition of organic material. The strength of the solution should be checked several times during the inspection. Sanitizers including peracetic acid (PAA) and chlorine dioxide may be used in post-harvest agriculture water as a treatment for bacteria in the water. Ensure any sanitizers used are food grade and manufacture's labeled instructions are followed.

## 5.4.6 - PROCESS AND CONTROLS

All operations must be conducted in accordance with adequate sanitation principles. All operations must be conducted under such conditions and controls necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

Fans and other air-blowing equipment should operate in a manner that minimizes the potential for allergen cross-contact and for contamination.

Where helpful to describe equipment and processes, draw flow plans or diagrams to show movement of materials through the plant. Generally, a brief description of each step in the process is sufficient. List all quality control activities for each step in the process and identify Preventative Control Points. Provide a full description when necessary to describe and document objectionable conditions, or

where the assignment specifically requests it. Observe whether hands and equipment are washed or sanitized after contact with insanitary surfaces. For example:

1. Workers do general work, then handle the product;
2. Containers contact the floor, then are nested or otherwise contact product or table surfaces;
3. Workers use common or dirty clothes or clothing for wiping hands;
4. Product falls on a dirty floor or a floor subject to outside foot traffic and is returned to the production line.

Be alert for optimum moisture, time and temperature conditions conducive to bacterial growth.

Keep in mind that in agricultural practices, some buildings may not be fully enclosed. This is a normal part of operations and may not indicate insanitary conditions. Evaluate the farm's operations including the process controls and cleaning operations.

In industries where scrap portions of the product are re-used or re-worked into the process (e.g., candy and macaroni products), observe the methods used in the re-working and evaluate from a bacteriological standpoint. Re-working procedures such as soaking of macaroni or noodle scrap to soften or hand kneading of scrap material offers an excellent seeding medium for bacteria.

When a product is processed in a manner which destroys micro-organisms, note whether there are any routes of recontamination from the "raw" to the processed product (e.g. dusts, common equipment, hands, flies, etc.).

#### 5.4.6.1 - Ingredient Handling

Raw materials and ingredients must be inspected and segregated or handled so they are clean and suitable for processing and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Water reused for washing, rinsing, or conveying food must not cause allergen cross-contact or increase the level of contamination of the food.

All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

21 CFR 117.100(b) further prohibits the mixing of a food containing defects at levels that render that food adulterated with another lot of food. This practice would render the final food adulterated, regardless of the defect level of the final food.

Material scheduled for rework must be identified and held to protect against allergen cross-contact and against contamination. This includes holding at proper temperatures and relative humidity and in such a manner as to prevent the food from becoming adulterated.

Observe the method of adding ingredients to the process. Filth may be added into the process stream from dust, rodent excreta pellets, debris, etc. adhering to the surface of ingredient containers. Evaluate the effectiveness of cleaning and inspectional operations performed on the materials prior to or while adding to the process. Determine specific trimming or sorting operations on low quality or questionable material. Observe and report any significant lags during the process or between completion of final process and final shipping. For example, excessive delay between packing and freezing may be a factor in production of a violative product.

#### 5.4.6.2 - Formulas

The Act does not specifically require management to furnish formula information except for human drugs, restricted devices and infant formulas. Nonetheless, they should be requested especially when necessary to document violations of standards, labeling, or color and food additives. Management may provide the qualitative formula but refuse the quantitative formula.

If formula information is refused, attempt to reconstruct formula by observing:

1. Product in production,
2. Batch cards or formula sheets,
3. Raw materials and their location.

#### 5.4.6.3 - Food Additives

Refer to the food additives programs in CP (Chapter 9) for instructions on conducting establishment inspections of firms manufacturing food additive chemicals. Information is also available in ORA's ["Guide to Inspections of Manufacturers of Miscellaneous Food Products - Volume II."](#)

On food inspections, direct your evaluation of food additives only to those instances of significant violation, e.g., failure to declare sulfiting agents on finished product labels, when required, or gross misuse.

Routine inspectional coverage will be directed primarily to the following two types of additives:

1. Unauthorized and illegal as listed in the Food Additive Status List (safrole, thiourea, et al), and
2. Restricted as to amount in finished food.

Because of special problems, exclude the following additives from coverage during routine inspections:

1. Packaging materials,
2. Waxes and chemicals applied to fresh fruit and vegetables (unless covered under the Produce Safety Regulation),
3. Synthetic flavors and flavoring components except those banned by regulations or policy statements (these products will be covered under other programs), and
4. Food additives in feeds (these products will be covered under other programs).

Substances Added to Food (formerly The Everything Added to Food in the United States ([EAFUS](#)) and the [Food](#)

[Additives Status List \(FASL\)](#) found on the CFSAN website contains an alphabetical listing of substances, which may be added directly to foods or feeds and their status under the Food Additives Amendment and Food Standards. In addition, a few unauthorized or illegal substances are included.

You may encounter substances not included in the Food Additives Status List (FASL). Such substances will include:

1. Safe substances not on the list of items [Generally Recognized as Safe \(GRAS\)](#) which are not published in the regulations, i.e., salt, cane sugar, corn syrup, vinegar, etc.;
2. Synthetic flavoring substances because of their indefinite status;
3. Substances pending administrative determination,
4. Substances granted prior sanction for specific use prior to enactment of the Food Additives Amendment.

Give primary attention to unauthorized substances. Document and calculate levels of restricted-use additives in finished food only where gross misuse or program violations are suspected as follows:

1. List ingredients, which may be restricted substances or food additives, and determine their status by referring to the current FASL. Document labeling on containers of these substances.
2. Obtain the quantitative formula for the finished product in question.
3. Determine the total batch weight by converting all ingredients to common units.
4. Calculate the theoretical levels in the final product of all restricted or unauthorized ingredients from the formula by using the Food Additives Nomographs. See IOM Exhibit 5-11.
5. Determine probable level of restricted ingredients by observing the weight of each ingredient actually put into the batch.

#### 5.4.6.4 - Color Additives

Evaluate the status of color additives observed during each establishment inspection by using the [Color Additive Status List](#) and the [Summary of Color Additives Listed in the United States in Food, Drugs, Cosmetics, and Medical Devices](#). Both of these links can be found on the CFSAN website. These lists provide the current status and use limitations of most color additives likely to be found in food, drug, device, or cosmetic establishments.

Determine if certified color additives are declared on finished product labels, when required.

Stocks of delisted and uncertified colors may be found in the possession of manufacturers where there is no evidence of misuse. Advise the firm of the status of these colors **additives**. If management wishes to voluntarily destroy such colors **additives**, witness the destruction and include the facts in your EIR. If the firm declines to destroy the colors **additives**, determine what disposition is planned, i.e., use in non-food, non-drug, non-cosmetic or non-medical device products. The validity of certification

information can be checked by accessing the online Color Certification Database system maintained by the **Food and Drug Administration, Color Certification Branch**. Contact the **Color Certification Branch** to be granted user privilege.

Where decertified or restricted-use colors **additives** are used in manufacturing food, drug, device, or cosmetics products, proceed as follows:

1. Collect an Official Sample consisting of the color **additives** and the article in which it is being used. Make every effort to collect interstate shipments of the adulterated product before attempting to develop a 301(k) or 301(a) case. When regulatory action is an alternative, obtain sufficient interstate records to cover both the color **additives** and the basic ingredients of the manufactured product. Refer to IOM Sample Schedule, Chart 9 - Sampling Schedule for Color Containing Products for guidance.
2. Document the use of decertified color **additives** after the decertifying date. Documentation should include batch formula cards, employee statements, code marks indicating date of manufacture, color certification number, etc. The presence of a color **additive** in the finished product will be confirmed by your servicing laboratory.

#### 5.4.6.5 - Quality Control

Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. The objective of quality control is to ensure the maintenance of proper standards in manufactured goods, especially by periodic random inspection of the product. Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination. Your inspection should determine if the firm's quality control system accomplishes its intended purpose.

The manufacturer, processor, packer and holder of food must utilize quality control operations that reduce natural or unavoidable defects to the lowest defect action level currently feasible.

Establish responsibility for specific operations in the control system. Determine which quality controls are critical for the safety of the finished product. These controls may include process control points, sanitation control points, allergen control points or other controls intended to ensure a safe product is manufactured.

#### 5.4.6.5.1 - INSPECTION SYSTEM

Determine what inspectional control is exercised over both raw materials and the processing steps. Such inspection may vary from simple visual or other organoleptic examination to elaborate mechanical manipulation **and/or laboratory tests**. Determine what inspection equipment is used, i.e., inspection belts, sorting belts, grading tables,



ultraviolet lights, etc. Ascertain its effectiveness, maintenance or adjustment schedules. Where indicated, determine the name of the manufacturer of any mechanical inspection device and the principles of its operation.

Evaluate the effectiveness of the personnel assigned to inspection operations. Determine if the inspection belts or pick-out stations are adequately staffed and supervised.

Determine the disposition of waste materials, which are unfit for food or feed purposes.

#### 5.4.6.5.2 - LABORATORY TESTS

Describe routine tests or examinations performed by the firm's laboratory and the records maintained by the firm. Tests may include in product testing, finished product testing or environmental monitoring. Determine what equipment is available in the laboratory and if it is adequate for the purpose intended. If the firm uses a consulting laboratory, determine what tests are performed and how often. Review laboratory records for the period immediately preceding the inspection.

#### 5.4.6.5.3 - MANUFACTURING CODE SYSTEM

Obtain a complete description of the coding system with any necessary keys for interpretation, or the need of ultraviolet light for visibility. (Specific requirements exist for codes applied to Low Acid Canned Foods (LACF) and Acidified Foods (AF)). Refer to [21 CFR 113.60\(c\)](#) and [114.80\(b\)](#).

#### 5.4.6.6 Packaging, Labeling, and Packing

Evaluate packaging, packing and labeling operations. "Packaging" is the processes and procedures used to place product into its immediate container. "Packing" refers to how packages or secondary packages are placed and configured for storage, shipping and distribution.

Evaluate storage of packaging materials including protection from contamination by rodents, insects, toxic chemicals or other materials. Appraise the manner in which containers are handled and delivered to the filling areas. Determine if there is likelihood of chipping of glass or denting, puncturing, tearing, etc., of packaging materials. Observe the preparation of containers prior to filling. Consider any washing, steaming, or other cleaning process for effectiveness. Determine, in detail, the use of air pressure or other cleaning devices.

#### 5.4.6.6.1 - QUANTITY OF CONTENTS

If slack fill is suspected, weigh a representative number of finished packages. See IOM 4.3.8 for net weight procedure. Sets of official weights are available in the division servicing laboratory. These may be used to check the accuracy of firm's weighing equipment.

#### 5.4.6.6.2 - LABELING

Check the sanitary condition of labelers and equipment feeding cans to, and away from, the labeler. Determine if old product is present on any equipment which touches the can end seams, in the presence of moisture carry-over from the can cooling operation. Check availability of floor drains in the labeling area. Absence of floor drains could indicate infrequent cleaning of the equipment unless it is physically moved to another area for cleaning.

Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

Determine what labels are used. Determine what labeling accompanies and/or promotes the product, including information on the establishment's internet website. Depending upon the claims made in promotional material, a food product may be a dietary supplement or drug product. Consult your supervisor with questions about claims. Obtain specimens of representative labels and labeling including pamphlets, booklets, and other promotional material as necessary.

#### 5.4.6.6.3 – NUTRITIONAL AND ALLERGEN LABELING

If the products contain allergens, ensure that the firm has controls in place to accurately identify the label declaration and procedures to ensure proper application to the final packaging. Review product labels to ensure major food allergens are properly declared in the ingredient list or in a "Contains" statement. Check for listing of subingredients that may contain allergens. See [Food Allergen Labeling and Consumer Protection Act of 2004 \(FALCPA\)](#) requirements for guidance.

For products that bear voluntary gluten-free claims, refer to the ["Gluten- Free Labeling of Foods"](#) page for guidance. Such claims must meet the requirements in the Gluten-Free labeling of foods regulation (21 CFR 101.91).

Refer to the ["Industry Resources on the Changes to the Nutrition Facts Label"](#) and [21 CFR 101.9](#) to ensure product labels meets the requirement for the Nutrition Facts label.

#### 5.4.6.6.4 – SANITARY OPERATIONS

Buildings, fixtures, and other physical facilities must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated.

Substances used in cleaning and sanitizing must be free of undesirable microorganisms and be suitable under the

conditions of use. Toxic compounds, e.g., detergents, sanitizers and pesticides, must be properly stored.

Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests.

#### 5.4.6.6.5 – SANITARY FACILITIES AND CONTROL

Each plant must be equipped with adequate sanitary facilities and accommodations including the following: water supply, plumbing, sewage disposal, toilet facilities, hand washing facilities and rubbish and offal disposal.

Inspect toilet facilities for cleanliness, adequate supplies of toilet paper, soap, towels, hot and cold water, and hand washing signs. Check if hand washing facilities are hidden, or if located where supervisory personnel can police hand washing.

Determine if there is backflow from, or cross connections between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

#### 5.4.6.6.6 Labeling violations

Refer to 21 CFR part 701 (Cosmetic Labeling) or 21 CFR part 740 (warning statements), 21 CFR Part 112 (Produce Safety) and applicable sections of CPGM 7329.001 for information on labeling requirements. Collect and review labels as required by a particular assignment. For routine inspections, samples of labels are not required unless significant violations are noted.

#### 5.4.6.6.7 Cosmetic product labeling making drug claims

See [CPGM 7329.001](#) (Part III.A. and III.B.1) to determine if there is cause to collect evidence supporting that a cosmetic is to be considered a drug. Examples of products marketed strictly as cosmetics but making drug claims include those which claim to promote hair growth, prevent baldness, prevent or treat dandruff, enhance eyelash growth and treat skin diseases such as acne.

Collect the following as evidence that could enable FDA to consider such a product an illegally marketed drug:

- 1- product labels, including outer containers and all inserts
- 2- promotional material in written and/or electronic format

If the product is suspected to contain an active pharmaceutical ingredient associated with drug claims also collect:

- 3- samples of product
- 4- samples of the active ingredient used in the cosmetic and ingredient certificate of analysis
- 5- records showing usage of the active ingredient in manufacturing of a cosmetic product batch

(NOTE: As stated in CPGM 7329.001 III.A, CDER and CFSAN have concurrent jurisdiction over any product purported as a cosmetic that meets the legal definition of a drug.)

#### 5.4.6.6.8 – QUALIFIED EXEMPT PRODUCE LABELING

When a food packaging label is required on food that would otherwise be covered produce it must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

When a food packaging label is not required on food that would otherwise be covered produce, it must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

For additional information on Qualified Exempt produce and labeling, refer to [21 CFR 112 Subpart A](#).

### 5.4.7 - SANITATION

Documented observation of the conditions under which food products are processed, packed, or stored is essential to the proper evaluation of the firm's compliance with the law. This involves the determination of whether or not insanitary conditions contribute to the product being adulterated with filth, rendered injurious to health, or whether it consists in whole or in part of a filthy, putrid or decomposed substance.

Observations that dirt, decomposed materials, feces or other filthy materials are present in the facility and there is a reasonable possibility these filthy materials will be incorporated in the food are also ways of determining products may have become contaminated.

#### 5.4.7.1 - Routes of Contamination

It is not sufficient to document only the existence of insanitary or filthy conditions. You must also demonstrate how these conditions contribute or may contribute to contaminating the finished product. Investigate and trace potential routes of contamination and observe all means by which filth or hazardous substance may be incorporated into the finished product. For example, defiled molding starch in a candy plant may contribute filth to candy passing through it, or filth in insect or rodent contaminated raw materials may carry over into the finished product. IOM

Section 4.3.7 contains instructions on sample collection techniques for adulteration violations, including instructions for field exams and sample collections to document evidence of rodent, insect, etc., contaminated lots, and instructions for in-line sampling, including bacteriological samples. Finished product sample sizes for filth and micro collections can be found in the applicable Compliance Program (CP) or **DDHAFO Inspection Guides**.

**5.4.7.1.1 - INSECTS**

Insect contamination of the finished product may result from insect infested raw material, infested processing equipment or insanitary practices, and by insanitary handling of the finished product. When routes of contamination with insect filth are encountered, identify the insects generally, e.g., weevils, beetles, moths, etc. If qualified, identify as to species. You must be correct in your identification. See IOM Appendix A.

**5.4.7.1.2 - RODENTS**

Rodent contamination of the finished product may result from using rodent defiled raw materials, exposure to rodents during processing, and by rodent depredation of the finished product. When evidence of rodents is discovered, you should thoroughly describe its composition, quantity, estimated age and location. Explain its significance and potential for product contamination. See IOM Section 4.3.7.4.2.3 – Summary of Sample for Rodent Evidence.

**5.4.7.1.3 - PESTICIDES**

Pesticide contamination of the finished product may be the result of mishandling of food products at any stage in growing, manufacturing or storage. The use of toxic rodenticides or insecticides in a manner, which may result in contamination, constitutes an insanitary condition. Where careless use of these toxic chemicals is observed, take photographs and provide other documentation showing its significance in relation the food products.

Additional guidance can be found in 21 CFR as follows:

1. [Part 117.10\(b\)](#) - Personnel
2. [Part 117.20\(b\)](#) - Plant Construction and Design
3. [Part 117.35\(c\)](#) - Pest Control
4. [Part 117.40\(a\)](#) - Equipment and Utensils

Additional guidance can be found in 40 CFR Part 180 - Tolerances and Exemptions From Tolerances For Pesticides in Food Administered by The Environmental Protection Agency as follows:

1. [Part 180.521](#) - Fumigants for grain-mill machinery; tolerances for residues, and
2. [Part 180.522](#) - Fumigants for processed grains used in production of fermented malt beverages; tolerances for residues.

Be alert for:

1. Possible PCB contamination. Articles containing PCBs (e.g., transformers, PCB containers stored for disposal, electrical capacitors) must be marked with prescribed labeling to show they contain PCBs. No PCB-containing heat exchange fluids, hydraulic fluids or lubricants are allowed used in food plants. All PCB storage areas must be marked to show the presence of PCBs. Observe food plant transformers for possible leakage. If observed, determine if food items are stored in the area, and sample for PCB contamination. If PCBs are encountered in a food establishment, immediately advise management this is an objectionable condition and advise your supervisor.
2. Possible mix-up of pesticides or industrial chemicals with food raw materials.
3. Improperly stored pesticides or industrial chemicals (lids open, torn bags in close proximity to foods, signs of spillage on floors, pallets, shelves, etc.).
4. Incorrect application methods including excessive use. Many pesticide labels give instructions for use and precautions on the container.
5. Improper disposal or reuse of pesticide or industrial chemical containers.
6. Evidence of tracking powder or improper use of bait stations or baited traps.
7. Improper handling of equipment. Movable or motorized equipment used for handling possible chemical contaminants should not be used for handling food products unless they are thoroughly decontaminated. For example, fork-lifts moving pallets of pesticides should not also be used to move pallets of flour, etc.
8. Use of unauthorized pesticides.
9. Use of foods treated with pesticides and marked "Not For Human Consumption" (e.g., Treated seed wheat, etc.).
10. Noticeable odor of pesticides.
11. Careless use of machinery lubricants and cleaning compounds.
12. Chemical contaminants in incoming water supply.

When inspecting products with a known potential for metals contamination, determine whether the firm tests for such contamination in raw materials.

Determine who administers the firm's rodent and insect control program. Determine responsibility for the careless use of toxic materials.

If pesticide misuse is suspected, obtain the following information;

1. Name of exterminator and contract status,
2. Name of pesticide,
3. Name of pesticide manufacturer,
4. EPA registration number,
5. Active ingredients, and
6. Any significant markings on pesticide containers.

Fully document the exact nature of any pesticide or industrial chemical contamination noted or suspected. If samples are to be collected to document misuse, exercise

caution to prevent contamination of the immediate area of use, product or yourself.

#### 5.4.7.1.4 - OTHER

Contamination of food products by bats, birds and/or other animals is possible in facilities where food and roosting facilities are available. Examine storage tanks, bins, and warehousing areas to determine condition and history of use. There have been instances where empty non-food use containers were used for food products.

Birds and other animals are normal in a farm operation. Evaluate the farm's wildlife management and their actions if there is any contamination or concerns.

#### 5.4.7.2 - Microbiological Concerns

During the inspection, identify likely sources and possible routes of contamination of the product with pathogenic microorganisms.

See IOM sections 4.3.7.6 and 4.3.7.7 for sampling guidance.

You should become familiar with the flow of the process and determine the potential trouble spots, which may be built into the operation. To document the establishment is operating under insanitary conditions which may result in the presence of pathogens in food, it is necessary to show that the manufacturing process may have, or has contributed to the bacterial load of the product. See IOM 4.3.7.7 for instructions on sampling for pathogens. If there are several products being prepared at once, do not try to cover the entire operation during one inspection. Select the product which has the greatest potential for bacterial contamination or which poses the greatest risk for the consumer.

It is extremely important for each EIR to contain complete, precise, and detailed descriptions of the entire operation. The EIR must be able to stand alone without the analytical results, which serve to support the observations.

Observations made during the inspection must be written in clear and concise language. The EIR will be reviewed in conjunction with analytical results of in-line, environmental and finished production samples collected. Based on this review and other information which may be available, the program division must then decide if the total package will support a recommendation for regulatory action.

Each inspection/process will be different, but the techniques for gathering the evidence will be the same. However, the critical points in the operation should always be defined and special attention given to these areas.

Depending on the type of product being produced and the process being used, it may be useful to record the time each critical step takes, encompassing the entire processing period from beginning to end, with correlating temperature measurements. This should be done especially for products which may support the growth of

microbial pathogens. During the entire inspection, be aware of and document delays in the processing of the product (e.g., **temperature** of product prior to, during and after the particular processing step, and **the length of time** the product has been delayed prior to the next step). Also, be aware of and document potential routes of environmental contamination.

Some products receive a thermal process at the end of production, which may reduce bacterial counts to or near zero, although post process contamination is still possible through cross-contamination from the environment. Include detailed observations of heating step, temperature, length of time, controls and documentation used/not used by the firm. Even in the presence of end-product thermal processing, there is a regulatory significance to insanitary conditions prior to cooking, coupled with increases in bacterial levels demonstrated through in-line sampling.

#### 5.4.7.2.1 - PROCESSING EQUIPMENT

Document the addition, or possible addition of pathogenic microorganisms from accumulated material due to poorly cleaned and/or sanitized processing equipment. All food-contact surfaces must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

Observe and report the firm's cleaning and sanitizing procedures and the condition and cleanliness of food contact surfaces before production starts, between production runs and at the end of the day. Document any residue on food contact surfaces of equipment, especially inside complex equipment not easily cleaned and sanitized. Report firm's clean-up procedures in depth, since it may lend significance to insanitary conditions of residues on the plant machinery which are left to decompose overnight or between shifts. Where possible, observe equipment both before and after cleaning to assess its adequacy. Observations of residues on plant machinery can dramatically document the addition of pathogenic microorganisms, if present, into the product.

Identify any vectors of contamination (e.g. birds, rodents, insects, foot traffic, etc.), and describe sources and the routes of contamination from them to the product. Support this with your actual observations.

#### 5.4.7.2.2 - EMPLOYEE PRACTICES

Document any poor employee practice and how they have or would provide a route for contaminating the product with microorganisms. For example, did employees (number/time of day) fail to wash and sanitize their hands at the beginning of processing, after breaks, meals, or after handling materials likely contaminated with a microbial pathogen, etc.; and then handle the finished product. Did employees handle product in an insanitary manner (cross contaminating raw product with cooked product, etc., how many, how often).

### 5.4.7.3 - Storage

Evaluate the storage of finished products in the same manner as for raw materials. Determine if products are stored to minimize container abuse, facilitate proper rotation, and adherence to the storage requirements. This includes refrigeration temperatures, critical temperature tolerance, aging of products, and proper disposition of distressed stock.

During holding, human food by-products that are destined for use as animal food must be accurately identified.

#### 5.4.7.3.1 - FOOD TRANSPORT VEHICLES

During food sanitation inspections, (See IOM 5.2.2.2 regarding issuance of FDA 482, Notice of Inspection while inspecting vehicles.), conduct inspections of food transport vehicles to include:

1. Evidence of insanitary conditions,
2. Conditions which might lead to food adulteration,
3. Physical defects in the vehicle,
4. Poor industry handling practices.

The following types of transport vehicles should be covered:

1. Railroad boxcars, both refrigerated and non-refrigerated, and hopper cars.
2. Any type of truck used to transport foods; both refrigerated and non-refrigerated.
3. Use extreme caution, if it is necessary to inspect tank railcars or tank trucks. Usually this coverage will be limited to determining what was transported in the tank previously and was the tank cleaned and/or sanitized as necessary between loads.
4. Vessels used to transport food in I/S commerce. Direct coverage primarily to intercoastal type vessels, including barges.
5. On farm vehicles used in covered produce activities such as trailers, farm trucks, fork lifts, tractors, equipment used between growing/harvesting, etc.

Coverage should be limited to food transport vehicles used for long haul (I/S) operations. Long haul vehicles are defined as those which travel at least 150 miles between loading and unloading or which do not return to the point of loading at the end of the day.

Regulatory actions are possible if unfit cars are loaded and, as a result of loading, adulteration occurs. Fully document any violations noted with appropriate samples and photographs. When vehicle insanitation is observed, it is imperative the carrier's and shipper's responsibility for the food adulteration be documented by appropriate evidence development, such as:

1. The nature and extent of the conditions or practices, and
2. The mechanical or construction defects associated with the food transport vehicle.
3. Individual responsibility for vehicle or trailer cleaning, vehicle assignments, load assignments, etc.

If gathering evidence about a single carrier, seek a series of occurrences at numerous locations involving as many different shippers as possible.

Basically, two types of vehicles will be covered.

#### 5.4.7.3.2 - VEHICLES AT RECEIVERS

When inspecting receivers of food products, examine the food transport vehicle prior to or during unloading. Make a preliminary assessment of food product condition, then inspect the vehicle after unloading to determine its condition and whether the unloaded food may have been contaminated during shipment. If the food appears to have been adulterated, collect a sample(s) for regulatory consideration. Samples collected from vehicles, which have moved the product in interstate commerce are official samples. You may also collect Documentary (DOC) Samples from the vehicle to substantiate the route of contamination.

#### 5.4.7.3.3 - VEHICLES AT SHIPPERS

When inspecting shippers of food products, examine the food transport vehicle just prior to loading to determine its sanitary/structural conditions. If the vehicle has significant sanitation or structural deficiencies, notify the shipper of these conditions and of the possibility of product adulteration. If the shipper loads food aboard the vehicle, alert your supervisor so he/she can contact the FDA program division where the consignee is located for possible follow-up. You may also collect samples from the load. These samples will become official when the Bill of Lading is issued.

### 5.4.8 - DISTRIBUTION

Report the general distribution pattern of the firm. Review interstate shipping records or invoices to report shipment of specific lots. If access to invoices or shipping records is not possible, observe shipping cartons, loading areas, order rooms, address stencils, railroad cars on sidings, etc., to determine customer names, addresses and destination of shipments. If no products are suspect, obtain a listing of the firm's larger consignees.

#### 5.4.8.1 - Promotion and Advertising

Determine the methods used to promote products and how the products reach the ultimate consumer. Determine what printed promotional materials are used and whether they accompany the products or are distributed under a separate promotional scheme. Check on the possibility of oral representations, i.e., door-to-door salesmen, spielers, etc. and obtain copies of brochures, pamphlets, tearsheets, instructions to salespersons, etc. Where indicated, obtain the lecture schedule of any promotional lecture program. If applicable, determine the general pattern of the media used for promotion and advertising.

### 5.4.8.2 - Recall Procedure

Determine the firm's recall procedure. Audit enough records to determine the effectiveness of established procedures. Firms that are subject to Preventative Controls have specific requirements for recall plan. Refer to [21 CFR 117.139](#).

Note: Produce farms are not required to have a recall procedure.

### 5.4.8.3 - Complaint Files

Review the firm's complaint files. Where possible, copy the names and addresses of representative complainants; include a brief summary of each significant complaint in the EIR.

During the inspection, identify who reviews complaints and their qualifications. Describe the criteria used by the firm in evaluating the significance of complaints and how they are investigated. Determine if records are kept of oral and telephone complaints. See IOM 5.2.8 for discussion of complaints with management and IOM 5.11.4.3.11 for reporting of complaints in the EIR.

Complaints may not be filed in one specific file, but may be scattered throughout various files under other subject titles including Product name; Customer name; Injured party name; Adjustment File; Customer Relations; Repair orders, etc.

During the inspection investigate all complaints received by FDA since the last inspections, or that were not covered during the previous inspection. See IOM 5.2.8, 5.4.1.1 and 5.11.4.3.11. Complaints can be accessed by clicking on the Consumer Complaint link in FMS, or by clicking the "Firm 360" link in OSAR.

### 5.4.9 - OTHER GOVERNMENT INSPECTION

See IOM 3.1 for general procedures on cooperating with other Federal, State, and local officials.

During Establishment Inspections determine the specific type of inspection service and inspecting units, which cover the firm, such as the name of the federal, state, county, or city health agency or department. Obtain the name and title of the inspectional official, and general method of operation.

#### 5.4.9.1 - Federal

Do not inspect firms, or those portions of the plant, subject to compulsory, continuous inspection under USDA's [Meat Inspection Act](#), [Poultry Products Inspection Act](#), or [Egg Products Inspection Act](#), except on specific instructions from your supervisor or assignment document.

Ingredients or manufacturing processes common to both USDA and FDA regulated products should be inspected by FDA. See IOM 3.2.1.4 for FDA-USDA Agreements in specific areas.

Provide routine FDA coverage of such firms as breweries and wineries, which may be intermittently inspected on a compulsory basis by the U.S. Treasury Department, U.S. Public Health Service, or other agencies.

All products inspected under the voluntary inspection service of the Agriculture Marketing Service (AMS), USDA, and the National Marine Fisheries Service (NMFS), US Department of Commerce, are subject to FDA jurisdiction and are usually given routine coverage. However, formal written Agreements or Memoranda of Understanding between FDA and other agencies are often executed and may govern the agreeing agencies' operations on this type of inspected plants. When assigned this type of plant for inspection, always check to see if an Agreement or a Memorandum of Understanding exists between FDA and the agency involved to determine the obligations of both agencies. See IOM 3.1.2.1 and 3.2.

If you are assigned to cover a Federally Inspected plant which is under either compulsory or voluntary inspection, present your credentials and an FDA 482 Notice of Inspection to management and:

1. Identify yourself to the inspector(s) and invite him/her to accompany you on the inspection but do not insist on their participation.
2. At the conclusion of the inspection, offer to discuss your observations and provide the in-plant inspector with a copy of your Inspectional Observations (FDA 483).

#### 5.4.9.2 - State and Local

State and local officials usually have extensive regulatory authority over firms in their area regardless of the interstate movement or origin of the food products involved. Joint FDA-State or local inspections are frequently conducted. These are usually arranged by program division administrative or supervisory personnel. See IOM 3.1.2 and 3.3.

#### 5.4.9.3 - Grade A Dairy Plant Inspections

If you are assigned to conduct an inspection or sample collection at a milk plant that is covered under the Grade A Milk program, which has milk and milk products labeled and sold as Grade A, you should verify the need to complete the assignment with your supervisor and the Milk Specialist. Grade A milk plants, milk, and milk products labeled as Grade A are inspected by state inspectors and check rated by FDA's Milk Specialists and you should not inspect these Grade A milk and milk products. Milk plants in the Grade A Milk program and covered by the Interstate Milk Shippers (IMS) program are identified in the [Interstate Milk Shippers List](#) of Sanitation Compliance and Enforcement Ratings. This reference lists the specific milk plant and each milk and milk product covered under the IMS program. These Grade A milk and milk products are covered by a MOU between the FDA and the states, which places primary inspectional responsibility with the state.

There are situations where you will need to conduct an inspection in a Grade A milk plant and cover products they

manufacture which do not carry the "Grade A" designation (such as juices). Fluid milk and milk products, cultured/acidified milk and milk products, eggnog, cream(s) sour cream, and yogurt are all considered Grade A and are required to be labeled as Grade A. The Grade A milk plant may also manufacture milk and milk products which are optional for the Grade A designation, depending upon the particular state. Cottage cheese is considered a Grade A optional milk product. If the state does not require the Grade A designation for cottage cheese, then the cottage cheese will not be included in the IMS listing of Grade A milk and milk products for that specific milk plant. Also, if the Grade A milk plant is manufacturing condensed or dried milk or milk products or condensed or dried whey or whey products, which are optionally labeled as Grade A, then those milk or milk products must be IMS listed and are covered under the Grade A Milk Program. Note: This same Grade A milk plant may also be manufacturing non-Grade A versions of these condensed/dried milk or milk products or condensed/dried whey or whey products.

### 5.4.10 - FOOD STANDARDS

The Federal Food, Drug, and Cosmetic Act requires the Secretary of Health and Human Services to promulgate reasonable definitions and Standards for food to promote honesty and fair dealing in the interest of consumers. When a Standard becomes effective, it establishes the common or usual name for the article, defines the article and fixes its standard of identity. It is then the official specification for the food. The food industry actively participates in the development of a Standard and supplies much of the data upon which the regulation is based.

The Food Standards (FS) Inspection is made to obtain data for use, together with information from other sources in developing a Food Standard. Food Standard inspections are also made to determine a firm's compliance with food standards regulations, when manufacturing a standardized food.

#### 5.4.10.1 - Food STANDARDS Inspection

Food Standard (FS) inspection assignments usually originate from CFSAN. When an inspection is planned for the purpose of collecting data to support a proposed food standard regulation, the program division may elect to advise the firm, if the CFSAN has not already done so. If the firm selected does not choose to cooperate, it may be necessary to visit additional plants in order to obtain the desired information. Selection of additional firms should be done in consultation with the CFSAN.

Some firms often contend their entire process and formulas are "trade secrets". Attempt to persuade management the term "trade secret" should only be used to cover the process and/or quantitative-qualitative formulation which is truly unique to the firm. In instances where the firm is reluctant to release any of the information requested, point out FDA will, within the limits of the Freedom of Information Act, make every effort to preserve the confidentiality of the

composition, make-up, and production levels of the product through the use of codes, which cannot be traced back to the firm. Include as much of the compositional and processing information as you can in the body of the report, without violating the firm's confidence.

#### 5.4.10.2 - Food Inspection Report

FS EIR's may be used as exhibits at public hearings and are subject to review by any interested party.

Three copies of the report are prepared. The original and one copy will be submitted to the CFSAN and one copy kept for the program division file. Sign the original and duplicates of the first and last pages of each report sent to the Center.

Divide the report into three sections.

#### 5.4.10.2.1 - ESTABLISHMENT INSPECTION RECORD (EI RECORD)

In order to relate the sections of the report to each other and to any assignments, and to assure any parts of the reports made public will not be identified as to the name of the firm or individuals therein, each program division will set up a master list of numbers. One number will be assigned to each establishment covered, e.g., "BLT FS-3". For each FS Inspection place the assigned number next to the firm name on the EI Record. All other pages of the report shall be identified only by this number, the name of the commodity, and date. Example: "EIR Frozen Fish Sticks 10-3-87 BLT FS-3". This indicates a FS EI of frozen fish sticks conducted by Baltimore OHAFO Division 2E on 10-3-87 in a plant designated as #3.

Where a producer may be reluctant to release any of the information requested, point out the FDA will, within the limits of the FOIA, make every effort to preserve the confidentiality of the composition, make-up, and production levels of his product through the use of codes, which cannot be traced back to the firm.

#### 5.4.10.2.2 - BODY OF REPORT

Prepare the body of the report following the narrative outline as for any other food EIR except for the restrictions below.

The body of the FS report should also contain information in regard to the approximate annual value and volume as well as the percent of interstate business for each product covered. This is necessary because the coversheet, which contains this information, identifies the firm and will not be made public. Processes and the listing of raw materials used by the firm, which are not restricted by the term "trade secret" should be included. Any opinions, recommendations, or other information obtained or offered by individuals interviewed should be reported. Any suggestions made by individuals interviewed regarding what should be placed in the Standards for the products

covered should be included. All individuals interviewed, firm name, etc. should have an identifying code assigned.

The body of the report should not include names and titles of individuals, (including USDA, USDI, or other inspectors), trade secret information, labeling, trade names, formulas, sample numbers, firm name or location of plant (other than by state or region), shipments, or other distribution information, legal status, or regulatory history. This information will be placed in the "Special Information" section of the report.

### 5.4.10.2.3 - SPECIAL INFORMATION SECTION

This is a separate attachment to the EIR which lists the names and titles of individuals (including other government inspectors) and firms with a reference code for each. The EIR should refer only to "Mr. A.," "Mr. B.," "Firm X," "Firm Y", etc. Do not use the firm or individual's actual initials in the body of the report. Include all information excluded from the body of the report and mount all labels obtained during the EI Labels may be quoted in the body of the report, but do not identify the firm. List the "Special Information Sheet" in the FACTS endorsement section as an enclosure.

Supplemental Reports - If, because of an additional visit or visits to the same firm on the same project, it is necessary to prepare another EIR, flag the report with the same number as assigned to the original report. For example, mark the EI Record "BLT FS-3 Supplemental Report", and the remaining pages, "EIR Frozen Fish Sticks 10-25-87 BLT FS-3 Supplemental Report."

### 5.4.10.3 - Violative Inspections

When an inspection made in connection with the Food Standards project shows insanitary or other conditions which are not germane to the assignment or in the Program division's opinion suggests regulatory action, an appropriate narrative of the violative conditions should be prepared as a Regulatory Addendum.

## 5.4.12 - PESTICIDES

### 5.4.12.1 - Pesticide Inspections

The objective of a Pesticide Inspection is to determine the likelihood of excessive residues of significant pesticides in or on products in consumer channels, and to develop sources of information for uncovering improper use of pesticide chemicals.

This requires directing coverage to two major areas:

1. Pesticide practices in the production and processing of field crops.
2. Application of pesticide chemicals in establishments storing and processing raw agricultural products.

Pesticide coverage must be provided during all food establishment inspections. Coverage of raw agricultural products will generally be on a growing-area basis.

Problem areas include:

1. Improper use of pesticides around animals - gross misuse of sprays and dips in animal husbandry may result in pesticide residues in foods.
2. Use of contaminated animal feeds - waste and spent materials from processing operations may contain heavy concentrations of pesticide residues, which were present in the original commodity. See [Compliance Policy Guide 575.100](#).
3. Past pesticide usage - past pesticide practices on growing fields. Past use of persistent pesticides may result in excessive residues in the current food crop. You may need to check on pesticide usage for several years prior to an incident to ensure you gather enough information. Some pesticides last for many years in the environment.

### 5.4.12.2 - Current Practices

Cooperative Activities - important sources of information relative to evaluating the "Pesticide Environment" include:

1. At the start of the growing season, spray schedules recommended for each crop by county agents, state experiment stations, large pesticide dealers, farmers cooperatives, et al should be obtained.
2. Visits to agricultural advisors may provide information relative to heavy infestation of insect pests and fungal infections on specific crops in specific areas.
3. Daily radio broadcasts in most agricultural areas may provide information on spray schedules, insect pests, harvesting and shipping locations, etc.
4. Field employees of fruit and vegetable canning and freezing plants usually recommend spray schedules, pesticides, and harvesting schedules for products produced by contract growers.
5. United States Weather Bureau Offices and their reports will provide data on weather conditions, which may affect insect growth and their development, size of fruit or leaf growth, and dissipation of pesticide chemicals.
6. USDA Market News Service daily price quotations, and weekly quotations in trade magazines provide information regarding harvesting schedules since market prices are indicators of how quickly a crop will be harvested in a given area. Growers who have the opportunity to obtain high prices may harvest their crops without regard to recommended pre-harvest intervals.
7. State Colleges of Agriculture seminars or short courses on food and vegetable production may alert you to significant departures from usual agricultural practices. Prior approval to attend such meetings should be secured from your supervisor.
8. Pesticide suppliers and distributors may provide information on spray practices, schedules, and the name and address of growers, etc.

NOTE: The U.S. Department of Agriculture has a Pesticide Data Program (PDP), which provides data on pesticide use and residue detection. This program helps form the basis



for conducting realistic dietary risk assessments and evaluating pesticide tolerances. Coordination of this program is multi-departmental, involving USDA, EPA and FDA, covered by a MOU (Federal Cooperative Agreements Manual). As a part of this program USDA collects data on agricultural chemical usage, and factors influencing chemical use, and collects pesticide residue data through cooperation with nine participating states. USDA provides this data to EPA, FDA and the public. Several USDA publications are listed below as reference material.

The contact point at USDA for pesticide residue matters is: Martha Lamont, Director  
Monitoring Program Office, Science Division  
Agricultural Marketing Service, USDA  
8609 Sudley Road, Suite 206  
Manassas, VA 20110  
703-330-2300

Reference materials - the following reference materials provide background and data necessary or helpful in evaluating current practices. This material should be available at the program division office.

1. Pesticide Chemicals - Regulations under the Federal Food, Drug and Cosmetic Act on tolerances for pesticides in food administered by the Environmental Protection Agency (EPA).
2. EPA's Pesticide Regulations - Tolerances for Raw Agriculture Products. (See [40 CFR 180](#))
3. EPA's Rebuttable Presumption Against Registration (RPAR) List.
4. Pesticide Index. - By William J. Wiswesser. A publication containing information on trade names, composition and uses of commercial pesticide formulations.
5. The Daily Summary or Weekly Summary. News releases and reports from USDA.
6. USDA's Weekly Summary Shipments-Unloads.
7. Agricultural Economic Report No. 717 Pesticide and Fertilizer Use and Trends in U.S. Agriculture (May 1995)
8. [Annual Pesticide Data Summary](#)
9. Reports from USDA's Crop Reporting Board.
10. USDA's Pesticide Assessment Reports.

### 5.4.12.3 - Growers

Preliminary investigation of growing areas at the start of the season will provide data necessary for program division work planning including production schedules, types and acreage of crops, pesticides used and the names and addresses of growers and shippers. The Produce Safety Network (PSN) can be of assistance in obtaining some of this information.

Growing Dates - The significant growing dates relative to pesticide usage are as follows:

1. Planting date,
2. Date of full bloom, and
3. Date of edible parts formation.

Harvest Dates - The dates of the anticipated harvest season will provide planning information relative to pre-harvest application and shipping.

Acreage - This will provide volume information for work planning.

### 5.4.12.3.1 - PESTICIDE APPLICATION

Ascertain the actual pesticide application pattern for each crop. Look for objective evidence to document actual grower practice. Check the grower's supply of pesticide chemicals, look for used pesticide containers, visit his source of supply, etc. Check spraying and dusting practices. Establish if pesticide chemicals are used in such a manner that excessive residues might result.

The following information provides a basis for evaluating pesticide usage:

1. Pesticide Chemical Applied - List the common name if there is no doubt as to the chemical identity of the pesticide. Include labeling indications and instructions.
2. Method of Application - Describe the method of application i.e., ground rig, airplane, greenhouse aerosol, hand, etc.
3. Formulation - Describe the formulation i.e., wettable powder, emulsifiable concentrate, dust, granules, aerosol, etc. Express as pounds of active ingredient per gallon or percent wettable powder.
4. Number of Applications and Dates.
5. Rate of Last Application - Calculate the amount of active ingredient per acre.
6. Pre-Harvest Interval (PHI) - Calculate the number of days between the day of the last application of pesticide and the harvest date or anticipated harvest date. Compare to the PHI.
7. Visible residue on grower's crop.
8. Summary of Usage - Determine the USDA Summary Limitations and evaluate the responsible usage.

### 5.4.12.3.2 - PESTICIDE MISUSE/DRIFT/SOIL CONTAMINATION

Pesticide residues, which exceed established tolerances, action levels, or "regulatory analytical limits", may be caused by pesticide misuse which can include:

1. Excessive application of a chemical on a permitted crop.
2. Failure to follow labeled time intervals between the last pesticide application and harvest.
3. Use of a non-approved pesticide on a crop.
4. Failure to wash a crop when pesticide labeling requires it (e.g., for certain EBDC's).

Other conditions, which may cause illegal residues, include spray drift and soil contamination.

Drift may be documented by determining which crops and pesticides have been grown/used in fields adjacent to those sampled. Determine direction of prevailing winds and wind condition on the day of spraying. Selective sampling will aid in determining if drift occurred. Compliance Samples collected to document pesticide drift should be Flagged as

a Pesticide Sample and noted in the Remarks section of the CR as "Drift Sample - Maintain as Individual Subs".

Soil contamination by compounds, which are relatively stable in the environment, may cause systemic uptake of the compounds by growing crops. Follow-up investigations to violative samples may, in some limited cases, include soil samples as an attempt to determine the source of the contaminant. Do not routinely collect soil samples.

#### 5.4.12.4 - Packers and Shippers

Follow the same general procedure as in IOM 5.4.12.3. Observe and report the following:

1. Treatment Before Shipping - This may include stripping of leaves, washing, vacuum cooling, application of post-harvest preservative chemicals, use of cartons with mold-inhibiting chemicals, waxes, colors, fumigation, etc.
2. Identification of Growers' Lots - Determine procedure or methods used to maintain the identity of each grower's lot. Provide the code and key if any.
3. Labeling - Quote labeling or brand names.
4. Responsibility - Determine whether the packer or shipper knows what sprays have been used on the products shipped.

#### 5.4.12.5 - Pesticide Suppliers

Pesticide suppliers should be visited routinely during growing-area coverage. They may provide valuable information about pesticides being used on various crops in the growing area. Some suppliers may suggest spray schedules or advise growers about pesticide usage.

Determine what representations were made by the manufacturer of pesticide chemicals for which there is only a temporary tolerance or experimental permit. Get copies of any correspondence relating to sale and use of these products. Obtain names of growers to whom sales are made if such sale was not for use on acreage assigned under the experimental permit. Collect Official Samples of any crops treated with the pesticide.

#### 5.4.12.6 - Pesticide Applicators

Pesticide applicators may provide valuable information about pesticides being used on various crops in the growing area. Interview several pesticide applicators, particularly those using airborne equipment. Determine the pesticide chemicals, their formulation, and on what crops they are currently being applied. Determine who supplies the pesticides and how they are prepared to assure proper concentration. If state law requires the applicator to keep a record of each spray application, request permission to review such records. Determine what steps are taken to assure drift on adjoining crops does not result in violative residues. Where there is likelihood of drift, collect Selective Samples from adjoining fields.

#### 5.4.12.7 - Sample Collections

See IOM Sample Schedule Chart 3 - Pesticides.

#### 5.4.13 – COSMETIC INSPECTIONS

There is no FDA pre-approval for cosmetic products or ingredients, with the exception of color additives. However, cosmetic firms are responsible for marketing safe and properly labeled products. Inspections can identify adulterated and misbranded cosmetics as defined in Sections 601 and 602, respectively, of the Food Drug and Cosmetic Act. Inspections cover three major areas:

- 1- Control of processes and quality of products - Products are manufactured in an adequate state of control to meet the firm's established quality standards.
- 2- Sanitation, cleanliness and hygiene – The facility is clean and orderly, sanitary conditions are being maintained and workers are attentive to preventing contamination
- 3- Labeling – Products are labeled in compliance with regulations and are accurately labeled to reflect contents

FDA inspections can reveal use of prohibited ingredients, noncompliance with requirements related to color additives, failure to adhere to requirements for tamper-resistant packaging where needed, and violations involving labeling without necessarily performing an on-site inspection. Assurance of cosmetic product safety also depends upon control of microbiological product quality during manufacturing and distribution of products. An on-site inspection is the only means by which FDA can determine if cosmetics are being manufactured under insanitary conditions whereby cosmetics may be contaminated with objectionable microorganisms. (See 5.4.13.3 (Contaminated Cosmetics) and 5.4.13.5 (Specific Types of Cosmetic Safety Concerns))

#### 5.4.13.1 Preparation and References

Refer to this section and the Compliance Program Manual titled "Cosmetics Program: Import and Domestic" (CPGM 7329.001) when performing a cosmetic site inspection. Refer to any direction from CFSAN or the district having to do with a concern about a particular product. Refer to the sections 5.1, 5.2, 5.3, 5.4.1.1, 5.4.6.1.1, 5.4.6.6.4, in the IOM, and read or be familiar with all pertinent references provided in this subchapter (5.4.13). Be familiar with the statutory requirements and definitions and parts of the Code of Federal Regulations Title 21 (21 CFR) applicable to cosmetics. For more background information on cosmetic site inspections see [Inspection of Cosmetics](#).

##### Related Resources:

- [Cosmetics Compliance Program: Import and Domestic \(PDF 310 KB\) \(CPGM 7329.001\)](#)
- [GMP Draft Guidance for Industry: Cosmetic Good Manufacturing Practices](#)
- [Import Alerts for Cosmetics](#)

### 5.4.13.2 – Documents and Records

While there is no requirement for the firm to provide records for your review, it is important to review documents and records, to determine if the site has adequate procedures and systems for manufacturing and monitoring to ensure production and distribution of safe cosmetic products. Therefore, make a request to review processing records, packaging and labeling records, raw material records and any records pertinent to the manufacture, packaging, labeling and distribution of the cosmetic product, including finished product testing, batch release, complaints and/or adverse events.

### 5.4.13.3- Contaminated Cosmetics

Inspect the firm's methods for preventing and controlling microbial and other forms of contamination and review records that may indicate batches that were manufactured and distributed in violation of any of the cosmetic adulteration provisions of the Act.

Typical causes of product adulteration are manufacturing under insanitary conditions, improper storage conditions and product design flaws and/or defects (i.e., ingredients, packaging) including use of an ineffective preservative system (see below). Observe and document when any of the following present a potential cause of insanitary conditions:

- 1- Overall cleanliness of the facility and sanitation practices (including programs and systems for pest control and waste disposal)
- 2- Personal hygiene and employee health (including training of staff and monitoring of employees by supervision)
- 3- Handling of ingredients, materials and products by employees (including procedures for making transfers, training and use of PPE)
- 4- Microbiological quality of ingredients (including whether ingredient batches received from suppliers are tested by the manufacturer and how ingredients are stored) (see next section on raw material quality)
- 5- Water systems (including system design and control and monitoring of microbiological quality)
- 6- Equipment design (including potential for stagnant water)
- 7- Cleaning and sanitization of equipment surfaces contacting process stream or products (including utensils and shared equipment)
- 8- Buildup of previous batches of material on equipment surfaces during prolonged manufacturing campaigns

Susceptibility of cosmetic products to microbiological growth is governed the by water activity of the formulation. Preservatives are added to mitigate the risk of microbial growth, but each preservative system's capability has unique limitations. As proof of effectiveness of preservation, the formulation can be subjected to microbial challenge testing. Check to see if the manufacturer (or

product distributor) has performed and retained documentation of preservative efficacy testing on its cosmetic product formulations. See CPGM 7329.001 section on *Adequacy of Preservation* for more information. Also refer to preceding sections 5.4.7.1 and 5.4.7.2 for more information about documenting routes of contamination and microbiological concerns.

See CPGM 7329.001 Part V.1.c. for more information on current policy on microbiological quality of cosmetics, including products and levels of concern constituting potential health hazard.

### 5.4.13.4- Cosmetic Ingredients

Determine if the manufacturer has suitable procedures for supplier selection and qualification and adequate controls for chemical, microbial and physical contamination to ensure the ingredients are suitable for use in cosmetics. If the manufacturer uses ingredients that have been reconditioned or reprocessed, determine if there is adequate documentation to justify such use. Determine who (e.g. the firm's quality department, the product distributor) decides to approve suppliers, and accept or reject ingredient batches from suppliers. Determine if ingredients (and packaging materials) are stored and handled properly to prevent mix-up and contamination; and if there are suitable systems to identify and trace ingredients and packaging materials used in cosmetic products.

### 5.4.13.5 – Specific Types of Product Safety Concerns

You should be aware of certain cosmetic products that CFSAN/OCAC has identified as posing unusual safety hazards due to concerns about the product ingredients. Examples include:

- 1- tattoo inks
- 2- ingredients or products labeled "organic" or "natural"
- 3- products lacking traditional preservatives
- 4- products containing stem cells or human tissue
- 5- wet wipes (used by infants/children and adults)
- 6- cosmetic non-alcohol oral care products
- 7- eye area products
- 8- potential use by immuno-suppressed or institutionalized individuals

There are currently no prohibitions on the use of many of these ingredients and FDA's regulatory policy is still in development. OCAC will provide training on these specific topics and others that may emerge in the future. If in doubt about the status of a particular ingredient or type of product you encounter on an inspection, contact CFSAN/OCAC.

### 5.4.14 – Foreign Supplier Verification Program

See Subchapter 6.8 Foreign Supplier Verification Program for inspectional instructions.

## SUBCHAPTER 5.5 - DRUGS

### 5.5.1 - DRUG INSPECTIONS

Authority for inspection is discussed in IOM 2.2. [FD&C Act Sections 501\(a\)-\(d\)](#) and [501\(j\)](#) [21 U.S.C. 351(a)-(d), (j)] describe the ways in which a drug may be or may become adulterated. [Section 502 of the FD&C Act](#) [21 U.S.C. 352] does the same, with respect to misbranding. [Section 505 of the FD&C Act](#) [21 U.S.C. 355] requires that new drugs be approved by FDA. Therefore, the purposes of a drug inspection are:

1. To evaluate a firm's adherence to the concepts of sanitation and good manufacturing practice; i.e., production and control procedures include all reasonable precautions to ensure the identity, strength, quality, and purity of the finished products;
2. To identify deficiencies that could lead to the manufacturing and distribution of products in violation of the Act, e.g., non-conformance with Official Compendia, super/sub potency, substitution;
3. To determine whether a firm is distributing drugs that lack required FDA approval including counterfeit or diverted drugs;
4. To obtain correction of those deficiencies;
5. To determine if drugs are manufactured by the same procedures and formulations as specified in the Drug Application documents;
6. To determine the drug labeling and promotional practices of the firm;
7. To ensure the firm is reporting NDA field alerts as required by [21 CFR 314.81](#) and Biological Product Deviation Reports (BPDRs) for therapeutic biological products as required by [21 CFR 600.14](#);
8. To determine if the firm is complying with the requirements of the Prescription Drug Marketing Act (PDMA) and regulations; and
9. To determine the disposition of Drug Quality Reports (DQRS) received from the Drug Surveillance and Data Reporting Branch (DSDRB)/CDER; and
10. To determine if the firm is complying with post market Adverse Drug Experience reporting requirements as required by 21 CFR sections [310.305](#) (prescription drugs without approved NDA/ANDA), [314.80](#), [314.98](#), and [314.540](#) (application drug products), and [600.80](#) (therapeutic biological products), and [Section 760 of the FD&C Act](#) (non-application nonprescription products) [21 U.S.C. 379aa].

11. **For pharmacy compounding inspections determine if compounded drug products meet the conditions of section 503A or 503B of the FDCA**

### 5.5.1.1 - Preparation and References

Become familiar with current programs related to drugs. Determine the nature of the assignment, i.e., a specific drug problem or a routine inspection, and if necessary, consult other program division personnel, such as chemists, microbiologists, etc., or center personnel, such as office of compliance staff. Review the establishment program division files of the firm to be inspected including:

1. Establishment Inspection Reports,
2. Firm Profiles,
3. OTC monographs and other pertinent references for non-application products,
4. Drug Applications (New, Abbreviated and Investigational) and the Knowledge Transfer Memo, if the Center has provided it for a specific pre-approval inspection,
5. Therapeutic Biologics License Applications,
6. Sample results,
7. Complaints and Recalls,
8. Regulatory files,
9. Drug Quality Reports (DQRs), NDA Field Alert Reports (FARs), and Biological Product Deviation Reports (BPDRs),
10. Drug Registration and Listing
11. Facility Dossier where applicable

#### 12. **Inspection Assignment memo where applicable.**

During this review identify products which:

1. Are difficult to manufacture,
2. Are complex dosage forms,
3. Require special tests or assays, or cannot be assayed,
4. Require special processes or equipment,
5. Are new drugs and/or potent low dosage drugs, Are misbranded, unapproved, fraudulent, or are compounded human drug products that do not meet the conditions of section 503A or 503B of the FDCA

Review the factory jacket, FACTS OEI and registration/listing data, and all complaint reports which are marked follow-up next inspection. These complaints are to be investigated during the inspection and discussed with management. See IOM 5.2.7.

Become familiar with current regulations and programs relating to drugs, [CP 7356.002](#), et al. When making GMP inspections, discuss with your supervisor the advisability of using a microbiologist, analyst, engineer, or other technical personnel to aid in evaluating those areas of the firm germane to their expertise. Review the [FD&C Act, Chapter V, Drugs and Devices](#). Review parts of 21 CFR [210/211](#) applicable to the inspection involved and Bioavailability ([21 CFR 320](#)). In the case of APIs, review [FD&C Act section 501\(a\)\(2\)\(B\)](#) [21 U.S.C 351(a)(2)(B)] and the ICH industry guideline entitled "[Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients](#)."

Review the current editions of the United States Pharmacopeia (USP), and Remington's Pharmaceutical Sciences for information on specific products or dosage

forms. See IOM 1.10.3 for special regulatory information by product category.

Review [21 CFR 203](#) "Prescription Drug Marketing", [21 CFR 205](#) "Guidelines for State Licensing of Rx Drug Distributors", and CP 7356.022, Enforcement of the Prescription Drug Marketing Act (PDMA).

Before conducting drug preapproval inspections (CP 7346.832) it is important to be familiar with the application and coordinate accomplishment of Center goals communicated by (1) inspectional memos, (2) pre-inspection briefings, and/or (3) Center participation on the inspection team.

The Office of Manufacturing Quality (OMQ) in CDER has established two mechanisms for you to obtain technical assistance before, during, or after an inspection:

1. [Office of Manufacturing Quality \(OMQ\)](#). This webpage contains organizational charts, names and phone numbers of OMQ individuals identified as technical specialists in various areas.
2. [Questions and Answers on Current Good Manufacturing Practices for Drugs](#). This forum is intended to provide timely answers to questions about the meaning and application of CGMPs for human, animal, and biological drugs, and to share these widely. These questions and answers generally clarify statements of existing requirements or policy.

### 5.5.1.2 - Inspectional Approach

Follow Compliance Program Guidance Manual (CPGM) 7356.002 and others as appropriate when conducting drug CGMP inspections. In-depth inspection of all manufacturing and control operations is usually not feasible or practical. A risk-based systems audit approach is recommended in which higher risk, therapeutically significant, medically necessary and difficult to manufacture drugs are covered in greater detail during an inspection. (Note: The status of a drug as medically necessary is determined by CDER. For information, contact Office of Compliance/Recalls and Shortages Branch via email at [cderrecalls@fda.hhs.gov](mailto:cderrecalls@fda.hhs.gov)) The latter group includes, but is not limited to, time release and low dose products, metered dose aerosols, aseptically processed drugs, and formulations with components that are not freely soluble. If the inspection is conducted for CDER- led combination product, see also IOM 5.12.

CPGM 7356.002 incorporates the systems-based approach to conducting an inspection and identifies six (6) systems in a drug establishment for inspection: Quality, Facilities and Equipment, Materials, Production, Packaging and Labeling and Laboratory Control Systems. The full inspection option includes coverage of at least four (4) of the systems; the abbreviated inspection option covers of at least two (2) systems. In both cases, CPGM 7356.002, indicates the Quality System be selected as one of the systems being covered. During the evaluation of the Quality System it is important to determine if top management makes science-based decisions and acts promptly to

identify, investigate, correct, and prevent manufacturing problems likely to, or have led to, product quality problems.

When inspecting drug manufacturers marketing a number of drugs meeting the risk criteria, the following may help you identify suspect products:

1. Reviewing the firm's complaint files early in the inspection to determine relative numbers of complaints per product.
2. Inspecting the quarantine, returned, reprocessed, and/or rejected product storage areas to identify rejected product.
3. Identifying those products which have process control problems and batch rejections via review of processing trends and examining reviews performed under [21 CFR 211.180\(e\)](#).
4. Reviewing summaries of laboratory data (e.g., laboratory workbooks), OOS investigations, and laboratory deviation reports.

### 5.5.2 - DRUG REGISTRATION & LISTING

Registration and listing is required whether or not interstate commerce is involved. See Exhibit 5-12 and IOM 2.9.1.1 for additional information.

Two or more companies occupying the same premises and having interlocking management are considered one establishment and usually will be assigned a single registration number. See IOM 5.1.1.11 - Multiple Occupancy Inspections for additional information.

Independent laboratories providing analytical or other laboratory control services on commercially marketed drugs must register.

FACTS will indicate if the establishment is registered for the current year. If you determine registration and listing is required, advise your supervisor. After checking for past registration, cancellation, etc., the program division will provide the firm with the proper forms and instructions.

Each establishment is required to list with FDA every drug in commercial distribution, whether or not the output of such establishment or any particular drug so listed enters interstate commerce. During the establishment inspection, you should remind the firm of its responsibilities for ensuring its drug listing accurately reflects the current product line and updating its listing as necessary to include all product changes, NDC changes, and discontinuations in accordance with [21 CFR 207](#). If registration and listing deficiencies are found, document it in your EIR, collect a documentary sample and/or contact your supervisor.

### 5.5.3 - PROMOTION AND ADVERTISING

[21 CFR 202.1](#) which pertains only to prescription drugs, covers advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Determine what department or individual is responsible for promotion and

advertising and how this responsibility is demonstrated. Ascertain what media (radio, television, newspapers, trade journals, etc.) are utilized to promote products.

Do not routinely collect examples of current advertising. Advertising should be collected only on assignment, or if, in your opinion, it is clearly in violation of [Section 502\(n\) of the FD&C Act](#) [21 U.S.C. 352 (n)] or 21 CFR 202.1.

## 5.5.4 - GUARANTEES AND LABELING AGREEMENTS

Determine the firm's policies relative to receiving guarantees for raw materials and issuing guarantees on their products. Also determine firm's practices regarding shipment of unlabeled drugs under labeling agreements. See IOM 5.3.7.2.

## 5.5.5 - OTHER INSPECTIONAL ISSUES

### 5.5.5.1 - Intended Use

Please see the discussion of jurisdiction in section IOM 5.11.4.3.6.

### 5.5.5.2 - Drug Approval Status

The investigator should ascertain whether the drugs manufactured by the firm are covered by an NDA, ANDA, NADA, ANADA, OTC monograph, or marketed under a claim of DESI or [another exemption status](#).

### 5.5.5.3 – Drug Status Questions

If you have questions about misbranding, new drug status, API/finished drug product status, drug/cosmetic, or drug/food (dietary supplement) status, , contact the Office of Unapproved Drugs and Labeling Compliance in CDER's Office of Compliance at 301-796-3100 or [CDEROU DLC PM TRACK@CDER.FDA.GOV](mailto:CDEROU DLC PM TRACK@CDER.FDA.GOV).

If you have questions about the status of compounded human drugs products, contact the [the Office of Compounding Quality Compliance in CDER's Office of Compliance](#) at 301-796-3100 or [Compounding@fda.hhs.gov](mailto:Compounding@fda.hhs.gov).

### 5.5.5.4 – Verification of Compliance with PDMA Requirements

The investigator should ascertain whether a manufacturer uses samples of prescription drugs to market their products. If so, they need to comply with the regulations at 21 CFR 203 Subpart D – Samples. Refer to CPGM program 7356.022, ENFORCEMENT OF THE DRUG SAMPLE DISTRIBUTION REQUIREMENTS OF THE PRESCRIPTION DRUG MARKETING ACT (PDMA). If you have questions concerning this portion of an inspection, contact the Office of Compliance at 301-796-3100 or [DrugSupplyChainIntegrity@fda.hhs.gov](mailto:DrugSupplyChainIntegrity@fda.hhs.gov).

## 5.5.5.5 - Drug/Dietary Supplement Status

In instances where the drug/dietary supplement status of a product is unclear, the investigator should collect all related labeling and promotional materials including pertinent Internet web sites. This labeling and promotional material is often useful in determining the intended use of a product (See [21 CFR 201.128](#)). Labeling, promotional materials and Internet web sites often contain information, for example, disease claims, that can be used to determine the intended use of a product and thereby if it is a dietary supplement or a drug and an unapproved new drug.

## 5.5.5.6 - Approved Drugs

Check the current programs in your CPGM, [Section 505 of the FD&C Act](#) [21 U.S.C. 355] and [21 CFR part 314](#) for required information. You may ask your designated pre-approval manager for CMC information of the targeted drug application. You may take the program division's copy of the NDA into the plant as a reference during the inspection. Document and report all deviations from representations in the NDA even though they may appear to be minor.

## 5.5.5.7 - Investigational Drugs

Follow the instructions in pertinent programs in your CPGM or as indicated in the specific assignment received.

## 5.5.5.8 - Clinical Investigators and/or Clinical Pharmacologists

Inspections in this area will be on specific assignment previously cleared by the Administration. Follow guidance in the CPGM or assignment.

## 5.5.5.9 – Delaying, Denying, Limiting or Refusing Drug Inspections

Use reasonable discretion when discerning whether action taken by a drug firm during an inspection constitutes delaying, denying, limiting, or refusing drug inspection. If you are unsure whether an action taken by a firm constitutes delaying, denying, limiting, or refusing drug inspection, contact your supervisor.

As needed, refer to the *Guidance for Industry – Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection*, for examples of firm actions that may cause a drug to be deemed adulterated under FD&C Act section 501(j). Remember, however, that these examples are not exhaustive, and that guidance documents do not establish legally enforceable rights or responsibilities and are not legally binding on the firm or the agency. See IOM 1.10.1.

## 5.5.8 - DRUG INSPECTION REPORT

See IOM 1.1 English language requirement. The requirements in IOM 5.11.4.3, and any applicable

Compliance Program Guidance Manuals can be used to help you prepare your report.

This does not cover the reporting requirements for a directed inspection with a narrow focus, such as a complaint follow-up or investigation into a recall. In those cases, use your judgment and guidance in IOM 5.11.4 about the depth of reporting required. Follow the instructions and format for a human drug inspection report as contained in IOM 5.11.4.2 and 5.11.4.3.

The human drug inspection report does not require full and detailed narratives for every area for every inspection. The firm's state of compliance, the previous inspectional report and information, complexity of operations and other aspects all are determinants in how much reporting will be necessary. In many cases, brief summaries addressing the format areas will be sufficient.

## SUBCHAPTER 5.6 - DEVICES

### 5.6.1 - DEVICE INSPECTIONS

See IOM 2.2 for discussion of statutory authority.

The term "device" is defined in [Sec. 201\(h\) of the FD&C Act](#) [21 U.S.C. 321 (h)]. In-vitro diagnostics ([21 CFR 809](#)) are devices, as defined in 201(h) of the Act [21 U.S.C. 321 (h)], and may also be biological products subject to [Section 351 of the PHS Act](#).

Inspections involving devices should be made only by those individuals qualified by training and experience in the device area. Electronic product radiation is defined in [21 CFR 1000](#). Because of the specific nature of inspections and investigations involving radiation, only personnel who have special training in this field should be assigned such work. However, others may participate for training purposes. Specific Compliance Program Guidance Manuals designate the type of individual and special training required for work in these areas.

**CAUTION:** Radiation-emitting devices and substances present a unique hazard and risk potential. Every effort should be taken to prevent any undue exposure or contamination. Monitoring devices must be used whenever radiation exposure is possible. Investigators should also be on the alert for, and avoid contact with, manufacturing materials and hazards associated with the manufacturing of many types of devices, which may present a threat to health, e.g., ethylene oxide, high voltage, pathogenic biomaterials, etc. See IOM 1.5 for additional safety information.

#### 5.6.1.1 - Technical Assistance

Each program divisions have engineers and radiological health personnel available for technical assistance and consultation. Do not hesitate to make use of their services.

Engineers, quality assurance specialists, and national expert investigators in OMPTO as well as in OHAFO are

available for on-site consultation and assistance in problem areas. Refer to FMD-142. The subject matter experts are also available by telephone for consultation and to answer questions regarding regulation and program interpretation and QS/GMP application. Additionally, the CDRH Office of Health Technologies, within the Office of Product Quality (organized by device product) can be contacted as necessary.

WEAC has various personnel (biomedical, sterility, electronic, materials, mechanical, nuclear and plastics engineers) available for telephone consultation and on-site assistance at 781-756-9700.

#### 5.6.1.2 - Sample Collection During Inspection

Because of the limited funds available for samples and the relatively high cost of device samples, it is essential you consider, in consultation with your supervisor, the following factors before collecting a physical sample of a device:

1. If follow-up to a QS/GMP deviation, will sampling demonstrate the deviation and/or a defective product? Documentary Samples may be more suitable for QS/GMP purposes.
2. Likelihood of the analysis showing the device is unfit for its intended use.
3. Samples costing over \$250.00.
4. Laboratory capability to analyze the sample. See IOM 4.5.5.3.6 for sample routing information.

If you are still uncertain, discuss with your supervisor and contact the CDRH Laboratory or WEAC 781-756-9700 for assistance.

Contact CDRH for assistance as follows:

In-vitro Diagnostic Devices - Office of Science and Engineering Laboratories (HFZ-113).

**NOTE:** Device samples do not require 702(b) portions. Include in the FDA 525 and with the C/R, if destined for different locations, a copy of the firm's finished device specifications, test methods and acceptance and/or rejection criteria.

#### 5.6.1.3 - Types of Inspections

General device inspections will be conducted under various Compliance Programs found in the Compliance Program Guidance Manual. The majority of these will be QS/GMP inspections, but often the reason for the inspection will vary. For example, inspections may be conducted to assist the pre-market clearance process (PMA or Class III 510(k)), to specifically address MDR concerns, or to assure in-depth coverage of an aspect of manufacturing (sterility). The following describes some of these inspections. If the inspection is conducted for CDRH- led combination product see also IOM 5.12.

## 5.6.2 - MEDICAL DEVICE QUALITY SYSTEM/ GOOD MANUFACTURING PRACTICES

Section 520(f) of the FD&C Act [21 U.S.C. 360j(f)] provides the Agency with authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of medical devices conform to good manufacturing practices. The medical device Quality System/Good Manufacturing Practices Regulation (QS/GMP)([21 CFR 820](#)) became effective on June 1, 1997.

21 CFR 820 is established and promulgated under the authority of Sections [501](#), [502](#), [510](#), [513](#), [514](#), [515](#), [518](#), [519](#), [520](#), [522](#), [701](#), [704](#), [801](#) and [803](#) of the FD&C Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381 and 383). Failure to comply with the provisions of 21 CFR 820 renders a device adulterated under Section 501(h) of the FD&C Act [21 U.S.C. 351(h)].

The regulations promulgated under 21 CFR 820 establish minimum requirements applicable to finished devices, as defined in [820.1\(a\)](#). This regulation is not intended to apply to manufacturers of components or parts of finished devices, but instead recommended to them as a guide. In some special cases, components have been classified as finished devices (dental resins, alloys, etc.) and are subject to the QS/GMP. Manufacturers of human blood and blood components are not subject to this part, but are subject to [21 CFR 606](#).

The QS/GMP includes regulations regarding Purchasing Controls, [21 CFR 820.50](#), Receiving, In-process and Finished Device Acceptance, [21 CFR 820.80](#), and Traceability, [21 CFR 820.65](#), that require finished device manufacturers exercise more control over the components they use in their devices. The preamble of the QS/GMP states: "Since FDA is not regulating component suppliers, FDA believes that the explicit addition to the CGMP requirements of the purchasing controls...is necessary to provide the additional assurance that only acceptable components are used." And "...inspections and tests, and other verification tools, are also an important part of ensuring that components and finished devices conform to approved specifications." It further states, "...traceability of components must be maintained so potential and actual problem components can be traced back to the supplier."

The medical device QS/GMP is an umbrella GMP that specifies general objectives rather than methods. It is left to the manufacturer to develop the best methods to meet these objectives. You must use good judgment in determining compliance with the QS/GMP, keeping in mind that it is an umbrella GMP and all requirements may not apply or be necessary. The purpose of the QS/GMP is to assure conformance to specifications and to ensure that all requirements that will contribute to assuring the finished device meets specifications are implemented. You should not insist that a manufacturer meet non-applicable requirements. Refer to IOM Exhibit 5-13 for types of establishments that are required to comply with the QS/GMP.

### 5.6.2.1 - Pre-Inspectional Activities

Prior to the start of any medical device inspection, the factory jacket or establishment history of the establishment should be reviewed. You should review the previous inspectional findings and subsequent correspondence between the establishment and FDA; any MDR or consumer complaints where it was determined follow-up would occur at the next inspection; and any notifications of recalls since the last inspection.

MDR data most useful in preparing for an inspection includes specific MDRs for the manufacturer (i.e., query by establishment's short name) for the time frame since the last inspection, or MDRs for the generic devices manufactured by that establishment (i.e., query by product code) for some reasonable time frame. This data assists you in determining potential problem areas in the manufacture or design of the device, or lot or batch specific issues. MDR information can be accessed through the Total Product Lifecycle Reports (TPLC). A medical device report data request may be submitted to Office of Health Technologies, within the Office of Product Quality. The agency's Voluntary Malfunction Summary Reporting Program grants an alternative that permits manufacturer reporting of certain device malfunction MDRs in summary form on a quarterly basis. For general questions regarding MDR reporting requirements, contact the MDR Team at [MDRPolicy@fda.hhs.gov](mailto:MDRPolicy@fda.hhs.gov).

The establishment's reported registration and listing data should be verified during any GMP inspection to assure there have been no changes and the registration and listing data was accurately reported. Changes or inaccuracies should be immediately reported to the program division medical device registration and listing monitor. See also [Field Management Directive \(FMD\) 92](#).

510(k) and PMA data assists you in determining what devices the establishment is manufacturing and whether any new devices have been designed or changed since the last inspection. This data is useful in focusing the inspection on new or changed devices as well as devices that are higher risk devices, i.e., Class II or III versus Class I. This information can be accessed through IMAGE 2000 plus and TPLC.

Since information about medical device firms is distributed in many different databases, CDRH information is pulled into Total Product Life Cycle (TPLC) reports and ORA created Establishment History Reports (**EHR1**). **EHR1** Reports combine detailed recall and inspection history information. TPLC Reports combine registration and listing, premarket, adverse event (MDR), and CDRH complaint details as well as high level recall and inspection information. ORA investigators can run these reports in order to prepare for inspections.

It is necessary to have access to both Business Objects and ORADSS in order to run **EHR1** and TPLC reports. If you require access, send a request to the Employee Resource & Information Center (ERIC). You need to



specify in your request to ERIC that you need access to the TPLC reports.

### Accessing EHR1 reports

Go to

<http://inside.fda.gov:9003/it/Applications/ORAApplcations/default.htm>

Under ORADSS click go

Click the Documents Tab; then click Folders

Navigate (by hitting the plus sign) into Public Folders and then the Domestic Reports subfolder

Double click on the Establishment History Report subfolder

Select EHR1 and double click

\*Note: For initial inspections, there will not be any inspection history in the EHR1 report

### Accessing TPLC reports

Go to <http://bi.fda.gov>

In the upper left corner, you will see tabs labeled "Home" and "Documents". Click on "Documents". At the bottom left, you will see tabs labeled "My Documents", "Folders", "Categories" and "Search". Click on "Folders". You may see a folder that is labeled "Public Folders". Click on the folder. Navigate (by hitting the plus sign) into the TPLC. The TPLC reports will appear to the right. Select a report by double clicking the report name

Beneficial reports include:

- TPLC Manufacturer Name – displays information on a firm based on the Manufacturer name entered. The manufacturer name entered must be in upper case as the reports are case sensitive. Since company names vary with the inclusion of commas, abbreviations (INC vs. INC. vs. INCORPORATED), or division names, it is best to first use the shortest name possible with a wild card character (%). For example, to search for "XYZ SURGICAL CO (PVT) LTD", it would be best to first use "XYZ%". This will return all manufacturers that have a name beginning with that phrase. Given that some firms might have similar names, the report might return several companies with a name beginning with "XYZ". The best option then is to look at those companies returned in the report and modify the name used in the search.
- TPLC Product Code Reviewer - displays information on one or more specific product codes entered. Ensure that the product codes entered are in upper case as the reports are case sensitive.

If you have general questions or need help accessing this information, please contact your CDRH Regulatory Inspections and Audits Team regional representative or

OMDRHO Operations at  
[ORADeviceInspectionPOC@fda.hhs.gov](mailto:ORADeviceInspectionPOC@fda.hhs.gov).

Firms participating in the [Medical Device Single Audit Program \(MDSAP\)](#) will not be subject to an FDA routine device inspection. Therefore, firm participation in MDSAP must be verified before conducting any routine inspections. Verification starts by accessing the [MDSAP Master List](#) on the program's internal SharePoint site. If the firm name and address do not appear on the Master List (do not search using FEI), additional verification is required by contacting an MDSAP subject matter experts (SMEs) via email at [MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov).

For inspections other than routine (i.e., for cause, EPRC), contact the MDSAP SMEs at [MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov) [prior to scheduling the inspection, if possible, but no later than five business days before the scheduled inspection](#), if the firm and corresponding address appears on the Master List. In the communication, please include the type of inspection that will be performed and the estimated inspection dates.

IOM 5.2 should be followed in regards to pre-announcement of medical device inspections.

#### 5.6.2.2 - Quality Audit

The inspectional approach for identifying inadequate auditing of a quality assurance program is limited by the agency's policy, which prohibits access to audit results. The policy is stated in [CPG section 130.300](#) (7151.02). Under the QS/GMP regulation ([21 CFR 820.180](#) (c)) this prohibition extends to evaluations or audits of suppliers, [21 CFR 820.50\(a\)](#), and Management Reviews conducted per [21 CFR 820.20](#). Evidence of inadequate auditing may be discovered without gaining access to the written audit reports. See the Guide to Inspections of Medical Device Manufacturers or Guide to Inspections of Quality Systems for inspectional guidance.

The preamble to the QS/GMP specifically states, "FDA will review the corrective and preventive action procedures and activities performed in conformance with those procedures without reviewing the internal audit reports. FDA wants to make it clear that corrective and preventive actions, to include the documentation of these activities, which result from internal audits and management reviews are not covered under the exemption at 820.180(c)." Therefore, these corrective and preventive actions and documentation are not excepted from inspectional scrutiny.

The QS/GMP regulation (21 CFR 820.180(c)) requires a manufacturer to certify in writing that audits and reaudits have been conducted whenever requested to do so by an investigator. Investigators through their supervisors should consult with CDRH Office of Regulatory Programs (HFZ-320) prior to requesting such certification.

### 5.6.2.3 - Records

FDA has distinct authority under [section 704\(e\) of the FD&C Act](#) [21 U.S.C. 374 (e)] to inspect and copy records required under section [519](#) or [520\(g\)](#) of the FD&C Act [21 U.S.C. 360i or 360j (g)]. Investigators should only collect copies of documents as necessary to support observations or to satisfy assignments. Manufacturers who have petitioned for and obtained exemption from the QS/GMP are not exempted from FDA authority to review and copy complaints and records associated with investigation of device failures and complaints.

You may advise manufacturers they may mark as confidential those records they deem proprietary to aid FDA in determining which information may be disclosed under Freedom of Information Act.

Records must be maintained for as long as necessary to facilitate evaluation of any report of adverse performance, but not less than two years from the date the device is released for distribution. Records required by the Radiation Control for Health and Safety Act must be maintained for five years. It is permissible to retain records in electronic or photocopy form, providing the copies are true and accurate reproductions.

### 5.6.2.4 - Complaint Files

Complaints are written or oral expressions of dissatisfaction with finished device identity, quality, durability, reliability, safety, effectiveness or performance. Routine requests for service would not normally be considered complaints. However, service requests should be reviewed to detect complaints, and as part of any trend analysis system, and to comply with 820.200(a)(3).

FDA has the authority to require a device firm to open its complaint files, and review and copy documents from the file.

Provisions in the FD&C Act pertaining to FDA review of records are:

1. For restricted devices the FD&C Act in Section 704(a)(1)(B) [21 U.S.C. 374 (a)(1)(B)] extends inspection authority to records, files, papers, processes, controls and facilities bearing on restricted medical devices. See [FD&C Act Sec. 704](#) [21 U.S.C. 374] for a full explanation and for a list of the items, e.g., financial data, which are exempt from disclosure to FDA.
2. For all devices, including restricted devices, refer to Section 704(e) of the FD&C Act [21 U.S.C. 374 (e)], which provides for access to, copying and verification of certain records.
3. [Section 519 of the FD&C Act](#) [21 U.S.C. 360i] requires manufacturers, importers, or distributors of devices intended for human use to maintain such records, and provide information as the Secretary may by Regulation reasonably require.
4. [Section 520\(g\) of the FD&C Act](#) [21 U.S.C. 360j (g)] covers the establishment of exemptions for devices for

investigational use and the records which must be maintained and open for inspection.

QS/GMP requirements for complaint files are found in [21 CFR 820.198](#). GMP requirements for complaint files first became effective on December 18, 1978. The Quality System Regulation, which went into effect on June 1, 1997, added to and modified the requirements for complaint handling. The regulation contains a provision that records maintained in compliance with the QS/GMP must be available for review and copying by FDA ([21 CFR 820.180](#)). Complaint files are QS/GMP required records; therefore, the manufacturer must make all complaints received on or after December 18, 1978 and the records of their investigation available for FDA review and copying. EIRs should contain enough information to allow cross-referencing between complaints and MDRs.

[21 CFR Part 803](#) requires medical device manufacturers to report deaths, serious illnesses, and serious injuries to FDA for which a device has or may have caused or contributed, and manufacturers must also report certain device malfunctions. The MDR reportable events must be maintained in a separate portion of the complaint files or otherwise clearly identified. These complaints must be investigated to determine whether the device failed to meet specifications; whether the device was being used for treatment or diagnosis; and the relationship, if any, of the device to the reported incident or adverse event.

When a firm determines complaint handling will be conducted at a place other than the manufacturing site, copies of the record of investigation of complaints must be reasonably accessible at the actual manufacturing site.

### 5.6.3 - STERILE DEVICES

Inspections of sterile device manufacturers are conducted per Compliance Program Guidance Manual 7382.845, as a production process under the Production and Process Control Subsystem. See the Guide to Inspections of Quality Systems for further guidance.

### 5.6.4 - LABELING

Specific labeling requirements for in vitro diagnostics (IVDs) are contained in [21 CFR 809.10](#).

Part 809.10(a) contains explicit labeling requirements for the individual IVD containers, and for the outer package labeling and/or kit labeling. Part 809.10(b) contains special labeling requirements for the product insert, which must be included with all IVD products. These two sections also contain the requirements for: lot numbers, allowing traceability to components (for reagents) or subassemblies (for IVD instruments); stability studies for all forms of the product; an expiration date, or other indication to assure the product meets appropriate standards; and, the requirements for establishing accuracy, precision, specificity and sensitivity (as applicable).

Part 809.10(c) lists the labeling statements required for IVDs which are being sold for investigational and research use. Determine whether the firm is limiting the sale of IVDs, labeled as such, to investigators or researchers. Document any questionable products and submit to CDRH OHT7:Office of Invitro Diagnostics and Radiological Health for review.

Warning and caution statements recommended for certain devices, along with certain restrictions for use, are described in [21 CFR 801](#). This same section also contains the general labeling regulations, which apply to all medical devices.

### 5.6.5 - GOVERNMENT-WIDE QUALITY ASSURANCE PROGRAM (GWQAP)

Inspections under the GWQAP are conducted upon request by Office of Enforcement and Import Operations (OEIO), Division of Compliance Systems (DCS). Each assignment is specific and may involve more than a single compliance program. Specific questions arising during or as a result of these inspections should be directed to OEIO/DCS.

### 5.6.6 - CONTRACT FACILITIES

Device manufacturers may employ the services of outside laboratories, sterilization facilities, or other manufacturers (i.e., injection molders, packagers, etc.). The finished device manufacturer is responsible for assuring these contractors comply with the QS/GMP and that the product or service provided is adequate. These contractors are subject to FDA inspection and some are subject to the QS/GMP regulation. This "...includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions," per [21 CFR 820.3\(o\)](#). Whether under contract or not if a firm manufactures a finished device by the definition found in 21 CFR 820.3(l) "*Finished device*" means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized they are subject to QS/GMP. NOTE: if the product manufactured by the contractor also meets the definition of a component *and* a finished device, the contractor is subject to the QS/GMP regulation.

Determine how a manufacturer evaluates and selects potential contractors for their ability to meet the manufacturer's requirements, as required by [820.50](#), Purchasing Controls. Conducting audits can be an effective method for assessment. However, not all contractors allow audits. Audits may not be feasible in some instances. In other instances, the activity the contractor is conducting may not have a significant impact on the device safety or function; therefore, expending the resources necessary to audit the contractor may not be warranted.

Evaluations may be accomplished by other means such as requesting that the potential contractor fill out a

questionnaire about their quality system, asking other customers of the contractor about their experiences with the firm, or basing assessments on past performance. Evaluations must be documented. The extent to which a manufacturer has evaluated a contractor, as well as the results of the evaluation, should govern the degree of oversight exercised over products and services supplied by the contractor.

### 5.6.7 - SMALL MANUFACTURERS

When inspecting one-person or very small manufacturers for compliance with the QS/GMP master record and written procedure requirements, the investigator should realize that detailed written assembly, process, and other instructional procedures required for larger firms may not be needed. In a small firm, division of work is at a minimum, with one person often assembling and testing the finished device. In many cases, blueprints or engineering drawings could be adequate procedures. The QS regulation requires that certain activities be defined, documented and implemented. The regulation does not require separate procedures for each requirement and often several requirements can be met with a single procedure. The complexity of the procedures should be proportional to the complexity of the manufacturer's quality system, the complexity of the organizational structure and the complexity/risk of the finished device being produced. In assessing the need for detailed or lengthy written procedures, the investigator should make judgments based on training and experience of the individuals doing the work and the complexity of the manufacturing process. However, this does not mean small manufacturers have any less responsibility for complying with the QS regulation or assuring safe and effective devices are produced.

### 5.6.8 - BANNED DEVICES

[Section 516 of the FD&C Act](#) [21 U.S.C. 360f] provides a device for human use may be banned by regulation ([21 CFR 895](#)) if it presents substantial risk of illness or injury. Investigators should become familiar with this regulation. When you determine, during an inspection or investigation, that banned devices are being distributed, the distribution, manufacture, etc., should be documented as for any other violative product.

### 5.6.9 – REPORTS OF CORRECTIONS AND REMOVALS

Manufacturers, importers, and distributors of medical devices are to promptly report to the FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health as provisioned by the Safe Medical Devices Act of 1990 and 21 CFR Part 806. Refer to IOM Ch. 7 – RECALL ACTIVITIES and 7.2.3 MEDICAL DEVICE RECALLS for more information.

## 5.6.10 – TRACKED MEDICAL DEVICES

A “tracked medical device” is a device regulated by CDRH and for which the firm has received “tracking orders”. CDRH has a dedicated mailbox to manage inquiries about tracked devices and the related regulation at [TrackedDevicesMailbox@FDA.HHS.GOV](mailto:TrackedDevicesMailbox@FDA.HHS.GOV).

### 5.6.11 - DEVICE INSPECTION REPORTS

See IOM 1.1, English language requirement. You should write your EIR following the guidance in IOM 5.11.4, 5.11.4.1, 5.11.4.2, 5.11.4.3. Section headings can be added to address the needs of other Compliance Program Guidance Manuals such as 7383.001 for pre-market and post-market PMA inspections. Include in your report the systems, processes, products, and product classification covered during the current inspection.

## SUBCHAPTER 5.7 - BIOLOGICS

### 5.7.1 - DEFINITION

A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide) or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in [21 CFR 600.3](#). Biological products also meet the definition of either a drug or device under [Sections 201\(g\) and \(h\)](#) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Veterinary biologics are subject to the animal Virus, Serum, and Toxin Act which is enforced by USDA (21 U.S.C. 151-158).

### 5.7.2 - BIOLOGICS INSPECTIONS

The periodic CGMP inspections and compliance operations of plasma fractionated products, allergenic products, vaccines, gene and cell therapy products, and biological in vitro diagnostic devices are led by investigators from ORA's Office of Biological Products Operations (OBPO). OBPO investigators also lead inspections of unlicensed CBER-regulated medical devices (e.g., blood establishment software). See IOM 2.2 for a discussion of statutory authority. CBER maintains the lead for pre-licensing and most pre-approval inspections of biological products, while ORA customarily leads PMA/510(k) inspections.

#### 5.7.2.1 - Authority

Biological products are regulated under the authority of [Section 351 of the Public Health Service Act](#) and under the Food, Drug, and Cosmetic Act, as drugs or devices, with the exception of certain human cells, tissues, and cellular

and tissue-based products (HCT/Ps) regulated solely under [Section 361 of the Public Health Service Act](#) (see [21 CFR 1271.10](#)). Blood and blood products for transfusion are prescription drugs under the FD&C Act. Under the FD&C Act, source plasma and recovered plasma may have the legal identity of either a drug or device depending on its intended use. Section 351(a) of the PHS Act provides for licensure of biological products and inspection of the products covered is per 351(d). Most biological drugs are licensed. The investigational new drug application regulations ([21 CFR 312](#)) also apply to biological products subject to the licensing provisions of the PHS Act. However, investigations of blood grouping serum, reagent red blood cells, and anti-human globulin in-vitro diagnostic products may be exempted ([21 CFR 312.2\(b\)](#)).

#### 5.7.2.1.1 - BLOOD AND SOURCE PLASMA INSPECTIONS

For blood bank and source plasma establishment inspections ([CP 7342.001](#) & [7342.002](#)) use the CGMPs for Blood and Blood Components ([21 CFR 606](#)) as well as the general requirements for biological products ([21 CFR Part 600](#)), the general biological product standards ([21 CFR Part 610](#)), and the additional standards for human blood and blood products ([21 CFR Part 640](#).) The drug GMPs ([21 CFR 210/211](#)) also apply to biological drugs. In the event it is impossible to comply with both sets of regulations, the regulation specifically applicable to the product applies. This would generally be Parts 606 and 640 of the regulations in the case of blood bank and source plasma establishments.

#### 5.7.2.1.2 – HUMAN TISSUE INSPECTIONS

21 CFR [Part 1271](#) contains six subparts:

1. [Subpart A of part 1271](#) – general provisions
2. [Subpart B of part 1271](#) - registration
3. [Subpart C of part 1271](#) - screening and testing of donors to determine eligibility
4. [Subpart D of part 1271](#) - provisions on CGTP
5. [Subpart E of part 1271](#) - certain labeling and reporting requirements
6. [Subpart F of part 1271](#) - inspection and enforcement provisions.

The subparts apply as follows:

Subparts A through D apply to all HCT/Ps, i.e., to those HCT/Ps described in [Sec. 1271.10](#) and regulated solely under section 361 of the PHS Act, and to those regulated as drugs, devices, and/or biological products. Subparts E and F, which pertain to labeling, reporting, inspection, and enforcement, apply only to those HCT/Ps described in [Sec. 1271.10](#) and regulated solely under section 361 of the PHS Act. However, with the exception of two provisions ([Sec. 1271.150\(c\)](#) and [1271.155](#)) subparts D and E are not being implemented for reproductive HCT/Ps described in [21 CFR 1271.10](#) and regulated solely under section 361 of the PHS Act.

HCT/Ps subject to the provisions of 21 CFR Part [1271](#) include, but are not limited to, bone, ligaments, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue.

For HCT/P inspections, use the [CP 7341.002](#), "Inspections of Human Cells, Tissues, and Cellular and Tissue-Based Products."

### 5.7.2.2 – Donor Confidentiality

Blood bank, source plasma, and human tissue establishments are sensitive to maintaining confidentiality of donor names. The mere reluctance to provide records is not a refusal. However, FDA has the authority under both the PHS and the FD&C Acts to make inspections and [21 CFR 600.22\(g\)](#) and [1271.400\(d\)](#) provides for copying records during an establishment inspection. For prescription drugs, [section 704 of the FD&C Act](#) specifically identifies records, files, papers, processes, controls, and facilities as being subject to inspection.

If you encounter problems accessing records, explain FDA's authority to copy these records. IOM 5.2.5 should be followed if a refusal is encountered. When donor names or other identifiers are necessary, they may be copied, but the information must be protected from inappropriate release. See IOM 5.3.8.6.

### 5.7.2.3 – Inspectional Objectives

The inspectional objective for biological products is to assure the products are safe, effective, and contain the quality and purity they purport to possess and are properly labeled. The inspectional objective for HCT/Ps is to assure that HCT/Ps are recovered, processed, stored, labeled, packaged and distributed, and the donors are screened and tested, in a way that prevents the introduction, transmission, or spread of communicable diseases. Facilities will be inspected for conformance with:

1. Provisions of the PHS Act and FD&C Act,
2. Applicable regulations in:
  - 21 CFR [210-211](#)
  - 21 CFR 600-680, and
  - 21 CFR [820](#)
3. HCT/P regulations in [21 CFR 1270](#) and [1271](#).
4. FDA Policies, which include guidance to the industry, and the [Compliance Policy Guides Chapter 2](#).

### 5.7.2.4 - Preparation

Review the program division files of the facility to be inspected and familiarize yourself with its operation and compliance history. Review:

1. Appropriate Compliance Programs and related [Compliance Policy Guides \(CPG\), Chapter 2](#). NOTE: Federal Cooperative Agreements Manual; MOU with the Department of Defense, and MOU with the Centers for Medicare and Medicaid Services (CMS) on transfusion services;

2. Correspondence from the firm depicting any changes since the last inspection;
3. Firm's registration and product listing information;
4. Biological Product Deviation Reports, Adverse Reaction Reports, complaints, and recalls;

Through guidance documents, CBER sets forth its inspection policy and regulatory approach. A list of these documents is attached to the current Compliance Program Guidance Manuals (CP) available on the CBER internet site at ([CBER CP Website](#)).

The OSHA regulation [29 CFR 1910.1030](#) dated December 6, 1991, was intended to protect health care workers from blood borne pathogens, including those involved in the collection and processing of blood products. The regulation defines expectations for the use of gloves, hand washing facilities, decontamination of work areas, waste containers, labeling and training of employees and exemptions for volunteer blood donor centers. FDA Investigators should adhere to these safety guidelines during inspections or related activities in establishments that process biologically hazardous materials.

Become familiar with the OSHA regulations and their applicability to [21 CFR 606.40\(d\)\(1\)](#) and (2), which require the safe and sanitary disposal for trash, items used in the collection and processing of blood and for blood products not suitable for use. Consult your program division biologics monitor for copies of the above references. Additional copies may be obtained from OO, OMPTO, Division of Medical Products and Tobacco Program Operations or see [CBER's web site](#).

### 5.7.2.5 - Inspectional Approach

Use the Compliance Program (CP) for inspectional instructions. Particular attention should be given to biological products deviation reports indicative of problematic areas or processes, adverse reactions, transfusion or donation associated fatalities and hepatitis and HIV lookback procedures. The follow-up investigations to such reports should also be covered.

Complaints, in particular those involving criminal activity, must be promptly investigated and coordinated with other agency components as needed.

For blood banks and source plasma establishments, refer to CP 7342.001 and 7342.002 for a discussion of the systems approach to inspection. The CP incorporates a systems-based approach to conducting an inspection and identifies five (5) systems in a blood bank and source plasma establishment operation for inspection. Each system may not be in a particular establishment operation; therefore, the inspection should focus on the systems present. The CP directs an in-depth audit of the critical areas in each system. A multi-layered system of safeguards has been built into the blood collection, manufacturing and distribution system to assure a safe blood supply.

For HCT/P establishments, refer to CP 7341.002.

For Biological Drug Products, refer to CP 7345.848.

For Licensed In-vitro Diagnostic Devices Regulated by CBER, refer to CP 7342.008.

If Investigators encounter products not specifically referenced in the regulations, they should contact CBER/OCBQ/ Division of Inspections and Surveillance for guidance.

### 5.7.2.6 - Regulations, Guidelines, Recommendations

Guidance documents for industry are made available to the public in accordance with good guidance practice regulations at [21 CFR 10.115](#). The contents of most of these documents are incorporated into the establishment's SOPs and/or license applications or supplements.

Deviations from guidance documents must not be referenced on an FDA 483. However, since these documents are often related to specific GMP requirements, in most cases deviations can be referenced back to the GMP. If a deviation is observed during an inspection and the investigator relates it to the regulations or law, then the item may be reported on the FDA 483. During the discussion with management, the relationship of the deviation to the regulation or law, or accepted standard of industry, should be clearly explained.

If an establishment indicates it is not aware of any of these documents, provide them the guidance document(s) or direct them where to find these documents on [www.fda.gov](http://www.fda.gov). Provide the firm with the email address for industry in order to obtain additional information from CBER at [industry.biologics@fda.hhs.gov](mailto:industry.biologics@fda.hhs.gov).

If a firm claims approval for an alternative procedure, verify by reviewing the firm's written approval letter. Approved alternative procedures may be verified by contacting CBER/Division of Blood Applications or the appropriate CBER product office.

### 5.7.2.7 - Technical Assistance

The services of National Experts and Program Experts in ORA/OMPTO are available for telephone or on-site consultation and assistance in problem areas (see FMD-142).

### 5.7.2.8 Biologics Establishment Inspection Reports

See IOM 1.1, English language requirement. You should write your EIR following the guidance in IOM 5.11.4, 5.11.4.1, 5.11.4.2, 5.11.4.3. Section headings can be added to address the needs of specific Compliance Program referenced in conducting the inspection. Where applicable and per the CP, the report should state the levels of the inspection and systems that were covered. The reasoning for the level and systems covered must be reported, as directed in the CPs. The report should also

include a summary, the FDA 482, the FDA 483, if issued, and the required eNSpect record in OSAR.

The scope of the reporting should reflect requirements and regulations for each area, the firm's state of compliance, previous inspectional report(s) and information, complexity of operations, and other aspects that may affect the reporting that will be necessary.

For directed inspections with a narrow focus, such as complaint follow-up or center-directed assignments include information to appropriately cover the assignment. Follow specific instructions included in any associated assignment memorandum.

## 5.7.3 - REGISTRATION, LISTING AND LICENSING.

### 5.7.3.1 - Registration and Listing

See IOM 2.9.3.1

#### 5.7.3.1.1 – TRANSFUSION SERVICES

Most transfusion services are exempt from registration under [21 CFR 607](#). This includes facilities that are certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR Part 493 to perform the FDA-required tests on blood or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services, and are engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components. Such facilities include establishments:

1. Collecting, processing and shipping blood and blood components under documented emergency situations,
2. Performing therapeutic phlebotomy and therapeutic plasma exchange after which the product is discarded,
3. Preparing recovered human plasma and red blood cells,
4. Pooling products/platelets for in-house transfusion,
5. Thawing frozen plasma or cryoprecipitate for transfusion.

All VA Blood Banks and Hospital Transfusion Services must register with FDA since they are not inspected by CMS.

#### 5.7.3.1.2 - HCT/PS

Establishments manufacturing HCT/PS (human cells, tissues, or cellular or tissue-based products) as defined in [21 CFR 1271.3\(d\)](#) must register and list using form FDA 3356. Examples of HCT/PS include, but are not limited to, bone, ligament, skin, cornea, hematopoietic stem cells derived from peripheral and cord blood, manipulated autologous chondrocytes, and semen or other reproductive tissue.

Establishments that only manufacture investigational HCT/PS under an IND or IDE are not required to register and list until the HCT/P has been licensed, approved, or

cleared by FDA. Establishments manufacturing HCT/PS regulated as drugs and/or biological products must register and list with FDA pursuant to 21 CFR 207. Establishments manufacturing HCT/PS regulated as medical devices must register and list with FDA pursuant to 21 CFR 807.

### 5.7.3.1.3 - LABORATORIES

Laboratories performing infectious disease testing of donors of blood or blood components or HCT/P are an FDA obligation and required to register. Clinical laboratories were previously exempted from registration by [21 CFR 607.65\(g\)](#), but FDA revoked this regulation. Your inspections should focus on activities relevant to blood product and HCT/P testing operations.

### 5.7.3.1.4 - MILITARY BLOOD BANKS

Inspection of military blood banks is an ORA responsibility. These facilities are required to meet the same standards as other blood banks although military emergencies may require deviations from the standards. A separate license is held by each branch of the service; although each individual establishment may be licensed or unlicensed, all are required to register. Program divisions should notify the appropriate military liaisons 30 days before inspection of a military facility. For additional information on inspection of government establishments, see Compliance Program Guidance Manual 7342.001, the Federal Cooperative Agreements Manual, and the MOU with Department of Defense Regarding Licensure of Military Blood Banks.

Foreign notification of Military Blood Banks is done by the Trip Planner in preparation of the international trip.

[Field Management Directive 92](#), Agency Establishment Registration and Control Procedures, details the registration process within the agency.

Ensure the firm's current registration forms reflect actual operations.

### 5.7.3.2 – MOUs

Under the 1983 Memorandum of Understanding (MOU) between the FDA and the Centers for Medicare and Medicaid Services (CMS, formerly Health Care Financing Administration - HCFA), CMS agreed to survey these facilities that engage in minimal manufacturing in order to minimize duplication of effort and reduce the burden on the affected facilities while continuing to protect transfusion recipients. However, no transfer of statutory functions or authority is made under the MOU and the FDA retains legal authority to inspect these unregistered transfusion services whenever warranted. When appropriate, program divisions should conduct inspections jointly with the CMS regional liaison. If you determine during a routine inspection an establishment is a CMS obligation under the MOU, you should terminate the inspection and report as such. See Federal Cooperative Agreements Manual - FDA/HCFA MOU.

### 5.7.3.3 - Biologics License

See IOM 2.9.3.2. A biologics license application (BLA) shall be approved only after inspection of the establishment(s) listed in the application and upon a determination that the establishment complies with the standards established in the BLA and the requirements prescribed in applicable regulations ([21 CFR 601.20\(d\)](#)). CBER maintains the lead for [pre-license \(PLI\) and pre-approval \(PAI\)](#) inspections of biological products. These inspections are part of the review of a BLA or BLA supplement. CBER identifies the scope of the inspection and invites ORA to participate in [or may request ORA lead the PLI or PAI](#).

Copies of CBER's PLI and PAI inspection reports are forwarded to the Program Divisions and are stored in the firm's eCMS file. [These inspection reports can also be located in eNSpect and OSAR.](#)

### 5.7.3.4 - Approval of Biological Devices

There must be a pre-approval inspection (PAI) of the establishment for compliance with the QS/GMP regulation and the firm's PMA. For licensed devices, CBER conducts the pre-license inspection (PLI). Devices used in the collection and testing of blood for transfusion are approved/cleared through the PMA/510(k) authorities. ORA Investigators customarily inspect the CBER regulated devices, which are subject to PMA/510(k) applications.

### 5.7.4 - TESTING LABORATORIES

Blood bank, source plasma, and HCT/P establishments may use outside testing laboratories to perform required testing.

Laboratories conducting testing for licensed blood banks are usually licensed. CBER may approve the use of a non-licensed laboratory to do required testing, provided the lab is capable of performing the tests and the lab registers with CBER prior to CBER approving the licensing arrangement.

Laboratories performing required testing for source plasma manufacturers must either be:

1. licensed or
1. certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by CMS.

Instructions for inspecting testing laboratories are included in the appropriate CP. Coordinate the inspection of non-registered laboratories with CMS regional office contacts. If a testing laboratory is located outside of the program division, request an inspection by the appropriate program division office, where appropriate.

See updated information on: Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays; and HCT/P donors for Relevant Communicable Disease Agents at

FDA.gov.

## 5.7.5 - BROKERS

Blood establishments may use brokers to locate buyers for products such as recovered plasma or expired red blood cells. These articles are used for further manufacture into products such as clinical chemistry controls and in-vitro diagnostic products not subject to licensure. Fractionators also use brokers to locate suppliers of plasma under the short supply provisions ([21 CFR 601.22](#)). During inspections, determine if the facility is selling products to any brokers. If brokers are used, determine if the brokered products are shipped to a facility operated by the broker or directly to the consignee.

Brokers who take physical possession of blood products and engage in activities considered manufacturing or labeling are required to register and are included in the OEI for routine inspection under the blood bank compliance program. Brokers who only arrange sales of or store blood and blood components, but do not engage in manufacturing activities are not required to register.

## SUBCHAPTER 5.8 - TOBACCO PRODUCTS

### 5.8.1 - DEFINITIONS

The term "tobacco product" is defined in FD&C Act Section 201(rr) and means any product made or derived from tobacco that is intended for human consumption, including any component part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product.) The term "tobacco product" does not mean an article that is a drug under section 201(g)(1) of the FD&C Act, a device under section 201(h) of the FD&C Act, or a combination product described in section 503(g) of the FD&C Act.

The definition of certain tobacco products can be found in the FD&C Act under section 900.

### 5.8.2 – TOBACCO INSPECTIONS

See IOM 2.2 for discussion of statutory authority

Inspections involving tobacco product(s) at manufacturing facilities are led by ORA's Tobacco Operations Staff (TOS) within the Office of Medical Products and Tobacco Operations and are conducted pursuant to assignments issued by CTP. These assignments are issued to conduct inspections of entities engaged in the manufacture, preparation, compounding, or processing of tobacco products. Inspections may also be conducted to support the pre-market review process. Assignments may also be issued to conduct investigations and sample collections. CTP Subject Matter Experts may accompany ORA's Tobacco Operations Staff during inspections. Additional guidance on deemed tobacco products can be found on CTP's Deeming webpage.

<https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products>.

### 5.8.3 - RETAIL COMPLIANCE CHECK INSPECTION CONTRACTS

FDA issues contracts to assist with compliance check inspections of tobacco retail establishments to help enforce the Youth Access and Advertising Regulations that took effect on June 22, 2010, and were amended on August 8, 2016, to deem additional tobacco products within FDA's jurisdiction. FDA has a goal of establishing a contract, where feasible, with every U.S. State and Territory, but some States and Territories, for a variety of reasons, have been unable to do so. Therefore, FDA has awarded contracts to third-party entities that are able to hire commissionable inspectors to conduct compliance check inspections of tobacco retailers in those states and territories where FDA was unable to contract with a government agency. FDA has further expanded this program by awarding retail inspection contracts to American Indian and Alaska Native Tribes to conduct retail inspections within their jurisdictions. In addition, FDA may also conduct inspections using FDA personnel.

### 5.8.4 - GUIDANCE, COMPLIANCE & REGULATORY INFORMATION

The [Center for Tobacco Products](#) website contains resources for legal, regulatory, and policy issues related to tobacco products and information for small business assistance ([SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov))

## SUBCHAPTER 5.9 - VETERINARY MEDICINE

### 5.9.1 - CVM WEBSITE

The [Center for Veterinary Medicine](#) website contains; a listing of current and planned Guidance Documents; and on-line access to the [Animal Drug@fda](#) database listing new animal drug approvals. There is a "search" feature allowing you to search for documents containing various words or phrases. The website also contains organizational information for the Center and an explanation of the various laws and regulations which the Center enforces. Information on the website can provide guidance for inspectional efforts related to CVM obligations.

### 5.9.2 - VETERINARY DRUG ACTIVITIES

CVM is responsible for work planning inspections of therapeutic and production drugs, and Active Pharmaceutical Ingredients (APIs). Therapeutic drugs are used in the diagnosis, cure, mitigation, treatment or prevention of disease. Production drugs are used for economic enhancement of animal productivity. Examples include: growth promotion, feed efficiency and increased milk production.



Pre-approval inspections are conducted pursuant to pending NADA or ANADA applications.

Post approval inspections of veterinary drugs are conducted to determine compliance with the Current Good Manufacturing Practices (CGMPs) for Finished Pharmaceuticals under [21 CFR Part 211](#). These cGMPs apply to both human and veterinary drugs. Information on veterinary drugs approved can be found in the "Green Book" database accessed through CVM's website.

APIs are active pharmaceutical ingredients. Many of the APIs used to manufacture dosage form drugs are imported from foreign countries. The intended source for an API must be indicated in NADA/ANADA submissions for new animal drug approvals. Any change in a source for an API would require a supplement to the application.

Extra label drug use refers to the regulations in [21 CFR Part 530](#) codified as a result of the [Animal Medicinal Drug Use Clarification Act \(AMDUCA\)](#) of 1994. These regulations set forth the requirements that veterinarians must meet to prescribe extra label uses of FDA approved animal and human drugs. The regulations describe what is a valid veterinary-client-patient relationship as well as what is considered illegal extra label use. 21 CFR Part 530 addresses issues regarding extra label use in non-food as well as food producing animals. [21 CFR 530.41](#) contains a list of drugs that cannot be used in an extra label manner in food-producing animals. During an inspection or investigation if you encounter any situations on suspected illegal extra label use of any FDA approved animal or human drugs or those prohibited for extra label use in food animals, you should contact CVM's Division of Compliance (HFV-230) (240-276-9200).

21 CFR Part 530 also addresses compounding of products from approved animal or human drugs by a pharmacist or veterinarian. The regulations clearly state compounding is not permitted from bulk drugs. This would include APIs. CVM has an existing CPG on Compounding of Drugs for Use in Animals (CPG 608.400). A copy can be found on CVM's website. The Division of Compliance (HFV-230) has issued assignments to conduct inspections of firms, including internet pharmacies, who may be engaged in the practice of manufacturing under the guise of pharmacy compounding. You should contact the Division of Compliance (HFV-230) at 240-276-9200 to report instances of compounding or to seek guidance on inspectional issues, or regulatory and enforcement policies.

### 5.9.3 - MEDICATED FEEDS AND TYPE A ARTICLES

Animal feed is defined under [section 201\(w\) of the FD&C Act](#) [21 U.S.C. 321 (w)]. CVM is responsible for control of

medicated and non-medicated animal feeds, Type A medicated articles and pet foods.

The regulations for animal food labeling are in [21 CFR Part 501](#). The regulations for medicated feed mill licensure are in [21 CFR Part 515](#). The cGMPs for Medicated Feeds are in [21 CFR Part 225](#). The cGMPs for Type A Articles are in [21 CFR Part 226](#).

Inspections are routinely conducted of medicated feed mills and manufacturers of Type A Medicated Articles.

If you have questions related to cGMPs and enforcement policies and strategies concerning Medicated Feeds and Type A Articles you should contact the CVM/Division of Compliance (240-276-9200).

Guidance on pet food labeling requirements can be found on CVM's website.

### 5.9.4 - BSE ACTIVITIES

CVM is responsible for FDA's industry education and regulatory activities involving BSE and animal feed. BSE is "Bovine Spongiform Encephalopathy" and is often referred to as "mad cow disease." There are two BSE-related feed regulations: 21 CFR 589.2000, entitled "Animal Proteins Prohibited in Ruminant Feed" which was adopted in 1997, addresses the feeding of ruminant animals. A second rule, 21 CFR 589.2001, entitled "Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy" was adopted in 2009. 21 CFR 589.2001 prohibits the use of certain cattle-origin materials in the feed of all animals and is aimed primarily at rendering operations.

CVM has [Guidance Documents](#) in place dealing with BSE. The guidance documents address renderers, protein blenders, feed manufacturers, distributors and on farm feeders. The Compliance Program Guidance Manual and the inspection checklist are available on the CVM website, as are a variety of other BSE information, including a database containing a summary of the most recent inspection of each firm.

Questions on inspectional assignments and regulatory activities in the BSE area should be addressed to the CVM/Division of Compliance (HFV-230) at 240-276-9200.

#### 5.9.4.1 – Biosecurity Procedures for BSE Inspections at Poultry Facilities and Farms

Given our recent experiences with highly pathogenic animal viruses such as porcine epidemic diarrhea virus (PEDV) in 2013 and 2014, and highly pathogenic avian influenza (HPAI) in 2015, we expect everyone conducting feed inspections on FDA's behalf to observe routine, simple, biosecurity precautions for all of your routine feed inspection work going forward.

In summary: and in addition to FDA's Biosecurity Guidance/procedures:

- 1) Follow the biosecurity plan for the facility being visited if they have one.
- 2) Plan your daily work so you do not carry contamination from one location to another. As much as possible, plan to work from cleanest to dirtiest on a given day, whether this is within a single facility, or across multiple facilities.
- 3) Wear clean shoes and clothes and use clean equipment.
- 4) Practice good personal hygiene, such as hand-washing and bathing.
- 5) Change or clean your shoes between inspection sites if they get dirty or wear disposable shoe coverings.
- 6) Visiting a farm to conduct a feed inspection should not require any contact with farm animals in most situations, and animal contact should be avoided unless it is absolutely necessary.
- 7) Be cognizant of recent contact with any livestock or poultry, including your own or those belonging to friends, families or neighbors, pet birds, and things like hunting, and consider it as you plan your work.
- 8) As much as possible, avoid going from one farm to another on a single day. If you do need to go from one farm to another, it may be necessary to change clothes or shoes, or even take a shower which is why we are encouraging the planning of work in such a way that contamination is not carried from one site to another.
- 9) Make an appointment to conduct routine on-farm inspections.

For the most part, the information above is a brief, high-level summary of Section 5.2.10. "Routine Biosecurity Procedures for Visits to Facilities Housing or Transporting Domestic or Wild Animals

CVM asks that all routine assigned work (covered in the work-plan or an assignment) involving on-farm feed inspections be pre-announced. This will allow the CSO the opportunity to ask about biosecurity procedures and help make sure someone is present.

### 5.9.5 - DRUG RESIDUES

The presence of violative drug residues in food from slaughtered animals is a human health concern. Drug residue inspections are performed in response to reports of violative drug residue levels found in tissue sampled at slaughter by the USDA/Food Safety Inspection Service (FSIS).

Drug residues are commonly caused by medicating animals prior to marketing and failure to follow the drug's approved label directions. When a new animal drug is approved the approval is very specific in how the drug should be used, the dosage it should be given, route of administration, frequency of use and reason for use. A drug manufacturer conducts studies to determine withdrawal times and these times must be followed. Established tolerances for drug residues of new animal drugs in food can be found in [21 CFR Part 556](#).

Drug residue investigations are unique in comparison to other fieldwork. Although your investigation may begin at the USDA slaughter establishment or person named on the USDA/FSIS "Violation Notification Letter," you may inspect and/or visit more sites as part of your overall investigation. You may have to visit an auction barn, dealer, trucker, veterinarian, drug supplier, slaughter facility (USDA firm management or State personnel), etc. One or more of these establishments may be responsible for the drug residue. Thus, each establishment's activities may warrant a recommendation for regulatory action such as Warning Letter, Injunction, etc. when involvement with residue violations is documented.

Upon receipt of a FACTS assignment from CVM to conduct a drug residue follow-up investigation, the program division may also create additional operations, linked to the original CVM assignment, which will include all operations required to complete the CVM assignment. This could include multiple inspections, sample collections and/or investigations. You may not be aware of all the establishments you will visit prior to beginning your investigation. Appropriate operations should be added to or deleted from the program division assignment.

Each site visit is unique, and each produces its own set of unique documents and evidence requiring individual reporting by establishment. You should use good judgment during case development to assure you document your investigation thoroughly. Explain the chain of events and evidence, from the initial drug residue report, and how other establishments were involved. Collect samples (usually DOC samples) as appropriate. Consultation with your supervisor and/or compliance branch during these operations is essential to assure all evidence necessary to develop a quality case is obtained and submitted in an appropriate format.

Following completion of all operations, you should prepare a Memo of Investigation referencing the FACTS assignments for your supervisor's endorsement to the program division Compliance Branch, with a copy to the originating CVM office. This Memo will summarize each site visit (EI or Investigation), sample(s) collected and relevance to the overall CVM assignment. A copy of the memo will be routed to each appropriate factory file.

The individual operations will then stand alone and/or may be used together to build one or multiple cases.

For example, a site visit to a slaughter facility may obtain information on the animal from the USDA inspection personnel on site; and obtain verification from management the establishment ships in interstate commerce. Information obtained at the slaughter facility or other establishments may be documented in an affidavit from each individual providing salient information. A site visit to a veterinarian may be important to establish whether the drugs which caused the drug residue(s) were prescribed and, if so, how they were prescribed. When there is reason

to believe off-label use or other activities have occurred which may warrant a recommendation for regulatory action, an establishment inspection should be conducted, and your evidence included with your report. Refer to the Compliance Program 7371.006, "Illegal Residues in Meat, Poultry, Seafood and other Animal Derived Foods" for in depth instructions on how to conduct a drug residue inspection.

For information on drug residue violations and activities you should contact the CVM/Division of Compliance (HFV-230, 240-402-7001).

### 5.9.6 - VETERINARY DEVICES

Medical devices for animal/veterinary use are not subject to the premarket approval requirements like human medical devices. Once an animal use device is marketed the Center is concerned with safety and efficacy of the veterinary device. CVM often recommends firms use the human device GMPs in controlling the manufacturing of animal use devices. CVM also suggests labeling be sent in for review by the Division of Compliance (HFV-230) to avoid misbranding. Regulatory questions for veterinary/animal use devices should be directed to the CVM/Division of Compliance (HFV-230).

### 5.9.7 - ANIMAL GROOMING AIDS

Grooming aids for animals formulated and labeled only to cleanse or beautify the animal are not cosmetics within the meaning of [Section 201\(j\)](#) and not subject to the Federal Food, Drug, and Cosmetic Act. Where animal grooming aids are labeled to contain an active drug ingredient or otherwise suggest or imply therapeutic benefit, they may be considered to be drugs and/or new animal drugs as defined by Section 201(v) of the Act (see [CPG 653.100](#)).

Questions on labeling and regulatory concerns should be directed to the Division of Compliance (HFV-230) at 240-276-9200.

### 5.9.8 – PRODUCTS INTENDED FOR CONTROL OF FLEAS AND TICKS

Products for animal use intended for control of fleas and ticks may be regulated as drugs by FDA under the Federal Food, Drug, and Cosmetic Act or pesticides by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act. Products registered with EPA as pesticides must have an EPA registration number listed on the label. Questions regarding whether a product intended for control of fleas and ticks is regulated by FDA or EPA should be directed to CVM, Division of Compliance at [CVMCompliance@fda.hhs.gov](mailto:CVMCompliance@fda.hhs.gov). Questions regarding EPA-registered pesticide products should be referred to EPA at [pesticidequestions@epa.gov](mailto:pesticidequestions@epa.gov) or Environmental Protection Agency, Office of Pesticide Programs, 1200 Pennsylvania Ave., Washington, DC 20460.

## SUBCHAPTER 5.10 – BIORESEARCH MONITORING (BIMO)

Inspectional activities in the bioresearch monitoring (BIMO) program involve all product areas and centers. Establishments inspected include Sponsors, Monitors, Contract Research Organizations, Clinical Investigators, **Sponsor-Investigators**, Institutional Review Boards, In Vivo Bioequivalence / Bioanalytical Clinical and Analytical Sites, and Nonclinical Laboratories. BIMO also includes Post market Adverse Drug Experience (PADE) reporting and Risk Evaluation and Mitigation Strategies (REMS), both of which are post approval activities. BIMO inspections are conducted to determine the reliability of data submitted in support of premarket and pre-license applications as well as to ensure the rights and safety of research subjects are protected.

### 5.10.1 – BIMO Establishment Type Definitions

**Clinical Investigator** – A person who conducts a research study (i.e., recruits study subjects, administers the investigational product to humans or animal subjects or uses a device on subjects, prepares and maintains case history reports, etc.).

**Contract Research Organization (CRO)** – An entity employed or contracted by sponsors or CROs to oversee the progress of an investigation. A monitor is not a regulated entity unless they have assumed one or more obligations from the sponsor in writing. In such case, the monitor is regulated as a contract research organization.

**Institutional Review Board** – Also known as Institutional Review Committee for Human Studies and Ethics Committee internationally. An IRB reviews protocols for studies and evaluates informed consent documents and risk/benefit decisions made regarding study procedures. An IRB may or may not be affiliated with an institution such as a hospital.

**In Vivo Bioequivalence/Bioanalytical Clinical Site** – A facility or individual involved in the screening and/or dosing of human subjects for obtaining biological specimens (e.g., blood, saliva, urine, feces) for analysis of investigational product content to define absorption, distribution, metabolism and/or elimination characteristics of the investigational product or to establish its equivalency with a defined standard.

**In Vivo Bioequivalence/Bioanalytical Analytical Site** – A laboratory involved in the analytical testing of human biological specimens for levels of investigational product content or the in vitro testing of investigational products to establish equivalency with a defined standard. These facilities may be integrated with or separate from clinical sites obtaining human specimens.

**Nonclinical Laboratory** – A laboratory that conducts in vivo or in vitro experiments in which investigational products are studied prospectively in test systems under

laboratory conditions to determine their safety. Nonclinical studies do not include studies utilizing human subjects or clinical studies or field trials in animals. Nonclinical studies also do not include basic exploratory studies carried out to determine whether an investigational product has any potential utility or to determine physical or chemical characteristics of an investigational product.

**Sponsor** – A person or establishment that initiates, supports and usually monitors an investigational study on FDA regulated products, but who does not actually conduct the study.

**Sponsor-Investigator** – A clinical investigator who is also responsible for initiating an investigational study. This person has the responsibilities of both a sponsor and a clinical investigator.

**Postmarket Adverse Drug Experience (PADE)** – PADE inspections are conducted at pharmaceutical establishments, which may be the manufacturing site, but most often are at a corporate headquarters facility. The inspection is conducted where the complaint handling unit/department responsible for evaluating and reporting adverse drug events is located. The purpose of the inspection is to ascertain whether the firm is complying with the evaluation and reporting requirements.

**Risk Evaluation and Mitigation Strategies (REMS)** - A (REMS) is a required risk management plan that uses tools, as specified in Food and Drug Administration Amendments Act of 2007 (FDAAA), beyond routine professional labeling (the package insert) necessary to ensure that the benefits of a drug outweigh its risks. The purpose of a REMS inspection is to verify the REMS is implemented and functioning in accordance with the FDA approved REMS and to verify information in the REMS assessment report.

**Radioactive Drug Research Committee (RDRC)** – An Institutional Review Board subcommittee or branch, which is FDA approved, who reviews and approves certain research uses of radioactive drugs that are generally recognized as safe and effective (GRASE.)

### 5.10.2 – BIMO Assignments

Assignments are issued by the product centers to ORA. These assignments are primarily issued to conduct inspections of entities engaged in nonclinical or clinical research and were involved in studies submitted as part of an application for approval of new product. Typically, inspections are conducted well after a nonclinical or clinical study has been completed. Inspections may also be conducted of on-going research. Assignments may also be issued for-cause for allegations for potential noncompliance and to conduct investigations and sample collections.

Each assignment will identify the establishment type to be inspected. In BIMO, the Compliance Programs are based

upon the establishment type to be inspected and provide instruction on what to cover during the inspection. The areas of coverage relate to the specific regulatory requirements of each establishment type.

Assignments are prepared by each center using a template that was harmonized across all centers for the BIMO program. The assignment memo will identify the type of establishment to be inspected, the Compliance Program, the Program Assignment Code, background information, general instructions and any special instructions for inspectional coverage. Assignments are issued to ORA HQ, reviewed and assigned to the appropriate division. Assignments are received by the Director, Investigations Branch and then disseminated to the appropriate supervisory group for assignment to an investigator.

Occasionally, center personnel will participate in inspections with field investigators. Center personnel are subject matter experts on the products or processes which are the focus of the nonclinical or clinical research. In these cases, the ORA investigator will be the lead investigator. See IOM 5.1.2.5 – Team Inspections.

Assignments in BIMO will usually have background materials, which will be available to you via a link to Enterprise Content Management Server/System (ECMS). Background materials may include the protocol for the study you are assigned to inspect, certain line listing of data included in the application such as reported adverse events and measurements taken during the study, and the assignment memo. If there are specific areas to focus on during the inspection, the assignment memo will discuss these areas and there may be specific data included in the background materials for you to verify during your inspection.

Centers have final classification authority for inspections in the BIMO program. When inspections are completed and the EIR reviewed by your supervisor, an initial inspection classification will be assigned through eNSpect. The centers will determine and assign the final classification for the inspection after their review of the EIR and evidence collected is completed.

#### 5.10.2.1. READ-ONLY ACCESS TO ELECTRONIC DATABASES DURING BIORESEARCH MONITORING INSPECTION ASSIGNMENTS

As the conduct of clinical and non-clinical trials increasingly moves toward 100% electronic data capture, to include electronic case report forms, medical records, patient-reported outcomes, informed consent systems and other electronic study records, it has become necessary for bioresearch monitoring investigators to have access to these electronic systems and databases in order to successfully perform inspections. Overseeing the firm's personnel while they access their system is not always

practical in BIMO inspections, as this can result in the firm having to dedicate an individual to this task.

For these reasons, if all the following criteria are met, bioresearch monitoring investigators are permitted to access a firm's records via a read-only account, dummy terminal or comparable mechanism when necessary:

1. Responsible management at the firm is agreeable to allowing read-only access to electronic systems and/or databases;
2. Access to electronic systems/databases is read-only and will not permit you to change or alter data or programming in any manner;
3. You obtain written program supervisory approval to gain read-only access to the firm's electronic systems/databases in advance of doing so;
4. The firm has a representative that will be available to initially describe and review the layout of their records, and make themselves available throughout the inspection as additional information or copies of records are needed; and
5. You document this read-only access in your establishment inspection report or investigational memorandum accordingly.

While you may complete a form needed by the firm in order to obtain read-only access, such as an account request form, you will not sign such form as per section 5.1.2.3. You may acknowledge via email that you have completed any required training necessary for access.

### 5.10.3 – BIMO Compliance Programs

BIMO Compliance Programs are posted on the internet at:

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-program-guidance-manual-cpgm/bioresearch-monitoring-program-bimo-compliance-programs>

Compliance Programs in BIMO are designed to focus on the establishment type as clinical and nonclinical research crosses all product areas.

7348.003 In Vivo Bioavailability-Bioequivalence Studies–Clinical

7348.004 In Vivo Bioavailability-Bioequivalence Studies–Analytical

7348.808 Good Laboratory Practice (Nonclinical Laboratories)

7348.808A Good Laboratory Practice Program (Nonclinical Laboratories) EPA Data Audit Inspections

7348.809 Institutional Review Board

7348.809A Radioactive Drug Research Committee

7348.810 Sponsors, Contract Research Organizations, and Monitors

7348.811 Clinical Investigators and Sponsor- Investigators

7353.001 Postmarketing Adverse Drug Experience (PADE) Reporting Inspections

7353.001C Risk Evaluation and Mitigation Strategies (REMS) Reporting Inspections

### 5.10.4 – Postmarket Adverse Event Reporting

FD&C Act section 760 [21 U.S.C. 379aa] and 21 CFR sections 310.305, 314.80, 314.98, 314.540, and 329.100 require reporting of adverse events associated with the use of human drug products and section 600.80 requires reporting of adverse events associated with the use of biological products (including therapeutic biological products). Responsible firms include holders of applications (NDAs, ANDAs, or BLAs) and manufacturers, packers and distributors that are named on the labels of all FDA approved drug products, all prescription drug products, and OTC monograph drug products. Both foreign and domestic firms are required to develop written procedures and to maintain records related to adverse events. Firms must evaluate adverse event data to determine if the event has had a serious outcome such as death, disability, hospitalization, or was a life-threatening event, and if the event was expected (labeled) or unexpected (unlabeled) for the product. Responsible firms must submit adverse event information to FDA in expedited or periodic reports in an electronic format as described in the regulations. Adverse event information submitted to FDA should be complete and accurate based on the data received.

Refer to the Compliance Program Guidance Manual (CP) (section 7353.001) for the description of the program and for detailed instructions for conducting inspections.

### 5.10.5 - Risk Evaluation and Mitigation Strategies (REMS)

FD&C Act Section 505-1 [21 U.S.C. 355-1] gives the FDA the authority to require Risk Evaluation and Mitigation Strategies (REMS) for certain drugs to ensure that the benefits outweigh the risks. REMS are required risk management plans that use risk minimization strategies beyond the professional labeling to ensure benefits of certain prescription drugs outweigh their risks. An applicant may be required to establish a REMS as part of the approval process (or when new safety data for an approved product arises), and an inspection will focus on the applicant's adherence to the REMS. Each REMS is unique, can be used for a single drug or class of drugs, and may include one or more of the following: a medication guide, communication plan, elements to assure safe use (ETASU), or implementation plan. REMS must also include a timetable for submission of assessments.

REMS are subject to inspection and are enforceable under section 505 (o) of the FD&C Act as amended by FDAAA.

REMS inspections are conducted to verify that the REMS is implemented and functioning according to the FDA approved REMS document and to verify the information provided to FDA in the REMS assessment report. Since every REMS program varies, the detailed instructions for conducting inspections will be given to the investigator prior to each inspection.

### 5.10.6 BIMO Establishment Inspection Reports (EIRs)

In general, refer to IOM 5.11 for reporting requirements following BIMO inspections with a few exceptions as follows. The Summary of Findings format is not to be used for BIMO EIRs.

The BIMO EIR will utilize the Standard Narrative Report format but must also include content required by compliance programs and specific assignment instructions. This content should be included by adding the headings that are listed in the compliance program, e.g., Authority and Administration, Protocol, Institutional Review Board, Subjects' Records, etc. for a clinical investigator inspection.

There are a few section headings that may be deleted as they are not generally applicable to BIMO inspections. If you are creating your report within eNSpect and the system does not allow you to delete the heading, simply insert "N/A" within that section of the report. Headings that may be deleted for BIMO EIRs include: Manufacturing/Design Operations, Manufacturing Codes (may be applicable for Bioequivalence), and Recall Procedures. All other headings should be included. If they do not apply to your inspection (e.g., Sample Collection, Refusals), simply insert "N/A" into that section.

### 5.10.7 BIMO Affidavits

Affidavits will be obtained in accordance with IOM 4.4.8. In the BIMO program, affidavits (FDA 463a) will generally be obtained to document violative conditions or unusual circumstances observed during an inspection. Additionally, an affidavit will accompany all sample collection reports, whether or not the firm provides a statement on company letterhead attesting that the test and reference product reserve samples are representative of those used in inspected BA/BE studies, and that they were stored under conditions specified in accompanying records, e.g. protocol or labeling. This is because all bioequivalence samples are official samples, and as such must be accompanied by an affidavit.

## 5.10.8 BIMO Collection Reports (CRs)

Samples collected under the BIMO program primarily include bioequivalence samples. Refer to IOM 4.4.10 for reporting these sample collections. All subs collected for a bioequivalence sample including investigational product, reference, and placebo, will be included on one collection report. A scanned copy of the collection report and all associated documents will be uploaded into eNSpect as an attachment to the EIR.

Additional instructions specific to certain fields on BIMO CRs are as follows:

### 5.10.8.1 Sample Type

The sample type for all bioequivalence samples will be "Official". Select "Domestic-Import" if applicable. Note: Domestic-Import samples are also Official, however, this is the way the drop-down menu is set up.

### 5.10.8.2 Sample Description

Ensure that the field includes a description of the investigational product collected as well as the reference and placebo if applicable.

### 5.10.8.3 Reason for Collection

Reference the compliance program (e.g., CP 7348.003, "In vivo Bioavailability- Bioequivalence Studies- Clinical", the assignment memo, and the inspection dates (if applicable). There will not be a suspected violation for surveillance samples. Add the following statement and edit as appropriate, "Sample of bioequivalence investigational product, reference control and placebo. Sample is representative of test product used in study supporting Protocol (insert Study #)." You will specify the analysis desired as follows: "Collected for drug assay analysis." Include the application number, e.g., ANDA 12345.

### 5.10.8.4 Associated Firms

List all firms related to the investigational product. Associated firms for the reference and placebo can be listed in the Collection Remarks field or on a continuation sheet.

### 5.10.8.5 Product Code and Product Name

The product code and product name listed should be that of the test article.

**5.10.8.6 Brand Name**

List the brand names for the test article, reference and placebo (if applicable.)

**5.10.8.7 Product Label**

Quote the label and labeling from the test article, reference and placebo (if applicable.) Be sure to use Collection Remarks or a continuation if necessary and specify which labeling goes to which product.

**5.10.8.8 Sample Flags**

There should be no sample flags for bioequivalence samples, unless the sample is a complaint sample. This is rare.

**5.10.8.9 Estimated Value**

It may be difficult to estimate the value of a bioequivalence sample. If the firm is not able to provide you with the value of the lot remaining after sampling, use the estimated cost of the innovator if possible. If you cannot estimate, leave blank and note in the Collection Remarks, "Estimated Value is unknown."

**5.10.8.10 CR & Records Sent To FACTS Org**

For domestic CRs, select your division from the list of values and send the hard copy CR and all associated documents to the director of investigations for your division when complete. For samples collected on foreign inspections, select the appropriate center/division (e.g. CDER-CP for bioequivalence samples) from the drop-down menu and send the hard copy CR and all associated documents to the center/division office contact specified in the assignment memorandum.

**SUBCHAPTER 5.11 – REPORTING**

Following an inspection, you are required to prepare a report of your findings. Reporting includes the data and summary entered using eNSpect, a narrative report, attachments and exhibits. As soon as practical you have access to eNSpect after the close of an inspection, ensure the start and end date are entered. Investigators must select a suggested "Inspection Conclusion" in eNSpect for each process covered.

Reports must be completed within time frames commensurate with the inspection classification, the current regulatory action time frames for the anticipated regulatory action, applicable FMDs, SOPs, RPM and/or the assignment deadline, if any.

Your narrative report should be prepared to accurately and concisely communicate the findings of your inspection and be adequate for its intended use. For example, an inspection of a new firm, one that FDA has not inspected previously, should be a comprehensive inspection focused on assessing the firm's compliance with applicable regulations. The resulting report would detail the products manufactured, the processes used to manufacture those products, the conditions of the environment in which products are manufactured or stored, any violations observed, persons responsible for the firm's operations, their actual duties and their responsibility for observed violations, distribution practices, and so on, providing information responsive to each of the required elements.

For establishments that have been previously inspected, you should determine what changes in operations and responsible individuals have occurred since the previous inspection, detail those changes in the narrative report and report on the areas of concern for the current inspectional outcome. For example, a non-violative inspection may only require a Summary of Findings report with the information required in the Summary, Administrative Data, General Discussion with Management, Voluntary Corrections, Refusals, Samples Collected, Exhibits Collected and Attachments (see IOM 5.11.4.1).

An OAI follow-up inspection that reveals continuing violations supporting a regulatory action would require the Summary, Administrative Data, Individual Responsibility and Persons Interviewed, Objectionable Conditions and Management's Response, Supporting Evidence and Relevance, Discussion with Management, Exhibits Collected, Attachments, and if appropriate, Refusals, Samples Collected, and Voluntary Corrections. Additionally, any information related to changes in previous operations would also need to be included in this type of report.

The key for you to remember in writing your narrative report is to communicate the findings of your inspection so that others may take the appropriate action. Notice that the required elements always include the product, interstate commerce, the violations observed and responsibility of firm officials. This is to document the elements of proof – Jurisdiction, Interstate Commerce, Violation and Responsibility (JIVR). Write your EIR with the intended use in mind. Your report may be a brief summary of an inspection of a firm in a state of compliance with applicable regulations all the way to a firm where the agency must take regulatory action to correct deficiencies.

**5.11.1 - ESTABLISHMENT INSPECTION REPORT (EIR)**

See IOM 1.1 English language requirement. The EIR consists of the following: the eNSpect Establishment Inspection Report, investigator's narrative report, attachments and exhibits. Regarding the use of checklists that are completed during the inspection (such as the BSE Checklist), the original checklist should be submitted with unlabeled attachments. If you maintain the data in your

regulatory notes, instead of entering the data directly on the checklist during the inspection, then a copy of the checklist that was completed using the data from your regulatory notes should be included with the EIR. The signed original report is maintained electronically and is available in OSAR.

See IOM 5.10.6 for additional requirement for Bioresearch Monitoring EIRs.

See SOP-000063 "Submission and Processing of International Food Inspection and Investigation Reports" for additional information regarding the processing of foreign food reports.

### 5.11.2 – ENDORSEMENT

Supervisory Investigators evaluate inspection findings, determine the classification of the inspection, and recommend an action, in accordance with applicable compliance programs, assignments or policy. The final content of the endorsement of the establishment inspection report is determined by the supervisory investigator. However, Investigators should prepare proposed endorsement for their supervisor. Endorsements should fit in the available space provided in eNSpect, however, if the endorsement exceeds the character space provided in eNSpect, a separate endorsement should be prepared, fully identifying the firm with a summary of the endorsement included in eNSpect. The eNSpect endorsement field should identify that a separate endorsement has been prepared and uploaded to eNSpect. The eNSpect Record will be used as the endorsement and routing document to accompany the EIR. See also IOM 5.11.4.1.

Normally the endorsement consists of:

1. The reason for the inspection, i.e., workplan, or assignments from headquarters. State the subject of the assignment and reference.
2. A brief history of previous findings (e.g., FDA 483 observations, FDA 4056 observations, and discussion items) including classification of previous inspection, any action taken by the program division and/or corrective action taken by the firm in response to inspectional observations from the previous inspection.
3. A concise summary and evaluation of current findings and samples collected.
4. Refusals, voluntary corrections or promises made by the firm's management.
5. Identify FDA received consumer complaints covered during inspections and follow up disposition.
6. Classification and follow-up consistent with inspectional findings and in accordance with applicable compliance program, assignments, or policy. Action may include notification of other program divisions and headquarters as warranted.

7. Distribution consistent with program division policy and the requirements of the specific compliance programs and requirements as noted in IOM 1.7.3.

Note: When endorsing in eNSpect, include notification to the Division of Import Operations and Management (DIOM) when any violative, imported products are identified.

Note: In rare situations (e.g., extended leave, retirement, deployment) a participant may not be available to sign the EIR. The supervisor should state in the endorsement "endorser acknowledges the inability of the participant to sign the EIR due to unavoidable circumstances". (See section 5.11.4.3.21)

The existence of Personal Safety Alerts (IOM 5.2.1.3) or Personal Safety Plans (IOM 5.2.1.4) pertaining to the firm should be included in the endorsement section only and not in the EIR.

The signed endorsement should be updated to indicate if an amendment to the EIR (IOM 5.11.7) or an amended FDA 483 or and FDA 4056 (IOM 5.2.3.1.6.1 and 5.2.3.1.6.2) has occurred. **PROFILES:** Updating eNSpect with the Compliance Status for each profile class code associated with the firm's operations and/or products, is the responsibility of ORA Field and Center Investigators, Supervisors and Compliance Officers.

**See Exhibit 5-14 for more information on profiling CGMP/QS Compliance Status.**

#### 5.11.2.1 – Reporting Verified Corrective Actions

A compliance achievement, also known as a verified corrective action, is the observed repair, modification, or adjustment of a violative condition, or the repair, modification, adjustment, relabeling, or destruction of a violative product when either the product or condition does not comply with the Acts enforced by the FDA.

Both FACTS and eNSpect are used to report verified corrective actions, which are not the result of legal action. When you are unable to enter the action in eNSpect because the PAC is not available or the 483 was issued outside of eNSpect, investigator should enter corrective actions into FACTS CARS as directed in 5.11.2.1.1.

The supervisor may enter the correction if the investigator is unavailable.

##### 5.11.2.1.1 - REPORTING CRITERIA

There are three criteria for reporting into the FACTS CARS system:

1. The detection or identification of the problem. A problem may be observed by FDA, other federal officials, or by state or local authorities and referred to FDA; and as a result of an inspection, investigation, sample analysis, or detention accomplished by ORA or states under contract to ORA.



2. The correction of the problem. The correction is directly attributable to the efforts of ORA or state officials under contract to ORA (involving contract products only); and is unrelated to the filing of a legal action, i.e., seizure, prosecution, injunction.
3. The verification of the correction of the problem. The correction is verified by the FDA, other federal officials or state or local authorities and reported in writing to the FDA; and is based on an inspection, investigation, sample analysis, or letter from a firm to FDA certifying the problem has been corrected.

### 5.11.2.1.2 - DATA ELEMENTS

For instruction on entering corrective actions in eNSpect refer to the [user manual](#).

For instruction on entering corrective actions in FACTS see Exhibit 5-15.

Only when the corrective action(s) has been verified should a FACTS CARS be reported. The data elements are those entered/coded in FACTS (See IOM Exhibit 5-15):

1. PAC. Should there be insufficient space to code all corrections verified on an occasion, record the most significant corrections.
2. PROBLEM TYPE. The problem type is the problem(s) identified during the operation(s). Use the List of Values (LOV) found in this field on the Compliance Achievement Reporting Screen. If "Other" is chosen, you should include an explanation in the "Remarks" field.
3. CORRECTIVE ACTION. The action the establishment took to correct the identified problem. Use the LOVs found in this field on the CARS screen. If "Other" is selected, you should include an explanation in the "Remarks" field.
4. VERIFICATION DATE. Use the date the corrective action(s) is verified, either through an establishment inspection, an investigation, or a letter from the establishment certifying the corrections have been made. Include documentation to verify the action such as repair receipts/plans.
5. CORRECTING ORGANIZATION. The FDA, other federal agency, or state or local authority, which observed the verified correction. Use the LOVs found in this field on the CARS screen.
6. REPORTING ORGANIZATION. The FDA, other federal agency, or state or local authority, which is actually inputting the verified correction. Use the LOVs found in this field on the CARS screen.
7. REASON FOR CORRECTION. The action the FDA took to make the correction happen. Use the LOVs found in this field on the CARS screen. If "Other" is chosen, you should include an explanation in the "Remarks" field.

### 5.11.3 – eNSpect ESTABLISHMENT INSPECTION REPORT COVERSHEET

Per SOP-000051, each ORA Program Division and HQ Office is responsible to ensure all investigators verify,

correct, and enter changes to the OEI (including Profile data for profilable firms) on the firm's maintenance screens in eNSpect during each inspection, investigation and during any OEI update. Consult with your supervisor and your OEI Coordinator to assure data is accurately updated.

Inspectional accountable time reported into eNSpect consists of the hours devoted to file reviews (operational preparation), actual onsite inspectional time, document preparation (attachments and exhibits) and EIR (narrative) write-up. Accountable time does not include travel time. One occasional exception could be when more than one participant prepares and discusses the assignment while they are traveling together.

You should report the actual amount of inspection accountable time it took you. Do not report the module time given in the ORA Workplan. Additional time required to complete the assignment due to giving or receiving training should be reported separately from inspectional time.

#### 5.11.3.1 – Inspection Basis

The inspection basis is the underlying reason for conducting an inspection.

**Compliance** – A directed inspection to evaluate potential violative situations that the agency has become aware of at the firm or industry and have not already resulted in an official agency action. These may include complaints (trade or consumer) which are not the primary reason for the inspection, recalls not classified as Class I, MedWatch Reports, Adverse Drug Experience Reports, information from confidential informants, etc.

**Consumer Complaint** – A directed inspection in which the primary purpose is to follow up on a consumer complaint. When a consumer complaint is received, and the follow-up action chosen is to conduct an inspection to confirm allegations within the complaint or root causes that may have led to the condition described in the complaint, this value should be selected.

**F/U to Class I Recall** – A directed inspection in response to a Class I Recall conducted by the establishment. The inspection is conducted to determine the root cause and corrective actions addressing the violation(s) associated with the product.

**F/U to Class I Recall and F/U to Injunction** – A directed inspection conducted in response to a Class I Recall conducted by the establishment AND pursuant to Permanent Injunction and in accordance with the Consent Decree. In this instance, a firm under permanent injunction has conducted a Class I Recall and the inspection is conducted to determine the root cause and corrective actions addressing the violation(s) associated with the product. Additionally, the inspection covers the requirements of the Consent Decree for the Injunction.

**F/U to Class I Recall and F/U to Warning Letter** – A directed inspection conducted in response to a Class I

Recall conducted by the establishment AND to follow up on issues cited in a Warning Letter issued to the establishment. In this instance, a firm that has received a Warning Letter has conducted a Class I Recall and the inspection is conducted to determine the root cause and corrective actions addressing the violation(s) associated with the product in addition to covering corrective actions responsive to the violations cited in the Warning Letter. The Warning Letter may have issued as a result of the previous inspection or other circumstance.

**F/U to Class I Recall and OAI Inspection F/U** – A directed inspection conducted in response to a Class I Recall conducted by the establishment AND to follow up to a previous OAI-classified inspection, where a regulatory or administrative action has not been completed. This value captures the situation where the previous inspection of the firm was classified OAI, but no official action was taken, and the firm has conducted a Class I Recall. The inspection is focused on the root causes of the violations leading to the recall and may also address previously cited violations. Before conducting an inspection of a firm where the previous inspection was classified OAI with no regulatory action taken, be sure to discuss what areas to cover with your supervisor and/or compliance officer.

**F/U to Injunction** – An inspection conducted pursuant to Permanent Injunction and in accordance with the Consent Decree.

**F/U to Warning Letter** – An inspection conducted to follow up on issues cited in a Warning Letter issued to the establishment. This inspection is focused on the firm's actions to resolve issues cited in the Warning Letter.

**OAI Inspection F/U** – An inspection conducted to follow-up previous OAI-classified inspection where a regulatory or administrative action has not been completed. There can be a number of situations where an action is not taken although the observations cited during the previous inspection met the threshold for an OAI classification. Consult your supervisor and/or compliance officer prior to initiating these types of inspections.

**Surveillance** – An inspection conducted as a routine assignment with no other indicators of non-compliance. For example, an inspection of a firm whose previous inspection was classified NAI; there have not been any complaints or recalls, etc.

#### 5.11.4 - NARRATIVE REPORT

See IOM 1.1, English language requirement. You should use eNSpect for all EIRs. The narrative report is the written portion of the EIR, which accurately describes the investigator's inspectional findings. The narrative report may be prepared in two formats depending on the type of inspection and inspection classification. A Summary of Findings narrative report may be used for NAI and VAI classified, non-initial inspections (IOM 5.11.4.1 and IOM 5.11.4.2), or as directed by your supervisor. The full Standard narrative report is used for initial and potential Official Action Indicated (OAI) classified inspections (IOM 5.11.4.3.1). Additional requirements for human drug and

medical device establishment inspection reports are described in IOM 5.5.8 and 5.6.9. For all reporting formats, include additional information as directed by your assignment, Compliance Program Guidance Manual, or your Supervisor.

EIRs populated in eNSpect should automatically include the firm name and FEI. Those populated outside of eNSpect should include the firm name, FEI in the header and the footer should include the page number.

All reports should be prepared or uploaded into eNSpect.

Your Establishment Inspection Report (EIR) should:

1. Be factual, objective, and free of unsupportable conclusions.
2. Be concise and descriptive while covering the necessary aspects of the inspection.
3. Not include opinions about administrative or regulatory follow-up.
4. Not include information that could identify confidential or anonymous informants (See IOM 5.2.9.2)
5. Generally, be written in the first person using the active voice.
6. Be signed by all FDA and commissioned personnel participating in the inspection. See IOM section 5.1.2.5.1 when more than one FDA or commissioned person participated in the inspection.

Refer to [IOM 5.11.7](#) for an Amendment to EIR.

#### 5.11.4.1 – Summary of Findings report for NAI Inspections

Investigators should use "Summary of Findings", stand-alone, narrative reports for NAI domestic establishments, unless otherwise directed by your supervisor, the assignment or the Compliance Program Guidance Manual. Use the report format given in 5.11.4.3.1- Standard Narrative Report, Comprehensive Reports- for all foreign inspections.

The Summary of Findings Report may not be written solely in the eNSpect provided "Inspection Summary" heading. The Summary of Findings report should include:

1. The reason for the inspection;
2. The date, classification and findings of the previous inspection;
3. The actual inclusive dates of the inspection (these may be included as part of a header or in the body of the EIR.)
4. Report the current registration(s) status or any changes to registration status. Per CPG section 110.300, do not report the FURLS Registration number.
5. The name of the person to whom credentials were shown and the FDA-482, Notice of Inspection or FDA 482d Request for FSVP Records was issued and the person's authority to receive the FDA 482 or FDA 482d. Explain if you were unable to show credentials or issue forms to top management. Include

the name of the person to whom the FMD-145 correspondence should be directed to and their email address. If an email address does not exist for this person, then this should be noted.

6. The inspectional approach (comprehensive or directed); the scope of the inspection; a brief description of the business; a description of the products produced; and a brief description of the products, processes or systems covered during the inspection. Indicate which aspects of the firm's processes or systems you observed versus those which the firm described to you;
7. The manufacturing codes and if necessary their interpretation.
8. Significant changes (e.g., personnel, facilities, products, processes) since the previous inspection;
9. Voluntary Corrections
10. Samples collected
11. Exhibits collected;
12. Attachments
13. The investigator's signature.

**5.11.4.2 – Summary of Findings for VAI Inspection**

Investigators should use "Summary of Findings", standalone, narrative reports for VAI domestic establishments, unless otherwise directed by your supervisor, the assignment or the Compliance Program Guidance Manual. Use the report format given in 5.11.4.3.1 - Standard Narrative Report, Comprehensive Reports for foreign inspections.

All violative EIR's should in addition to the information required for non-violative reports contain the following:

1. The objectionable conditions or practices described in sufficient detail so someone reading the report will clearly understand the observation(s) and significance.
2. The objectionable conditions or practices cross-referenced to FDA 483 or FDA 4056 citations, samples collected, photographs, or other documentation including exhibits attached to the EIR.
3. Information as to when the objectionable conditions or practices occurred, why they occurred, and who is or was responsible, developed to the highest level in the firm.

**5.11.4.3 - Individual Narrative Headings**

There are many acceptable ways of organizing a narrative report. The key is to cover the required information in IOM 5.11.4, 5.11.4.1 and 5.11.4.2, or as required by the assignment, Compliance Program Guidance Manual, or your supervisor. The appropriate use of headings should not result in repetition of the same information in different sections. You are encouraged to create headings as necessary to present the inspectional findings in the most concise manner. For NAI and VAI classified inspections, a single heading such as "Summary of Findings" is sufficient (for exceptions, see IOM 5.11.4.1 and 5.11.4.2). eNSpect should be used to generate the FDA 483, FDA 483a, and FDA 4056. In certain instances, if you experience computer

problems, do not delay the issuance of the FDA 483, FDA 483a, or FDA 4056. See IOM 5.2.3. You should use eNSpect for all EIRs.

**5.11.4.3.1 - STANDARD NARRATIVE REPORT**

This is intended to outline the minimal information needed to produce a narrative report that supports further agency regulatory action, as warranted. Investigators are encouraged to add additional report headings as needed to communicate important information about the inspection, relevance of inspectional observations that may impact public health, and /or to address specific requests from directed assignments.

**Comprehensive Reports (Include all applicable sections)**

A comprehensive EIR should be prepared for initial inspections as well as foreign inspections in all program areas. It is essential to describe the products manufactured, the process the manufacturing and storage environment, distribution patterns/interstate commerce, individual responsibility of key employees, history of business, all objectionable conditions observed, etc. All things pertinent to the operations and management of the establishment should be included in these reports. The comprehensive report may also be used for other situations requiring full reporting such as Routine Surveillance - OAI. An abbreviated inspection does not necessarily equate to an abbreviated report.

Required elements

- 5.11.4.3.2 – Summary
- 5.11.4.3.3 – Administrative data
- 5.11.4.3.4 – History
- 5.11.4.3.5 – Interstate (I.S.) Commerce
- 5.11.4.3.6 – Jurisdiction (Products Manufactured and/or Distributed)
- 5.11.4.3.7 – Individual Responsibility and Persons Interviewed
- 5.11.4.3.8 – Firm's Training Program
- 5.11.4.3.9 – Manufacturing/Design Operations
- 5.11.4.3.10 – Manufacturing Codes
- 5.11.4.3.11 – Complaints
- 5.11.4.3.12 – Recall Procedures
- 5.11.4.3.13 – Objectionable Conditions and Management's Response
- 5.11.4.3.13.1 – Supporting Evidence and Relevance
- 5.11.4.3.13.2 - Discussion with Management
- 5.11.4.3.14 – Refusals
- 5.11.4.3.15 – General Discussion with Management
- 5.11.4.3.16 – Additional Information
- 5.11.4.3.17 – Samples Collected
- 5.11.4.3.18 – Voluntary Corrections
- 5.11.4.3.19 – Exhibits Collected
- 5.11.4.3.20 – Attachments

### Routine Surveillance – NAI Reports

When FDA has an inspectional history for the firm and no deficiencies were observed by the investigator, a brief report may be prepared. The intent of this report is to include only the required information about the firm and what areas were covered during the inspection. “Change reporting” means information that differs from the previous inspection report such as changes in management, products produced, manufacturing processes, etc. Where these changes have occurred, the applicable section heading in the EIR should be included. The elements may also be captured in a “Summary of Findings Only” report without header information. See IOM 5.11.4.1.

#### Required elements

- 5.11.4.3.2 – Summary
- 5.11.4.3.3 – Administrative data
- 5.11.4.3.10 – Manufacturing Codes
- 5.11.4.3.14 – Refusals
- 5.11.4.3.15 – General Discussion with Management
- 5.11.4.3.17 – Samples Collected
- 5.11.4.3.18 – Voluntary Corrections
- 5.11.4.3.19 – Exhibits Collected
- 5.11.4.3.20 – Attachments

#### Change reporting only

- 5.11.4.3.4 – History
- 5.11.4.3.6 – Jurisdiction (Products Manufactured and/or Distributed)
- 5.11.4.3.7 – Individual Responsibility and Persons Interviewed
- 5.11.4.3.8 – Firm’s Training Program
- 5.11.4.3.9 – Manufacturing/Design Operations

### Routine Surveillance – VAI Reports

For firms with an inspectional history and the outcome of the inspection is a VAI classification, the below elements would be required, plus change reporting. Note that the difference in the NAI versus the VAI report is the inclusion of narrative addressing objectionable conditions observed during the inspection. Each objectionable condition or practice must be documented in the EIR along with discussion of the evidence, relevance and discussion with management.

#### Required elements

- 5.11.4.3.2 – Summary
- 5.11.4.3.3 – Administrative data
- 5.11.4.3.10 – Manufacturing Codes
- 5.11.4.3.13 – Objectionable Conditions and Management’s Response
- 5.11.4.3.13.1 – Supporting Evidence and Relevance

- 5.11.4.3.13.2 - Discussion with Management
- 5.11.4.3.14 – Refusals
- 5.11.4.3.15 – General Discussion with Management
- 5.11.4.3.17 – Samples Collected
- 5.11.4.3.18 – Voluntary Corrections
- 5.11.4.3.19 – Exhibits Collected
- 5.11.4.3.20 – Attachments

#### Change reporting only

- 5.11.4.3.4 – History
- 5.11.4.3.6 – Jurisdiction (Products Manufactured and/or Distributed)
- 5.11.4.3.7 – Individual Responsibility and Persons Interviewed
- 5.11.4.3.8 – Firm’s Training Program
- 5.11.4.3.9 – Manufacturing/Design Operations

### Routine Surveillance – OAI

For an OAI surveillance inspection, follow the guidance under Comprehensive Reports.

### OAI Follow-up Inspection Reports

OAI follow-up inspections are inspections conducted following an OAI classified inspection. Inspections of this nature are conducted to determine whether corrective actions have been implemented or significant violations continue. The outcome of these inspections may range from NAI to OAI. The intended use of the EIR should be the driving force of the content of these EIRs. Typically, the follow-up should be done relatively soon after the previous inspection, so changes to products, process, personnel, etc. should be minimal. The NAI and VAI reports should focus on corrective actions implemented by firm management to correct the violative conditions observed during the previous OAI inspection. Those reports may be Summary of Findings only or may follow the other NAI and VAI report formats above. An OAI follow-up inspection may lead to a regulatory action such as seizure, injunction and/or prosecution. Those reports should focus on documenting the continuing violations, responsibility for those violations, any corrective actions implemented or inadequate corrective actions and defining the new scope of violations observed including the products affected. Scope should include additional lots, products, timeframe and distribution. These reports should document all elements of JIVR (Jurisdiction, Interstate Commerce, Violation and Responsibility). This allows for the report to support whatever regulatory action is deemed necessary.

#### Required elements

- 5.11.4.3.2 – Summary
- 5.11.4.3.3 – Administrative data

- 5.11.4.3.7 – Individual Responsibility and Persons Interviewed
- 5.11.4.3.10 – Manufacturing Codes
- 5.11.4.3.13 – Objectionable Conditions and Management’s Response
- 5.11.4.3.13.1 – Supporting Evidence and Relevance
- 5.11.4.3.13.2 - Discussion with Management
- 5.11.4.3.14 – Refusals
- 5.11.4.3.15 – General Discussion with Management
- 5.11.4.3.17 – Samples Collected
- 5.11.4.3.18 – Voluntary Corrections
- 5.11.4.3.19 – Exhibits Collected
- 5.11.4.3.20 – Attachments

#### Change Reporting Only:

- 5.11.4.3.5 – Interstate (I.S.) Commerce
- 5.11.4.3.6 – Jurisdiction (Products Manufactured and/or Distributed)
- 5.11.4.3.9 – Manufacturing/Design Operations
- 5.11.4.3.11 – Complaints

### 5.11.4.3.2 - SUMMARY

1. Provide the reason for the inspection including if it was announced or unannounced (e.g., compliance program(s), by assignment number, trip number, etc.);
2. The inspectional approach (comprehensive or directed); the scope of the inspection; a brief description of the business; a description of processes used, and the products produced.
3. Provide a summary of the findings, date, and classification of the previous inspection and the firm’s response/corrective actions.
4. List the products, profile, systems and processes covered during the current inspection, and the types of records and documents reviewed. For human drug reports, list all systems the firm has currently employed.
5. Provide a summary of the current findings (i.e., reportable observations, nonreportable observations, and discussion items), refusals, samples collected, warnings given to management, and a summary of management’s response or voluntary corrections.

### 5.11.4.3.3 - ADMINISTRATIVE DATA

1. The firm name, address, phone, fax, website address, and e-mail address of the firm
2. Report the names and titles of the Investigator(s), Analyst(s), non-FDA officials, etc. Report the name of the firm’s responsible official who gave permission to non-FDA officials without inspection authority to accompany you during your inspection. See IOM 5.1.1 and 5.2.2.
3. The inclusive date(s) of the current inspection, i.e., list the actual dates in the plant.

4. If a team inspection and some individuals were not present during the entire inspection, indicate dates in plant for each team member.
5. For foreign inspections with Locally Engaged Staff (LES)/Foreign Service National (FSN) participation include this language:

This inspection was supported by \_\_\_\_\_ (during the period of \_\_\_\_\_), who is a Locally Engaged Staff (LES) hired by the United States Embassy and assigned to FDA to work in support of FDA activities. All information, including documents collected during this inspection and any translation from local language to English by \_\_\_\_\_(LES) that supports the Form FDA 483, Inspectional Observations (if Form FDA-483 was issued), FDA 483a FSVP Observations, Form FDA 4056, Produce Farm Inspectional Observations and the Establishment Inspection Report (EIR) was collected in collaboration with the FDA investigator(s).

#### Report:

1. Full names and titles to whom FDA Official Credentials were shown,
2. Full names and titles to whom **any** FDA forms were issued to or signed by during the inspection (FDA 482, 483, 484, 463, 4056, etc.); where appropriate, explain the reason a form(s) was not issued to or signed by the most responsible individual (this may be reported in the Individual Responsibility and Persons Interviewed heading below),
3. Full name, title, address (if different from the address of the inspected establishment), and email address of the top management official to whom the FMD 145 letter should be addressed. If an email address does not exist for this person, then this should be noted.
4. Full names, titles and addresses (if different from the address of the inspected establishment) of most responsible corporate official(s) to whom other correspondence, e.g., Warning letter, should be addressed
5. If this was a team inspection, who wrote which section of the EIR.
6. Full names and titles of inspectors from other government agencies (i.e. federal, state, local or foreign) at the facility during the inspection.
7. Full names and titles of who provided translation of foreign language documents.
8. If an inspection is conducted at premises also used for living quarters document that you are inspecting a residence and if the owner was agreeable. (IOM 5.1.1.9)
9. Full name and title of the individual provided with guidance documents and list the documents provided.

### 5.11.4.3.4 - HISTORY

1. Report the legal status of the firm (corporation, partnership, limited liability company, sole proprietorship, etc.), and the state and year of incorporation.
2. List the parent corporation, corporate address and relevant subsidiaries with respective FEIs.
3. Provide a summary of any agency actions and prior warnings (do not cite any action only recommended but not approved). You should also report any significant/relevant inspectional history pertinent to the current EI or recommendation.
4. Include any relevant recalls, market withdrawal, etc. since the last inspection.
5. Report the hours of operation and any changes from past inspections (include seasonal variations).
6. Report all current registration(s) status or any changes to registration status. Per [CPG section 110.300](#), do not report the FURLS Registration number.

#### 5.11.4.3.5 - INTERSTATE (I.S.) COMMERCE

1. Report the estimate of the percentage of products shipped outside of the state (or exported to the U.S.) and the basis of the estimate.
2. Report the firm's general distribution patterns.
3. If there is an apparent violative product, provide examples of interstate shipments of violative product(s); or
4. If no such shipments, provide examples of interstate shipments of major components of apparent violative products - with complete interstate documentation in either case.
5. For foreign inspections, list significant U.S. consignees to whom the firm's products are shipped.
6. For Human Drugs - domestic firms, identify the general types of customers and provide the names and addresses for several regular customers of a few of the firm's products.

#### 5.11.4.3.6 - JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

1. Include a list of a representative number of currently marketed products in all program areas subject to FD&C Act or other statute enforced by FDA or counterpart state agency, including any believed violative.
2. Collect appropriate labeling (product and case labels, inserts, brochures, manuals, promotional materials of any type) for those products believed violative or representing any significant new or unusual operation, industry or technology; or as directed by your supervisor.
3. Report the firm's general promotion patterns (i.e. website, advertisements, etc.).
4. Document any applicable labeling agreements (and obtain a copy) and statutory guaranty given or received per [Sections 301\(h\)](#) and [303\(c\)\(2\)](#) of the FD&C Act [21

U.S.C. 321 (h) and 333 (c)(2)] (IOM 5.3.7.2)

In addition, the label, labeling and promotional materials are a critical part of determining a product's intended use.

1. In instances where a regulatory action is being considered based on product labels, labeling, and/or other promotional materials, including any Internet websites, you should collect all available documentation. This includes all written, printed or graphic matter on the immediate container of an article or accompanying the article (the product's label and labeling, see [FD&C Act, 201\(k\)](#) and (m) [21 U.S.C. 321(k) and (m)] and IOM 4.4.9.1). Accompanying labeling could include brochures, pamphlets, circulars, and flyers, as well as audio and video tapes.
2. In cases where there may be a dispute about whether a product is a drug or a dietary supplement, you should collect all materials which claim a product can be used for the treatment of any disease.

#### 5.11.4.3.7 - INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Report with whom you dealt, and in what regard (both during and prior to the start of the inspection):

1. Who provided relevant information,
2. Who accompanied you during the inspection,
3. Who refused access to required records or any other refusal of information (Note: a separate heading for Refusals may be needed if refusals are significant, extensive or an Inspection Warrant is anticipated),
4. Who refused to permit inspection (IOM 5.2.5.1) and
5. For Human Drug inspection reports, also include the name, title, physical mailing address, phone, and fax number and e-mail address for any U.S. Agent or broker who represents the company when dealing with the FDA, and

Describe roles and authorities of responsible individuals, including the full names and titles of individuals providing you with information.

Describe roles, authorities and responsibilities of officials at headquarter or corporate organizations for this firm; including their names, titles and addresses.

Report changes to the following:

1. Who is the most responsible individual at the inspected firm? Who is the responsible head or designated correspondent? Refer to IOM 5.3.6, 5.3.6.1, and 5.3.6.2.
2. Report full names and titles of owners, partners, and corporate officers. Who has the duty, power and responsibility, and authority to prevent, detect, and correct violation(s), and how is this demonstrated and/or documented? See IOM 5.3.6.2.
3. Report the chain of command; include an organizational chart (create if necessary).
4. Obtain a copy of public annual report, if any.
5. List the names and titles of key operating personnel.

**5.11.4.3.8 - FIRM'S TRAINING PROGRAM**

Explain coverage of the firm's training program as stated in the applicable compliance program and/or as it correlates to the deficiencies observed during the inspection.

The firm's training programs are of particular significance where inspectional findings find people may not be adequately trained.

**5.11.4.3.9 - MANUFACTURING/DESIGN OPERATIONS**

1. Report only changes to the firm's general overall operations, including significant changes in equipment, processes, or products since the previous inspection. Include schematics, flow plans, photographs, formulations and diagrams, if useful.
2. List names and sources of new or unusual components or raw materials.
3. Report equipment considered new or unusual unless otherwise directed.
4. Submit pertinent formulas or batch manufacturing records (especially those being manufactured during your inspection) and processing instructions with labeling of suspect products.
5. Indicate which aspects of the firm's processes or systems you observed versus those which the firm described to you.

For human and animal food inspection reports, as applicable, include the following:

1. Describe the product(s) covered and include basic food information: finished product name, product description with packaging; pertinent ingredients, intended use and conditions of storage and distribution.
2. Describe the process flow (receiving through distribution) and a description of the process at each step.
3. For full scope preventive control or HACCP inspections describe the results of the hazard analysis and the adequacy and implementation of written programs.
4. Describe the firm's general sanitation procedures.
5. Describe any coverage of additional food safety regulations that apply to the product(s) inspected (e.g. LACF, infant formula, bottled water, etc.).

For human drug inspection reports:

This section of the EIR should be organized by system covered during the EI as outlined in CP 7356.002. In each section, include a brief summary of what you reviewed in order to meet the key system element outlined in the CP. You should add more detail for the system elements found to be deficient, or the subject of an FDA-483 observation.

For medical device inspection reports:

1. Describe manufacturing operations by sub system covered in your inspection (Management Controls, Design Controls, Production and Process Controls, Corrective and Preventive Action Controls, Material Controls, Facility and Equipment Controls, and Records/Documents/Change Controls). For ALL Level 2, 3, and "for cause" inspections: for production and process controls - indicate which production processes were covered/ reviewed. If a subsystem was not specifically covered during your EI, you do not need to separately describe the general operations of that subsystem.
2. For all inspections covering CAPA - indicate which data sources were available for review and which were actually reviewed; include a brief statement regarding coverage or non-coverage of applicable tracking requirements, MDRs, sterilization, and reports of corrections and removals.
3. If the Design Control system was covered, indicate the design project(s) covered during the inspection. Where design activities occur at a location other than the manufacturing site, list the name, address of the design location and responsibilities of those performing the design activities.
4. If applicable, identify the name and address of the specification developer if different from either the manufacturing site or where design activities occur.

**5.11.4.3.10 - MANUFACTURING CODES**

Describe the manufacturing coding system (lot, batch, product, etc.), and provide a key to interpretation of codes.

**For medical device inspections reports:** where appropriate, include a description of the system used to identify and maintain control of components during the manufacturing process, as well as, the codes used for traceability (for applicable finished devices).

**5.11.4.3.11 - COMPLAINTS**

Complaints include those reported to the FDA by consumers, health care professionals, industry, etc.; and all complaints received by the firm.

1. Report your review of the firm's complaint file(s).
2. In addition, if returned goods and/or documents for returned goods are examined, describe findings. If not examined, so indicate.
3. Report your follow-up of FDA received complaints including complaint number and action taken by the firm. Correlate consumer/trade complaints, Adverse Event Reports, MDR's, MedWatch reports to specific objectionable conditions observed.

### 5.11.4.3.12 - RECALL PROCEDURES

Describe plans and procedures for removing products from marketing channels if necessary. If these procedures are in written SOP-type format, you may reference any copies obtained to aid in your explanation.

### 5.11.4.3.13 - OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

If any observations were provided to management in writing (FDA 483, FDA 483a, or FDA 4056.) at the conclusion of the inspection list each observation and report each observation providing information organized under the two headings Supporting Evidence and Relevance, and Discussion with Management below.

**NOTE: Observations of a verbal nature (i.e., Discussion Items) should be reported in sufficient detail under the General Discussion with Management (correlate any Exhibits, samples, etc. to any "verbal" observations).**

#### 5.11.4.3.13.1 - Supporting Evidence and Relevance

Sufficiently describe the observation as necessary to relate the facts as you found them.

1. Identify specific pages of exhibits and/or samples (e.g., procedure title, section, paragraph, sentence), labeling text, interstate shipping records which in your judgment document violations so supervisors, compliance officers, and other reviewers can readily evaluate your evidence.
2. Describe verbal statements (verbatim if possible) by firm officials having knowledge, duty, power, and responsibility to detect, prevent, or correct the apparent violation.
3. Identify the responsible party for each apparent violation (i.e., if known.)
4. Identify which team member (if applicable) was responsible for the observation.
5. When appropriate explain how this observation relates to the overall situation; i.e., impact on the product, batches, or lots involved, and any relationship to other products, processes, or other FDA 483 or FDA 4056. observations.
6. The duration of the problem.

#### 5.11.4.3.13.2 - Discussion with Management

Discussion with management:

1. Report management's response to each specific observation, time frames given for corrections and/or corrective action.
2. Report any disagreements with or refusals to correct the observation.

For medical device inspection reports:

1. For each observation based on sampling of records, indicate which Sample Table and level of confidence was used and the actual number of records sampled.

2. If the number sampled is different than the actual number reviewed, so indicate.

### 5.11.4.3.14 - REFUSALS

Provide full details of all refusals of/for requested information, statutory information, photography, entry, etc. received during the inspection, including who made the refusal and, if available, why the refusal was given.

In the case of drug and medical device inspections, similarly provide full details of all instances of delaying, denying, limiting, or refusing an inspection encountered during the inspection.

### 5.11.4.3.15 - GENERAL DISCUSSION WITH MANAGEMENT

General Discussion with Management:

1. Report the names and titles of all present, including those present via electronic media (describe).
2. Include the name and title to whom the FDA 483, FDA 483a, or FDA 4056. was issued.
3. Provide additional discussion items not provided in writing at the conclusion of the inspection, such as: questionable labels, labeling and/or labeling practices, commercialization of products covered by IDE or IND, fraudulent health claims, registration/listing deviations, lack of approved PMA, 510(k), NDA, ANDA, etc. These include all verbal observations deemed not to merit inclusion on the FDA 483, FDA 483a, or FDA 4056. (IOM 5.2.3)
4. A description of each warning, recommendation, or suggestion given to the firm, and to whom given.
5. Management's general responses to the inspection and/or to groups of items listed on the report of observations or discussed at the conclusion of the inspection.
6. Report if management was informed that the conditions observed may, after further review by the Agency, be considered to be violations of the FD & C Act or other statutes. Legal sanctions available to FDA may include seizure, injunction, civil money penalties and prosecution. Significant deviations observed during a foreign inspection could result in a facility's product(s) being refused or detained upon entry into the United States.
7. Report if management was advised that if FDA receives an adequate response to the FDA-483, or other objectionable conditions, within 15 business days of the end date of the inspection, it may impact FDA's determination of the need for subsequent action.
8. Report all significant conversations with management or management representatives.

### 5.11.4.3.16 - ADDITIONAL INFORMATION

Report changes as appropriate.

1. Describe contractors used and for what purpose. **For Medical Device inspection reports:** also include names and addresses of all applicable third-party



- installers or servicing organizations used by the manufacturer. Include their responsibilities.
2. Describe suppliers (major raw material, active ingredient, etc.) used and for what.
  3. During inspections, when violative products imported into the U.S. or intended to be imported into the U.S., are encountered, document the product and foreign manufacturer in the EIR. Violative products could be rejected APIs due to non-conformance with the USP or applicable compendium, foods without appropriate labeling, etc. Send a copy of the EIR to OEIO/DIO. See IOM 5.2.1 and 5.11.2.
  4. For initial inspections, verify distribution patterns for the firm's products, raw materials, and components to firms which warehouse or further process products which may be subject to FDA regulations. Program divisions should incorporate information obtained into their Official Establishment Inventory improvement activities and complete form FDA 457, Product/Establishment Surveillance Report as appropriate. See IOM 8.1.5.4.
  5. Report pertinent facts, which do not fit another section of the EIR. (For firms located in foreign countries, include information relative to lodging and travel; for domestic firms, include information relative to location of firm if difficult to find; etc.).
  6. In accordance with IOM 5.3.4.3, if photographs are taken during the inspection include the statement: "The officially sealed original copy and unsealed working copy discs containing the photographs taken during the inspection are filed with the unlabeled exhibits and attachments."
  7. In accordance with IOM 5.11.5.1, if electronic records were received during the inspection include the statement: "The officially sealed original copy [USB, CD, DVD, etc.] [and unsealed working copy] containing the electronic records provided by the firm during the inspection are filed with the unlabeled exhibits and attachments."
- The bracketed information should be edited based on the actual storage devices obtained and if working copies were created.

**For human drug inspection reports - PDMA Coverage:**

1. Describe what sample loss, theft, or diversion reports were covered during the inspection.
2. Describe the firm's sample audit and security systems, including a review of the firm's SOP's. Significant problems which may contribute to the firm's inability to adequately monitor sample distribution via sales representative, mail or common carrier should be addressed under objectionable conditions.

**5.11.4.3.17 - SAMPLES COLLECTED**

List and describe samples collected during the inspection.

**5.11.4.3.18 - VOLUNTARY CORRECTIONS**

1. Provide a brief description of improvements initiated by the firm in response to a previous inspection, report of observations and/or a warning letter.

2. Report voluntary destructions, recalls, and similar actions since the prior inspection or during this inspection.
3. Report any follow-up to recalls identified during the inspection (may be by referencing Attachment B recall report).
4. Include recalls to specific objectionable conditions observed.
5. Provide the identity of person(s) responsible for the corrections.
6. Report any appropriate voluntary corrections in FACTS CARS. For human and animal food inspections, report any appropriate voluntary correction in eNSpect CAR.

**5.11.4.3.19 - EXHIBITS COLLECTED**

List all exhibits attached. See IOM 5.11.5, Exhibits.

Briefly, describe or title each exhibit attached and include the number of pages for each Exhibit listing.

NOTE: For complex inspections a cross-reference from the FDA 483, FDA 483a, or FDA 4056. and verbal observations to applicable exhibits and samples can be useful during further review.

**5.11.4.3.20 – ATTACHMENTS**

List all attachments. See IOM 5.11.6, Attachments.

Briefly, describe or title each attachment and include the number of pages for each attachment listing in eNSpect.

After issuance do not number, alter, or label FDA documents and/or forms (e.g., FDA 463a, FDA 482, FDA 483, FDA 4056).

**5.11.4.3.21 - SIGNATURE**

All participants will sign the final narrative portion of the EIR. The prescribed format is to include each person's name and title. Refer to current eNSpect user guide for guidance on electronic signatures for multiple participants.

In some cases, electronic signature by all participants is not possible. An example as to how this can be accomplished is to forward an electronic "draft" copy of the EIR for all to read and approve, then followed or accompanied by the original signature sheet. When signed, return to the lead investigator for uploading into eNSpect.

In rare situations (e.g., extended leave, retirement, deployment) a participant may not be available to sign the EIR. The supervisor should state in the endorsement "endorser acknowledges the inability of the participant to sign the EIR due to unavoidable circumstances".

## 5.11.5 - EXHIBITS

Exhibits are materials collected from the firm after the FDA 482 Notice of Inspection or FDA 482d Request for FSVP Records is issued and before the FDA 483, FDA 483a, or FDA 4056 is issued or the inspection is closed out. Collect only records and documents which are relevant to your inspectional findings or are required by the assignment or Compliance Program. Exhibits should contribute to the objective of the assignment, clarify the report, and document violations. Exhibits include flow plans, schematics, layouts, batch records and procedures, etc. Reference and explain exhibits in your narrative report. Copies of procedures, patient records, etc., that do not serve as evidence of a violation should not be collected unless you are directed to do so.

Labeling exhibits should show the entire label and must be legible and easy to read. Pertinent portions of exhibits in foreign languages should be translated, A statement regarding who provided translation on the documents should be included in the Administrative section of the report.

For photographs included in the report see IOM 5.3.4.4.

Exhibits are identified and included with the final EIR. Electronic labeling should be used to identify exhibits submitted with an EIR. Identification should include at least the firm name, FEI Number, date(s) of the inspection, the initials of all FDA participants, exhibit number, and page number(s). See IOM 5.3.8.2. Refer to the SOP titled, "Using eNSpect to Create, Store, and Preserve Electronic Records Associated with an Establishment Inspection Report."

Exhibits do not include FDA forms, copies of assignments, or information obtained outside of the firm. For example, website downloads using a computer that is not traceable to the U.S. government, printed prior to the start of the inspection, are not exhibits. If the materials collected from the firm are not needed as exhibits, they should be destroyed in accordance with your Program Division or office policy.

Exhibits which include medical records obtained during an investigation or inspection should be handled in accordance with current personal privacy disclosure rules. Such patient records should remain intact and stored in the official files. When copies of these records are requested internal to FDA, they should be redacted by obliterating the patients full name (keeping first and last initial only), social security number, date of birth, race, personal address and any other personal identifiers. All external requests should be handled by the FOI officer. Submit at least three copies of new or suspect labeling or other material collected as exhibits for labeling purposes. See IOM 4.4.9 for exceptions. These should be mounted in a manner so complete sets are submitted that can be reviewed by individuals in separate offices, i.e., labels 1-10 in each of three sets.

### 5.11.5.1 - Electronic Records as Exhibits and Attachments

Electronic records included as exhibits or attachments to the EIR should be stored to protect the integrity of the data. Refer to IOM 5.3.8.3.3.1. Electronic records should be protected from degradation, including preventing exposure of the electronic storage media to extreme temperatures and magnetic fields where necessary. Additional precautions to preserve the electronic records may be required, and you should be guided by your program division procedures for handling electronic storage media. See IOM 5.11.5 Exhibits and 5.11.6 Attachments

Do not scan and upload the FDA 525 or envelopes containing the USB, CD, DVD, or other storage devices containing electronic records to eNSpect. The actual records included on the storage device and uploaded into eNSpect are the official exhibit. The original officially sealed storage device and unsealed working copies should be included with the unlabeled hard copy exhibits and attachments filed in accordance with applicable procedures. The following statement should be included in section 5.11.4.3.16 - Additional Information, "The officially sealed original copy [USB, CD, DVD, etc.] [and unsealed working copy] containing the electronic records provided by the firm during the inspection are filed with the unlabeled exhibits and attachments." The bracketed information should be edited based on the actual storage devices obtained and if working copies were created.

For information on handling photographic storage media see IOM 5.3.4.3 Preparing and Maintaining Digital Photographs as Regulatory Evidence.

## 5.11.6 ATTACHMENTS

Attachments as referred to here are any material not provided by the firm during the inspection and referred to in the EIR, such as assignments, Center provided protocols, website information printed during inspectional preparation, etc. Non-evidentiary material attached to the narrative portion of the EIR should be identified as "Attachments" similar to IOM 5.3.8.2. Documents attached to the EIR may be referred to under the attachments heading, such as a copy of the FDA 463a, the FDA 482, FDA 483, FDA 4056, etc. (in form number order); but such documents/forms may not be numbered, altered from their issued state, bear adhesive identification labels, etc. See the opening sentence of IOM 5.10.5. List and attach copies of associated reports (Recall Attachment B Report, etc.).

### 5.11.7 - Corrections to Endorsed Establishment Inspection Reports

If your EIR requires correcting or clarification after it has been endorsed, an amendment may be prepared at the request of your supervisor. Amendments should only be required for significant errors or omissions, e.g. dates,

incorrect names, lot numbers, type of operation, or grammatical errors that change the intended context of the report.

The amendment will be written using the original EIR as the starting document. The word “Amendment” should be placed after the words “Establishment Inspection Report” in the header. A sequence number should accompany the word Amendment. Example “Amendment 1”. Changes made to correct errors in the text of the EIR should remain visible; bold all additions and strike through all removals. The amended narrative report will be processed through eNSpect.

The coversheet must be re-endorsed by the supervisor. At the beginning of the endorsement text, indicate that an amendment has been made to the report with a brief explanation as to why an amendment was necessary and if additional documents were added to the report.

## SUBCHAPTER 5.12 – COMBINATION PRODUCTS

### 5.12.1 – COMBINATION PRODUCT INSPECTIONS

As set forth in part 3 (21 CFR part 3), a combination product is a product comprised of any combination of a drug and a device; a device and a biological product; a biological product and a drug; or a drug, a device, and a biological product (see also 2.7.1.3.7). These articles retain their regulatory identity when they become constituent parts of a combination product. Accordingly, the authority for inspections of combination products arises from the authorities for drug, device and biological product inspections as described in IOM 5.5, 5.6, and 5.7, respectively.

All combination products are subject to at least two sets of CGMP requirements. In 21 CFR part 4, subpart A, section 4.3 identifies a streamlined approach to demonstrate compliance with the drug CGMPs (21 CFR part 210 & 211) and the device Quality System (QS) Regulation (21 CFR part 820) for single-entity and co-packaged combination products that contain a drug or biological product constituent part and a device constituent part. This allows a combination product manufacturing facility to comply either with the drug CGMPs and specific called-out provisions from the device QS regulation (drug CGMP-based streamlined approach, see 21 CFR 4.4(b)(1)) or with the device QS regulation and specific provisions from the drug CGMPs (device QS regulation-based streamlined approach, see 21 CFR 4.4(b)(2)). Regardless of whether a streamlined approach is used, in addition, for a combination product that includes a biological product, the manufacturer must demonstrate compliance with all

applicable CGMP requirements for biological products (including standards) that are found within 21 CFR Parts 600 through 680 (21 CFR 4.3(c)). For a combination product that includes any HCT/P, the manufacturer must demonstrate compliance with all applicable regulations in 21 CFR Part 1271.

#### 5.12.1.1 – Preparation

Identify the combination products manufactured at the facility and, if not already known, identify the lead center. The lead center is the medical product center (e.g., CBER, CDER, or CDRH) that has primary jurisdiction for a specific combination product’s review and regulation. Questions on which center is lead for a combination product should be directed to [combination@fda.hhs.gov](mailto:combination@fda.hhs.gov). Typically, the application type for the combination product is aligned with the lead center (for example, generally, PMA and 510(k) products are CDRH-led, and NDA/ANDA products are CDER-led). The lead center serves as the primary point of contact before, during, and after the inspection. For a CDER-led combination product inspection, review IOM 5.5. For a CDRH-led combination product inspection, review IOM 5.6. For CBER-led combination product inspection, review IOM 5.7.

Obtain the following information before the inspection whenever possible:

- The CGMP operating system in use at the facility. Although most combination product manufacturers choose to follow a streamlined approach that aligns with the lead center/application type (e.g., a facility manufacturing a combination product approved under a PMA follows a device QS regulation-based streamlined approach), they may choose to follow either of the streamlined approaches or full compliance with both sets of regulations.
- Information about the facilities involved in the manufacturing (including design activities) for the combination product and the scope of CGMP responsibilities of the facility to be inspected.
- For pre-announced inspections, confirm that documentation to enable review of compliance with called out provisions will be available or accessible at the site being inspected.

#### 5.12.1.2 – Inspectional Approach

For combination product CGMP inspections for CDER-led or CDRH-led single-entity or co-packaged combination products, follow Compliance Program 7356.000 and associated commodity-specific compliance programs for

pre-approval, post approval, surveillance, for cause, and other risk-based inspections. For surveillance inspections where combination product coverage is conducted, prioritize combination products recently approved, cleared, or significantly changed (in terms of design) or those that include complex technology or manufacturing considerations. This applies unless there are indicators that there are safety and effectiveness concerns with other products.

For CBER-led combination product inspections, contact OBPO supervisory staff and CBER for assistance.

### **5.12.1.3 – Registration and Listing**

Combination products are generally registered and listed with the lead Center only. However, they may also be registered with a secondary Center. In both instances, the listing should reflect that the product is a combination product. If potential problems related to registration and listing are identified, contact the lead center for assistance.

### **5.12.1.4 – Combination Product Establishment Inspection Report**

A single EIR and, when applicable, FDA-483 should be used to document all observations made during an inspection at a combination product manufacturer.

### **5.12.1.5 – Limitations on Inspection**

The limitations on the agency's ability to access audit results (see IOM 5.6.2.2) also apply to an inspection of a combination product manufacturer.

5-1 FORM FDA 482 NOTICE OF INSPECTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO. 1431 Harbor Bay Parkway Alameda, CA 94502 (510)337-6700	
TO	2. NAME AND TITLE OF INDIVIDUAL Helen E. Castro, President		3. DATE 07/28/13
	4. FIRM NAME ABC Bread Company		5. HOUR 7:30 a.m.  p.m.
	6. NUMBER AND STREET 579 Main Street		
	7. CITY AND STATE & ZIP CODE Richmond, CA 94805		8. PHONE NO. & AREA CODE (510)123-4567
Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)] <sup>1</sup> and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264] <sup>2</sup>			
As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is <a href="http://www.sba.gov/ombudsman">www.sba.gov/ombudsman</a> .  FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at <a href="mailto:ombuds@oc.fda.gov">ombuds@oc.fda.gov</a> .  For industry information, go to <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a> .			
9. SIGNATURE(S) (Food and Drug Administration Employee(s))  <i>Sidney H. Rogers</i>		10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))  Sidney H. Rogers, Investigator	
<sup>1</sup> Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:  Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information		described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this <p style="text-align: right;">(Continued on Reverse)</p>	

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

<sup>2</sup> **Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:**

Part F – Licensing – Biological Products and Clinical Laboratories and\* \* \* \* \*

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - \*\*\*\*\*Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

\*\*\*\*\*

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than \$50, to furnish manufacturers of such

products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

\*\*\*\*\*

Sec. 360 B.(a) It shall be unlawful-

(1) \*\*\*

(2) \*\*\*

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

\*\*\*\*\*

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

5-2 - FORM FDA 482a

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS AND PHONE NO. 6751 Steger Dr. Cincinnati, OH 45237 (513)679-2700	
TO	2. NAME AND TITLE OF INDIVIDUAL Michael A. Weston, Plant Manager		3. DATE OF REQUEST 06/20/12
	4. FIRM NAME ABC Food Company		5. TIME OF REQUEST 8:30 <input checked="" type="checkbox"/> A.M. <input type="checkbox"/> P.M.
	6. NUMBER AND STREET 3114 Mapleleaf Avenue		
	7. CITY AND STATE Cincinnati, OH		8. ZIP CODE 45213
Written demand for examination and/or copying of the records required by 21 CFR 113.100, 21 CFR 114 and 21 CFR 500.23 is hereby given, pursuant to 21 CFR 108.25(g), 21 CFR 108.35(h) and 21 CFR 500 for the records described below in order to verify the pH, adequacy of processing, the integrity of container closures, and the coding of the products processed by your firm.			
9. RECORDS NECESSARY  All thermal process, production, and quality control / analytical records and maintenance records which may document any changes to the equipment or the thermal process mandated by 21 CFR 108, 113, and 114 [ <i>chose appropriate regulation, 113 LACF or 114 acidified</i> ] for all low acid canned foods and/or acidified food products [ <i>or specify product</i> ] which were produced by this firm since the last FDA inspection.			
10. SIGNATURE ( <i>Food and Drug Administration Employee(s)</i> )  <i>Sidney H. Rogers</i>		11. TITLE FDA EMPLOYEE  Investigator	



5-3 FORM FDA 482b

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS AND PHONE NO.  6751 Steger Dr. Cincinnati, OH 45237 (513)679-2700	
TO	2. NAME AND TITLE OF INDIVIDUAL Michael A. Weston, Plant Manager		3. DATE OF REQUEST 06/20/12
	4. FIRM NAME ABC Food Company		5. TIME OF REQUEST 8:30 <input checked="" type="checkbox"/> A.M. <input type="checkbox"/> P.M.
	6. NUMBER AND STREET 3114 Mapleleaf Avenue		
	7. CITY AND STATE Cincinnati, OH		8. ZIP CODE
Written request is hereby given pursuant to 21 CFR 108.25(c)(3)(ii), 21 CFR 108.35(c)(3)(ii) and 21 CFR 500.23 for the information described below, concerning processes and procedures, which is deemed necessary by the Food and Drug Administration to determine the adequacy of the processes for products processed by your firm.			
9. RECORDS NECESSARY  All documents and records mandated by 21 CFR 108 relating to or having a bearing on the adequacy of processes for all low acid canned foods and/or acidified food products [or specify product] that were produced in this firm since the last FDA inspection.			
10. SIGNATURE (Food and Drug Administration Employee(s))  <i>Sidney H. Rogers</i>		11. TITLE FDA EMPLOYEE  Investigator	

FORM FDA 482b (6/11)

PREVIOUS EDITION IS OBSOLETE.

REQUEST FOR INFORMATION

PSC Publishing Services (301) 443-6740 EF

## 5-5 FORM FDA 483

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER <b>Minneapolis District</b> 250 Marquette Ave. South, Suite 600 Minneapolis, MN 55401 Industry information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		DATE(S) OF INSPECTION <b>10/5-7/2008</b>	FEI NUMBER <b>0000112233</b>
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  <b>to: William S. Gundstrom, Vice President, Production</b>			
FIRM NAME <b>Topline Pharmaceuticals "T.L.P."</b>	STREET ADDRESS <b>2136 Elbe Place</b>		
CITY, STATE AND ZIP CODE <b>Jackson, MN 55326</b>	TYPE OF ESTABLISHMENT INSPECTED <b>Tablet Repacker</b>		
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.			
DURING AN INSPECTION OF YOUR FIRM (I) ( <del>WE</del> ) OBSERVED:			
List your significant observations ranked in order of significance.  See IOM 5.2.3, 5.2.3.1, 5.2.3.2, and 5.2.3.3			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Sylvia H. Rogers</i>	EMPLOYEE(S) NAME AND TITLE ( <i>Print or Type</i> ) Sylvia H. Rogers, Investigator	DATE ISSUED 10/7/2008

The observations of objectionable conditions and practices listed on the front of this form are reported:

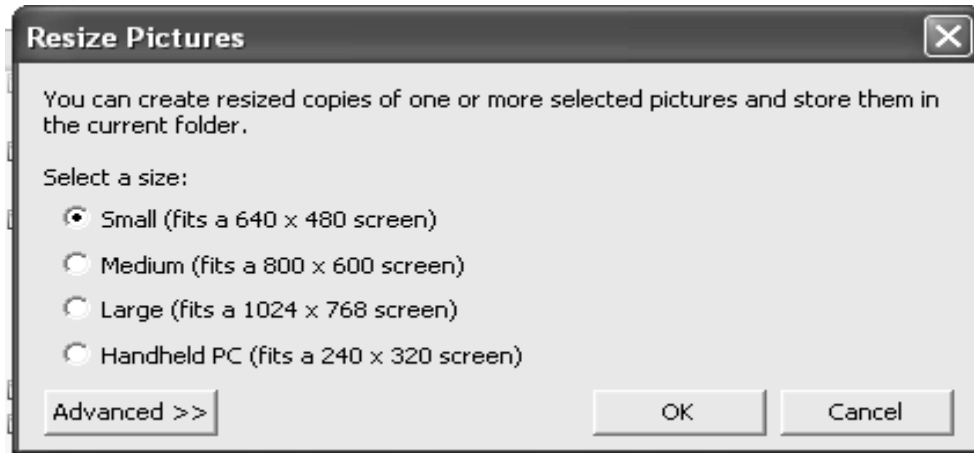
1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

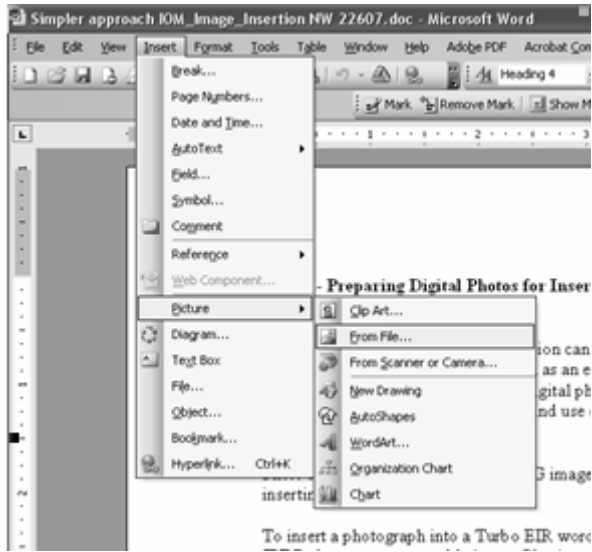
## 5-6 INSERTING DIGITAL PHOTOS INTO eNSpect (RESIZE PHOTO)

Screenshot - Resizing Pictures using Windows Explorer:



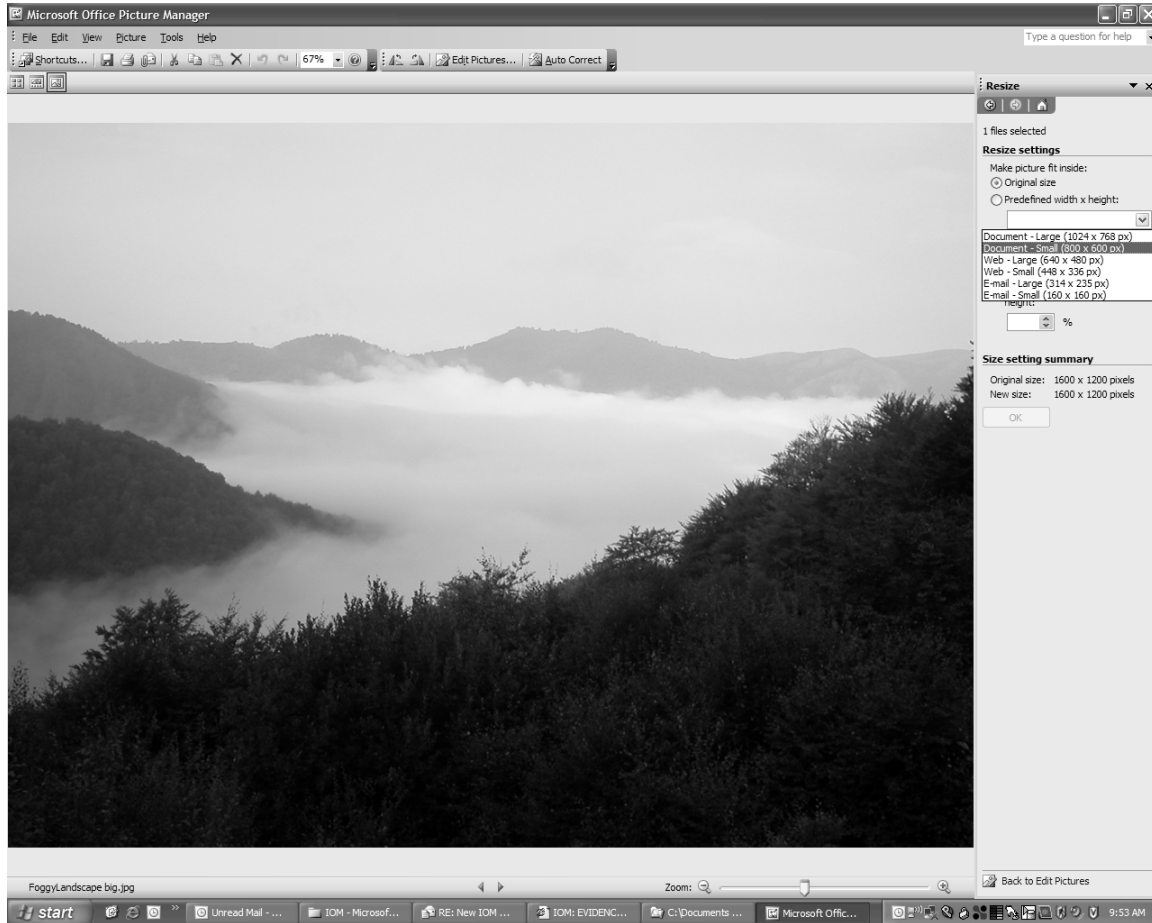
### 5-7 INSERTING DIGITAL PHOTOS INTO eNSpect (INSERT PHOTO)

Inserting a resized picture into Microsoft Word.



### 5-8 INSERTING DIGITAL PHOTOS INTO eNSpect (RESIZING USING MS OFFICE PICTURE MANAGER)

Screenshot - Using Microsoft Office Picture Manager to Resize a picture to 800 x 600 pixels.



5-9 FACTS CREATE SAMPLE ASSIGNMENT SCREEN

**FACTS Version 4.9.01 - [Create Assignment]**

Action Edit Options Related Info Reports Navigate Tracing FACTS Help Window Help

---

**Assignment**

Requesting Organization: MIN-IB-SPV Requester Completion Date: 11/21/2005 Priority: High ORA Req'd: N/A Compliance Number: 145 - 0

Subject: Pharma-Mix Digitalis ORA Cnrc Num: Survey Num:

Remarks: Request for samples as follow-up to violative EI Reporting Method: Notify SI DoMore by phone when accomplish

Background Information: Firm's manufacturing practices may lead to low potency POC Name: James W. DoMore

---

**Operations**

Op Code: 31 Sample Collection Rqstr Prty: High

Subject: Pharma-Mix Digitalis Target Date: 11/21/2005

Requester Remarks: Collect 12/100 tab bottles of lot DC-01234 as follow-up to vi

Estmtd Hours: 4 Estmtd Smp'l Cost: \$150.00 Reimbursable:

**Organizations**

Accomp Org	Num Of Ops	Perf Org (Adhoc Work)
NWJ-DO	1	

Buttons: Add, Delete, Prev Op, Next Op, Delete

---

**PACS & Products**

PAC	Description	Product Code	Description
56002	DRUG PROCESS INSPEC	63 F C E 04	Digitalis (Cardiotonic); Human - Rx/

Buttons: Add, Delete

---

**Firms & Cross References**

FEI	B	Name	Code	Value
3000900992		Drug Distributors, I		

Buttons: Add, Delete

**Lab References**

Sample Number: PAF: LID:

Buttons: Delete

**FACTS Editor**

Collect 12/100 tab bottles of lot DC-01234 as follow-up to violative EI of Pharma-Mix, Minneapolis, MN (FEI 3000901012), conducted on 9/31-10/05/2005. 30 cases were shipped to Drug Distributors Inc., 3910 Riverside St., Newark, NJ on 10/03/05 via Cross Country Express, Kansas City, MO. Invoice # 8328 10/05/05, B/L A-3026, 10-3-05.

Search OK Cancel

5-10 FORM FDA 482c NOTICE OF INSPECTION – REQUEST FOR RECORDS

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO.	
TO	2. NAME AND TITLE OF INDIVIDUAL		3. DATE
	4. FIRM NAME		5. HOUR a.m. p.m.
	6. NUMBER AND STREET		
	7. CITY AND STATE & ZIP CODE		8. PHONE # & AREA CODE

**Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(1)]<sup>1</sup>. Written request is hereby given to access and/or copy the records described below, pursuant to the Federal Food, Drug and Cosmetic Act, Section 414(a) [21 U.S.C. 350c]<sup>2</sup> and Title 21 Code of Federal Regulations, Section 1.361<sup>3</sup>.**

9. SIGNATURE ( <i>Food and Drug Administration Employee(s)</i> )	10. TYPE OR PRINT NAME AND TITLE ( <i>FDA Employee(s)</i> )
--	---

**Applicable portions of Sections 704 and 414 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 374 and 350c) and Title 21 of the Code of Federal Regulations, are quoted below:**

<sup>1</sup>Sec. 704.(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data, relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

<sup>2</sup>Sec. 414(a) RECORDS INSPECTION. - (1) ADULTERATED FOOD. - If the Secretary has a reasonable belief that an article of food, and any other

article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article, and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. (2) Use of or exposure to food of concern. --If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals. (3) Application.--The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

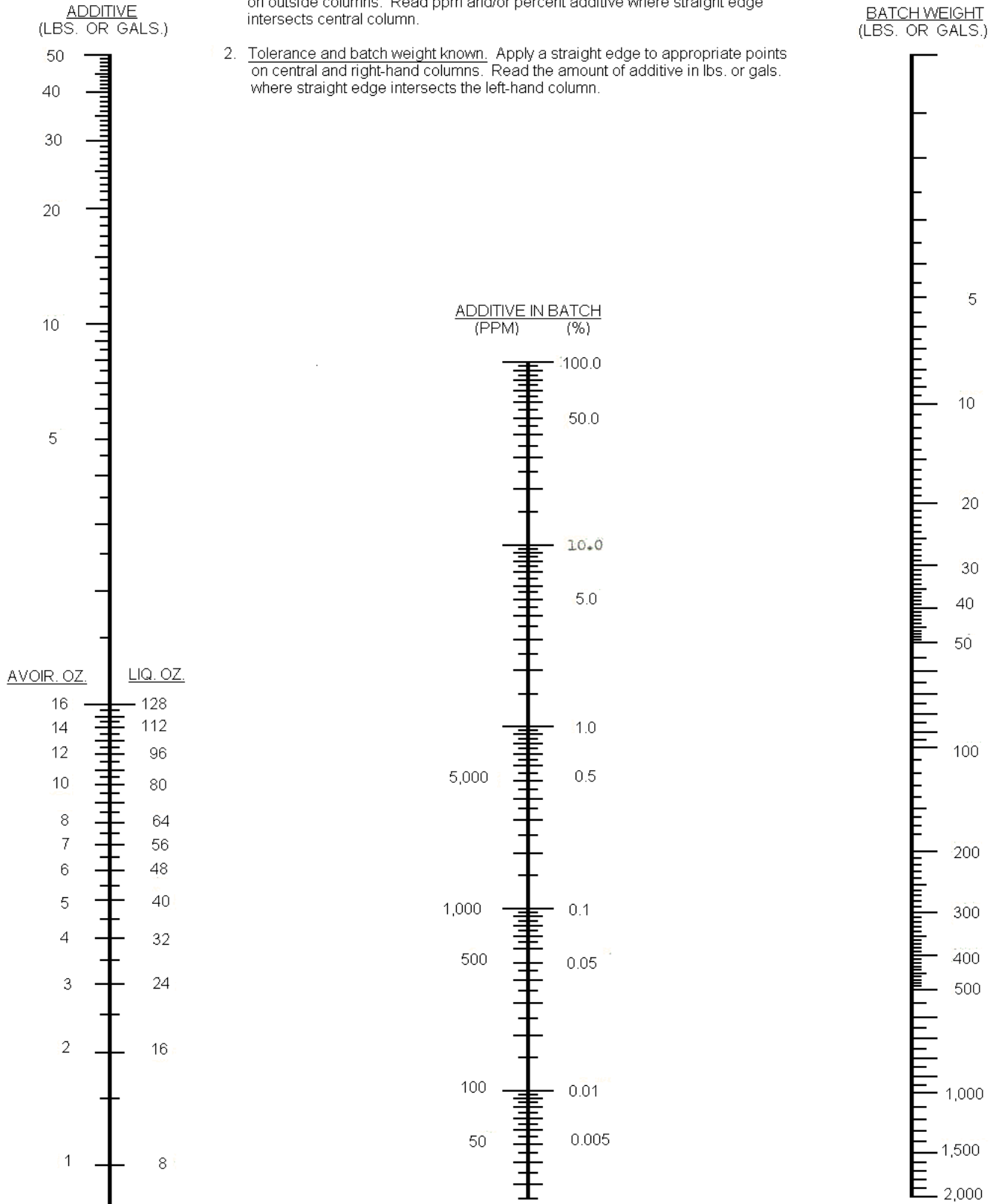
<sup>3</sup>21 CF CFR 1.361 What are the record availability requirements? When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human services who presents appropriate credentials and a written notice.



5-11 FOOD ADDITIVE NOMOGRAPH I

FOOD ADDITIVES NOMOGRAPH I

1. Additive and batch weight known. Apply a straight edge to appropriate points on outside columns. Read ppm and/or percent additive where straight edge intersects central column.
2. Tolerance and batch weight known. Apply a straight edge to appropriate points on central and right-hand columns. Read the amount of additive in lbs. or gals. where straight edge intersects the left-hand column.

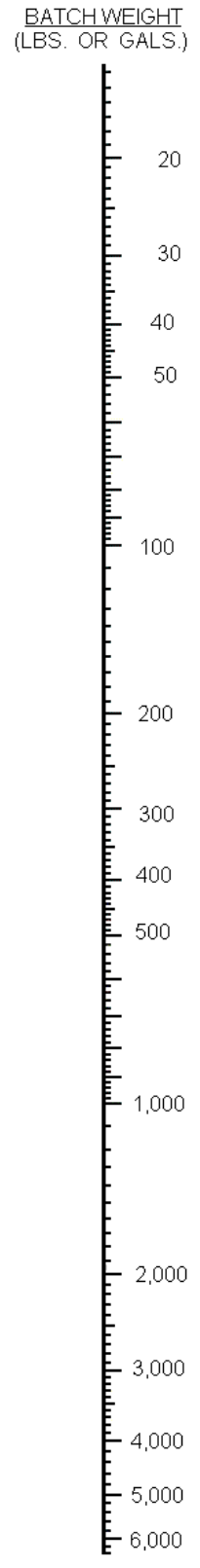
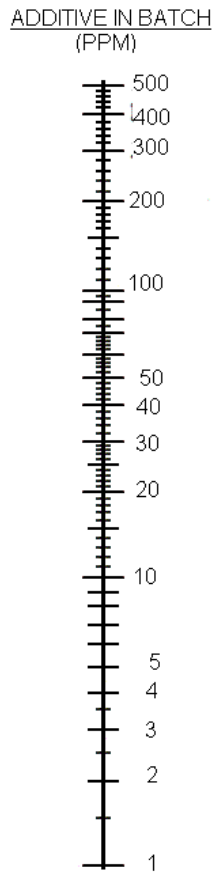
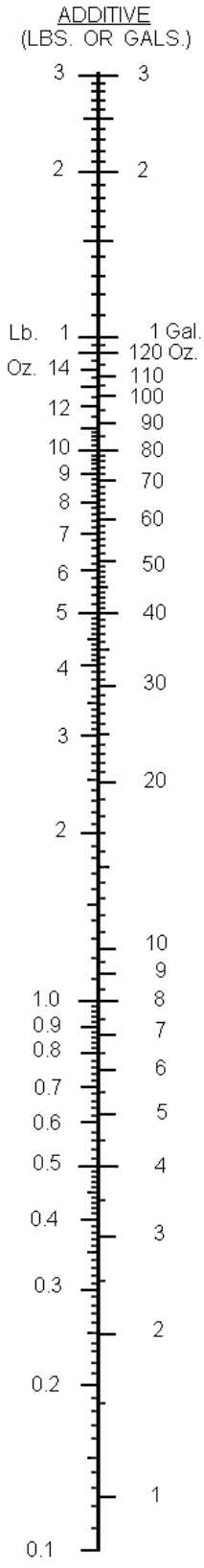


For more precise determination of additives in the 1-500 ppm range, use Nomograph II

5-11 FOOD ADDITIVE NOMOGRAPH II

FOOD ADDITIVES NOMOGRAPH II

1. Additive and batch weight known. Apply a straight edge to appropriate points on outside columns. Read ppm and/or percent additive where straight edge intersects central column.
2. Tolerance and batch weight known. Apply a straight edge to appropriate points on central and right-hand columns. Read the amount of additive in lbs. or gals. where straight edge intersects the left-hand column.



**5-12 SUMMARY OF REGISTRATION AND LISTING HUMAN PHARMACEUTICALS**

SUMMARY OF REGISTRATION AND LISTING REQUIREMENTS FOR THE MANUFACTURE OR DISTRIBUTION OF HUMAN PHARMACEUTICALS			
TYPE OF FIRM	REGISTRATION STATUS	LISTING STATUS	FACTS CODE
Manufacturer [including homeopathic & controlled drugs]	yes	yes	M
Contract Manufacturer	yes	yes	M
Own Label Distributor	no	yes	L
Wholesale Distributor (no manufacturing or distribution under own name and label)	no	no	W-*
Own Label Repacker	yes	yes	R
Own Label Relabeler [including recirculizer]	yes	yes	Y
Contract Relabeler	yes	yes	Y
Contract Testing Laboratory [dosage forms & active ingredient release]	yes	no	C
Contract Testing Lab [doing non-release tests]	no	no	C
Contract Sub-Manufacturer	yes	yes	M
IND Manufacturer [Clinical Drugs]	no	no	M
NDA and ANDA Manufacturer	yes	yes	M
Sponsor/Monitors/Clinical Investigator	no	no	4, 5, 6, 7
Contract Sterilizer	yes	yes	0
Fulfillment Packager [adding substantive labeling]	yes	yes	Y
Mail Order House [adding insubstantial labeling]	no	no	D
Printing House	no	no	None
Medical Gas Transfiller	yes	yes	MG
First Aid/Rescue Squad [transfilling for own use]	no	no	MG
Medical Gas Transfiller [operating out of a van]	yes	yes	MG
Contract Assembler	yes	no	M
Active Drug Substance Manufacturer	yes	yes	M
Excipient Drug Manufacturer	no	no	M
Manufacturer of Research Drugs	no	no	M
Drug Importer	no	no	A
Foreign Drug Manufacturer	yes	yes	M
Methadone Clinic	no	no	T
Retail Pharmacy	no	no	D
Salvage Operation	yes	no	X
Biopharmaceutical Clinical Facility	no	no	2
Outsourcing Facility	yes	no	OF

\*Includes W, WA, WF, WR, and/or WZ

## 5-13 SUBSTANTIALLY EQUIVALENT MEDICAL DEVICES

Operation		Submit 510(k)	Register	List	COMPLY W/GMP
1.	Manufacture and distribute device	YES: 807.81(a)	YES 807.20(a)	YES 807.20(a)	YES
2.	Contract manufacturer who commercially distributes device for specifications developer	NO: 807.81(a)	YES if domestic: 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES
3a.	Contract manufacturer who meets the definition of finished device manufacturer per 21 CFR 820.3(l).	NO	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
3b.	Contract manufacturer who does not meet the definition of finished device manufacturer per 21 CFR 820.3(l) (e.g., component manufacturer, subassembler)	NO	NO	NO	NO
4.	Manufacturer modifies device or new intended use and distribute	NO: preamble no. 17 & 18 FR 8/23/77 YES: 807.81(a)(3) with signif. change in device or use	YES 807.20(a)	YES 807.20(a)	YES
5.	Located in US and distribute US made device. No specification initiation (domestic distributor)	NO: 807.85(b)	NO: 510(g)(4) of act, 807.20(c)	NO 807.20(c)	NO
6.	Specification initiator and distribute only	YES: 807.81(a)	YES: 807.20(a)(1)	YES: 807.20(a)(1)	YES: 820.181, etc.
7.	Specification consultant only; no distribution	NO	NO:	NO	NO
8.	Relabeler or repacker: change labeling or packaging in manner other than adding own name	YES	YES: 807.20 (a)(3)	YES: 807.20(a)(3)	YES 820.3(w), 820.3(o) and Preamble Comment 28, FR 52610
9.	Relabeler or repacker: distribute under own name	NO: 807.85(b): no change to device or existing labeling and another person has a cleared premarket notification application	NO	NO	NO
10.	Kit assembler using pre-labeled & prepackaged devices only	NO: no change in device or existing labeling other than adding dist. name & address 807.81(a)(3)	YES: 807.20(a)	YES: 807.20(a)	YES
11.	Kit assembler changes intended use (801.4) of prepackaged/pre-labeled devices	YES: 807.81(a)	YES: 807.20(a)(3)	YES: 807.20(a)(3)	YES: 820.120, 820.130, etc.
12.	Kit assembler changes prepackaged/pre-labeled devices	NO: if no significant change to labeling or device: otherwise YES: 807.81(a)(3)(i)	YES: 807.20(a)(3)	YES: 807.20(a)(3)	YES
13.	Manuf. Accessory, component and package & label for health purpose to end user.	YES: 807.81(a)	YES: 807.20(a)(6)	YES: 807.20(a)(6)	YES
14.	Manuf. Components & dist. Only to finished device mfr.	NO: 807.81(a)	NO: 807.65(a)	NO	Use as guide: 820.1
15.	Contract mfr. Of subassembly or component (see no. 13, accessory)	NO	NO	NO	Primary mfr. must see that GMP is met 21 CFR 820.50
16.	Contract packager or labeler	NO	YES	YES	Yes 820.2(a)(1) 820.3(o)
17.	Contract Sterilizer	NO	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES
18.	Manufacture custom device (domestic or foreign)	NO: 807.85(a)(1)&(2)	YES 807.20(a)	YES 807.20(a)	YES: also see 520(b); 520(f)
19.	U.S. Establishment who manufactures for export only	NO	YES 807.20(a) and 807.25(g)(5)	YES 807.20(a) and 807.25(g)(5)	YES
20.	Foreign manufacturers and all foreign establishments	YES: 807.81	YES, 807.40(a)	YES 807.40(a)	YES
21.	Initial distributor/importer of device	YES: 807.81(a) or 807.85(b) unless 510(k) has been filed by foreign manufacturer or another init. Dist	YES: 807.20(a)(5)	NO: Must identify foreign manufacturer(s) or device(s) imported)	YES: 807.3(d), 820.198, 820.100, 820.200, etc.
22.	Installer-mfr.'s agent	NO	NO	NO	YES: 820.170
23.	Installer-user	NO	NO	NO	NO: for x-ray see 1020.30(d) report
24.	Device being investigated under ide	Exempt: 812.1(a)	NO	NO: 807.40(c)	Exempt per 812.1(a), except for Design Control per 820.30
25.	Mfr. Buys manufacturing rights for device (see no. 4)	NO: preamble 18 FR 8-23-77 only if same type of manuf. equip. is used and no signif. change to device	YES: 807.20(a)	YES 807.40(a)	YES
26.	Reprocessor of single use device	YES	YES: 807.20(a)(4)	YES: 807.20(a)(4)	YES
27.	Foreign exporter of device (device manufactured in foreign country)	YES: (original manufacturer's 510(k) maybe used)	YES: 807.40 (a)	YES: 807.40 (a)	YES 820.1(a)(2) YES

5-14 eNSpect PROFILE - COMSTAT

PROFILING A FIRM'S CGMP/QS COMPLIANCE STATUS

Table 5-14.1	Quick Reference Guide	5-14.3.11	Remark Status Field
Table 5-14.2	Example of a Maintain Profiles Screen	5-14.3.12	Remarks Field
5-14.1	Introduction	5-14.3.13	Out-of-Business Firm
5-14.2	Purpose	5-14.3.14	Firm Merge
5-14.3	Instructions	5-14.3.15	Troubleshooting
5-14.3.1	Pre-Inspection Preparation	5-14.4	Contact Information
5-14.3.2	Firm's Operations	5-14.5	Data Quality Assurance Projects
5-14.3.3	Maintain Profiles Screen	5-14.6	Establishment Profile Criteria
5-14.3.4	Previous Inspection Profile	Table 5-14.6.1	Device, Biologic, Drug, and Veterinary Establishments TO Profile
5-14.3.5	Firm information		
5-14.3.6	Inspection Coverage of Profile Class Codes	Table 5-14.6.2	Establishment and Operations NOT to Profile.
5-14.3.7	Discontinue and Delete Buttons	5-14.6.3	Pre-Approval Inspection
5-14.3.8	CGMP Inspection and Other Toggle Buttons	5-14.7	Profile Classes and Codes
5-14.3.9	Initial, In Review, and Final	5-14.7.1	Profile Class Codes
5-14.3.10	Final Profile Status	Table 5-14.7.1.1	Biologics
5-14.3.10.1	Other Status	Table 5-14.7.1.2	Devices
5-14.3.10.2	Acceptable Status	Table 5-14.7.1.3	Drugs and Veterinary
5-14.3.10.3	Unacceptable Status	Table 5-14.7.1.4	Special Veterinary

Table 5-14.1 Quick Reference Guide

Review Status	Profile Status	Data Entry Role	Remarks Field	Remarks Status Field	Purpose
Initial	Further Action Indicated	IB	Review and date Ex: "Referred to CB mm/dd/yy"		EI is potentially OAI
	Acceptable	IB	Usually no Remarks required.		EI is NAI or VAI.
In Review	Pending	CB	Recommended enforcement or alternative action; with date as well as review and date. Ex: "Recommend WL; Under review by [CB/Center]"		Enforcement or alternative action recommended.
Final	Other	IB/CB	Enter the action firm is operating under Ex: "Consent Decree (CD) for CGMP (Current Good Manufacturing Practices)/QS (Quality Systems) violations signed on mm/dd/yy." If the CD includes a sunset clause/date, add to Remarks. or "AIP invoked on mm/dd/yy."	When the firm is operating under CD/Injunction/AIP (Application Integrity Policy) and the CGMP/QS EI is: NAI or VAI, then "Acceptable (AC)"; or the inspection is OAI and further enforcement action is taken, then the Remarks Status is "Unacceptable (UN)."	Firm is operating under a CD or AIP, and a subsequent CGMP EI has occurred.  Enforcement Action may involve medically necessary products or be process or product specific. In this case, such conditions should be reflected in Remarks field (see 3.10 & 3.11(2)).
	Acceptable	IB/CB	No outstanding OAI inspections, no compliance actions.		NAI and VAI inspections; or OAI inspections where no enforcement action was taken and/or was downgraded to VAI.
	Unacceptable	CB	Enter regulatory action taken and date. Ex. WL issued 1/1/18. UTL issued 3/10/18. Reg meeting held 4/10/18.		Only <b>after</b> an enforcement action occurred as a result of a CGMP/QSIT EI.

**Table 5-14.2 Example of a Maintain Profiles screen****5-14.1 Introduction**

Firm profiles provide a snapshot of the firm's compliance status with CGMP or QS regulations. Profile status is monitored for domestic and foreign firms that manufacture, repack, label/relabel, sterilize, or test drug, medical device, or biological products.

**5-14.2 Purpose**

Firm profiles provide the compliance status as well as an inventory of product categories covered during a CGMP/QS inspection and are used to support:

- The Government Wide Quality Assurance Program (GWQAP).
- External users such as state and local regulatory authorities and foreign government agencies.
- Other FDA operations such as drug product approvals, export certificates and imports.

**5-14.3 Instructions****5-14.3.1 Pre-Inspection Preparation**

To obtain a comprehensive history of the firm you are going to inspect, go to ORADSS Domestic Reports folder named Establishment History Report and select EHR101 Firm Info and run the report entering the FEI you want reported. Make sure that a final status has been entered for all Profile Classes (PCs) for the previous inspection. If you find that one or more PCs have an initial status but not a final status, bring this to the attention of your supervisor and finalize prior entering any updates.

**5-14.3.2 Firm's Operations**

For profile purposes, the firm's operation type can be either as a single entity or in combination with other operations. Look at all the possibilities in the drop down menu before making a selection. Some selections allow for multiple operations. See below for examples:

- Specification Developer Only versus Specification Developer Also.  
When a firm is a specification developer and they do not manufacture any medical products onsite, select profile class code, SPD, and the Operation Type, "Specification Developer Only."

When a firm is a specification developer and they do onsite manufacturing of medical products which are not the subject of the specifications developed, select SPD with the Operation Type "Specification Developer Also" **and** select the appropriate profile

class of the products they manufacture with Operation Type "Manufacturer."

- Veterinary Drugs Also versus Veterinary Drugs Only.  
When a firm manufactures both veterinary and human drugs, select the appropriate profile class code(s) that defines its operation then select the Operation Type Veterinary Drugs Also. When a firm manufactures veterinary drugs only, select the appropriate profile class code(s) that defines its operation then select the Operation Type Veterinary Drugs Only.

**5-14.3.3 Maintain Profiles Screen**

When entering profile information, it is important to access the Maintain Profiles screen properly as accessing a profile screen incorrectly will result in data quality errors.

The correct way for Field Offices and Centers to access the Profile screen is to use eNSpect, accessed from the eNSpect App link found on the Inside. FDA's ORA Production Applications page. From the menu toolbar, enter the FEI or eNSpect Operation and once the inspection record is selected, click the left-hand side Firm tab then select the Firm Profiling tab. You are now ready to enter/update the profile status.

**5-14.3.4 Previous Inspection Profile**

It is important that the profile for the previous inspection be complete with a final profile status for each PC before updating the profile for the current inspection. If this is not done, a banner will appear saying "Initial data already exists," and it will not be possible to close the current inspection in eNSpect on the Firm Profiling screen.

**5-14.3.5 Firm Information**

The Firm Overview, Additional Details, and the Firm Profiling screens should agree in firm name, address, and FEI number. For questions, contact the GWQAP staff [gwqap@fda.hhs.gov](mailto:gwqap@fda.hhs.gov).

**5-14.3.6 Inspection Coverage of Profile Class Codes**

When a CGMP/QS systems-based inspection is performed, coverage should reflect the overall state of control for the firm's operations. For this reason, the PCs should reflect all product classes produced by the firm as well as those covered during the inspection.

When a firm manufactures more than one commodity, e.g., drugs and devices, and the inspection covers only the drug systems, then only update the PCs that represent the drug commodity. See 5-14.7 for more information about profile classes and codes.

### 5-14.3.7 Discontinue and Delete Buttons

Proper use of the Discontinue and the Delete buttons\*:  
 Discontinue button – The PCs should be discontinued if a firm goes out-of-business or no longer manufactures a drug, device, or biologic product.  
 Delete button - PCs and data entered in error can and should be deleted **prior** to clicking the save button and exiting the screen.

NOTE: If you save incorrect data before realizing it and you cannot delete it, contact the GWQAP Team for assistance. See 5-14.4 for Contact Information.

### 5-14.3.8 CGMP Inspection and Other Toggle Buttons

The CGMP Inspection toggle button is automatically activated when the Profile Required field is checked on the Maintain Inspection Results screen. The *Other* radio button should not be used for profiling purposes.

### 5-14.3.9 Initial, In Review, and Final

As reflected in Table 5-14.1 above, profile status should be entered as follows:

**Initial:** Normally entered by the Investigator. Potentially OAI inspections should be immediately entered as FAI and NAI/VAI as AC.

**In Review:** Pending should be entered by the Compliance Officer as soon as the record is received for review.

**Final:** AC should be entered by the Supervisor for NAI/VAI inspections; UN should be entered by the Compliance Officer for OAI inspections when a regulatory action has been taken.

NOTE: The Status Date automatically records the date that the information is entered or updated in Initial, In Review, and Final Profile Status. It is important to maintain the integrity of the profile information by not changing this date.

**Foreign firms:** The Divisions enter the initial status only and the appropriate Center enters the final profile class status.

For inspections covering CDER-regulated products the Office of Pharmaceutical Quality Operations (OPQO) will be the business unit entering the profile decision (Initial - Final) for foreign NAI and VAI EIRs. For OAI, OPQO staff

will be entering the Initial and In-Review status and CDER will enter the final profile decision.

### 5-14.3.10 Final Profile Status

It is important for the Field and Centers to understand that final profile status should be promptly entered when a final agency decision has been made. Profiles should not be held in Pending status if the Division or Center decides that the course of action is to not take enforcement action as defined by FMD-86, and, instead, re-inspect.

#### 5-14.3.10.1 Other Status

Other should be entered as the final profile status for all profile class codes when a firm is operating under a consent decree (CD) or Application Integrity Policy (AIP). See Tables 5-14.1 & 5-14.2 above for more information.

#### 5-14.3.10.2 Acceptable Status

AC should be entered as the final profile status when an inspection is classified as NAI or VAI and the firm is not operating under a CD or AIP. See Table 5-14.1 above for more information. If an OAI is not supported by an enforcement action, it is entered as AC as defined in Field Management Directive (FMD)-86.

#### 5-14.3.10.3 Unacceptable Status

UN should be entered as the final profile status when there is an outstanding OAI inspection.

##### 5-14.3.10.3.1 Continuation of Unacceptable Status

A UN status along with the regulatory action taken may be carried forward from one inspection to the next when the follow-up inspection reveals the firm had not addressed the violations identified in the original OAI inspection or an enforcement action. In this case, it is important that the Remarks field note this condition. See 5-14.3.11 Remarks field for more information.

##### 5-14.3.10.3.2 Changing from Unacceptable to Acceptable Status

A UN status may be changed to AC when the agency's review of the firm's response to a warning letter reveals the firm's corrective actions adequately address the violations identified, a re-inspection for verification may or may not be warranted. The Remarks field must note the reason for the change.

### 5-14.3.11 Remark Status Field

The Remark Status field is used mainly to indicate the compliance status of a current inspection while the firm operates under a CD or AIP. See Tables 5-14.1 & 5-14.2 for more information and examples.

It may also be used to indicate an exception to the general compliance status. The profile status when under a CD will be "Others." The Remarks Status Field will show the current compliance inspection status (AC/UN). The Remarks Field will note that the firm is operating under a CD (include date and any information required concerning the current inspection).

### 5-14.3.12 Remarks Field

The Remarks field is a narrative field that is to be used as often as needed to:

1. Track the status of any potential or completed enforcement or alternative action with dates. This may include an explanation for a continuation of an UN final profile status from one inspection to the next when the follow up inspection reveals the firm's corrective actions were found inadequate. See Table 5-14.1 above or 5-14.4 below for more information and accessing the ORA/OISM/DSS/ESB intranet site, respectively.
2. Indicate when a firm is operating under a CD or AIP with date. Note when there are specific conditions such as product(s) subject to the CD or AIP. This information must remain in Remarks for each PC until the CD/AIP is vacated or revoked.
3. Indicate the regulatory action and date regulatory action was issued.
4. Identify product(s) covered when using the catch all PCs MIS for devices, BMI for biologics and NEC for drugs; and
5. Indicate where a sterilization process(es) takes place such as onsite at the manufacturer, or offsite by a contract sterilizer. If offsite, include the name, address, and FEI of the contract sterilizer.

NOTE: After entering the information once, a copy and paste method can be used to update the Remarks field for each profile class involved as follows:

- a. Highlight the narrative text by clicking in the Remarks field.
- b. Select CTRL C to copy.
- c. Select CTRL V to paste.

### 5-14.3.13 Out-of-Business Firm

When a profiled firm goes out of business, changes operations, or discontinues production of FDA regulated products, record the appropriate information in the eNSpect Application. From the Offline Field Client select the Firm Information tab followed by the Firm Profiling tab to discontinue each profile class code then select Save.

Navigate to the Assignment Details Page and select the **Convert to Investigation** followed by selecting the **OOB (Out of Business)** Washout Reason and confirm the selection. Synchronize to upload data to eNSpect Online.

From the Online Application select the assignment and Navigate to the Firm Overview tab. Select the Work Obligation as **N No** from the drop-down and select the **Save Assignment** button.

Once the Investigation is complete, the Out of Business data will get synched with the Firm Management Services and will update the firm's operational status to **Out of Business** and Work Obligation to **No**.

For assistance, contact the GWQAP Team. See 5-14.4 below for contact information.

### 5-14.3.14 Firm Merge

Before attempting to merge two or more firm records, always check to ensure all profile class codes have been finalized. Do not attempt to merge if the profile status is left in Initial or In Review. Merging firms where the profile classes are not finalized will cause problems that can only be resolved by GWQAP staff. See 5-14.4 below for contact information.

### 5-14.3.15 Troubleshooting

Troubleshooting information may be found at the GWQAP intranet site. See 5-14.4 for intranet site location.

### 5-14.4 Contact Information

To reach the Government Wide Quality Assurance Program select <http://inside.fda.gov:9003/ORA/Offices/OPOP/ISM/DSS/ucm557080.htm>. To contact the GWQAP Team email [gwqap@fda.hhs.gov](mailto:gwqap@fda.hhs.gov).

### 5-14.5 Data Quality Assurance Projects

Our GWQAP stakeholders, including the Department of Veterans Affairs (VA), the Defense Logistics Agency (DLA), as well as several Local, State, and Foreign Governments, use an external view of eNSpect profiles through the COMSTAT application to help them make procurement decisions for medical products. Since these stakeholders can view only the latest acceptable or unacceptable final profile status, profile classes **must** be finalized.

Each Division and Center is responsible for management of firm profiles specific to it by entering profile information and providing a profile status as soon as a final Agency



decision is made. The GWQAP Team in the Division of Systems Solution/Enforcement Systems Branch (DSS/ESB) is responsible for monitoring the Divisions and Centers profile entries and communicating with the same on profile issues when profile information is incomplete, incorrect, or missing. To accomplish this, on a quarterly basis, an Online Reporting Analysis Decision Support System (ORADSS) program is run. Duplicate entries and non-finalized profile entries are addressed and a follow up is made with the Divisions and Centers when incomplete entries and/or errors are found. This data is maintained in an Excel program. It is the responsibility of the GWQAP Team to assure that eNSpect and COMSTAT views are accurate, complete, and current.

Accessing and Running an ORADSS Report

1. From Inside. FDA select IT Applications located under Services.
2. Select ORA Applications and click the ORADSS link.
3. Select Folders in the lower left corner.
4. Select the + Public Folders.
5. Select + Domestic Reports.
6. Select Firms.
7. Select FIR034\_Profiles by Division.
8. A dialog box will appear to enter information
  - a. From the top of the dialog box, select the appropriate Home District.
  - b. Select GMP Insp Date (Start) by entering xx/xx/xxxx into the window that appears.
  - c. Select GMP Insp Date (End) by entering xx/xx/xxxx.
  - d. Select Enter to Run Query.
9. Saving the Report in Excel
  - a. From the toolbar, select the down arrow of Export.
  - b. Click Export Document as and select Excel.
  - c. Excel will open with the imported data.
10. Removing Duplicate Entries in eNSpect
  - a. Contact the GWQAP Team.

Under this procedure:

1. Profile Monitors are responsible for running quarterly reports from January 1- December 31.
2. The GWQAP Team is responsible for conducting quarterly work group meetings and to follow-up with each Division to ensure profiles are up-to-date.

5-14.6 Establishment Profile Criteria

Table 5-14.6.1 Device, Biologic, Drug, and Veterinary Establishments TO Profile

Manufacturer	Makes a new or a changed product from one or more ingredients.
Remanufacturer	Processes, conditions, renovates, repackages, restores, or performs any other act to a finished device that significantly changes the device's performance or safety specifications or intended use.
Reprocessor	Performs remanufacturing operations on a single use device.
Packer/ Repacker	Packs a product or products into different containers without making any changes in the form of the product.
Labeler/Relabeler	An establishment which affixes the original labeling to a product or changes in any way the labeling on a product without affecting the product or its container.
Contract Sterilizers	Performs sterilization or irradiation of products or components of products regulated by FDA on a contract basis.
Control Testing Laboratories	Performs production quality control work related to products regulated by FDA on a contract basis.
Assemblers of Medical Device Kits	Responsible for assembling finished devices into medical device kits.
Specification Developer	Initiates or develops specifications for a device that is distributed under the establishment's own name but is manufactured by a second person.
HCT/P Establishment	Manufactures licensed/approved HCT/Ps that are regulated under the FD&C Act, PHS 351, 21 CFR 1271 and the drug (CGMP), medical device (QSR) or biological product regulations, i.e. "351 HCT/Ps"

Table 5-14.6.2 Establishment and Operations NOT to Profile

Blood Banks
Methadone Clinics
Manufacturers of "Research Use Only" Products
Pharmacies (including pharmacy compounders) and Retail firms
Distributors
Plasmapheresis Centers
Custom Device Manufacturers
Veterinary Medical Device Firms
X-ray Assemblers
Mammography Clinics
Manufacturers of General Purpose Articles (Devices)
Physicians Offices, Hospitals and Clinics
Laser Light Shows/Television and Microwave Oven Manufacturers
Sun tanning Establishments
Device Component Manufacturers
Clinical Investigators/Bioresearch Monitoring
Any Non-GMP Inspection

HCT/P establishments that manufacture products regulated solely under PHS 361 and 21 CFR 1271, i.e. "361 HCT/Ps"
HCT/P establishments that manufacture unlicensed/unapproved products that are regulated under the FD&C Act, PHS 351, 21 CFR 1271 and the drug (CGMP), medical device (QSR) or biological product regulations, i.e. "351 HCT/Ps"

**Catch-all codes:** MIS for devices, NEC and CRU for drugs, and BMI for biologics can be used when product does not fit into any product class identified by the list of PCs. When using these codes, identify the type of product in the Remarks field for that code. If the product is a sterile product, don't forget to include the appropriate sterilization.

**5-14.6.3 Pre-Approval Inspections**

Pharma product specific Pre-Approval and Post Approval Inspections, should not be profiled unless the inspection is the initial inspection of a new profile class and the inspection results in an approval recommendation (VAI or NAI). Withhold recommendations for initial profile classes (the EI is classified as OAI) are not profiled, this assures the product cannot be marketed in the U.S. until a follow-up inspection verifies implementation of appropriate corrective actions or until corrections are substantially verified through other appropriate means.

Device Pre-Approval (PMA) inspections that cover the firm's systems should be treated like any other QS inspection. In all cases the initial profile status should be entered by the Investigator.

**5-14.7 Profile Classes and Codes**

The profile system is based upon product categories or classes and is not product specific. Select the most appropriate profile class(es) to describe the product(s) the firm manufactures or otherwise processes.

When describing devices, often more than one class is needed to describe the operations/assembly involved in the device. A rule of thumb is to think of the composition of the device and then select the profile classes that define the make-up of that device and its assembly. For example, a catheter and needle unit is profiled as MTL (metal fabrication and assembly) and PRF (plastic or rubber fabrication and assembly). A Cutter, orthopedic cast, 110 volt AC-DC, is profiled as MTL, PRF and ELE (electrical) For devices that have software and are operated by computer, codes COS (software) and COH (computer hardware) should be added.

SPD (specification developer) should be used if a firm only develops the design and specifications and has the device manufactured by someone else. Do not include other profile classes unless the firm also manufactures other medical products on-site.

When describing combination product (see IOM 5.12.1) multiple profile codes may be needed. (e.g. for a combination product CGMP inspection of a facility manufacturing a sterile- filled prefill syringe, use profile codes SVS-Sterile-filled small volume parenteral drugs and IDD-injectable delivery device (syringes, auto injectors/pens)).

**5-14.7.1 Profile Class Codes**

For more information, contact your Division Profile Monitor or the GWQAP team. See 5-14.4 for contact information.

**Table 5-14.7.1.1 Biologics**

BIOLOGICS	
Profile Class Code	Definitions
AEV	ANTITOXINS AND ANTIVENINS
AFP	ANIMAL DERIVED FRACTIONATION PRODUCTS
ALP	ALLERGENIC PRODUCTS
BBP	BLOOD AND BLOOD PRODUCTS UNLICENSED
BGR	BLOOD GROUPING REAGENTS
BMI	BIOLOGICAL PRODUCTS NOT OTHERWISE CLASSIFIED (Blood collection bags with anti-coagulant, plasma volume expanders, Limulus Amebocyte Lysate (LAL) test kit, etc.; Note specific product(s) in <i>Remarks</i> field)
CBS	COMPUTER BIOLOGICAL SOFTWARE
CGT	CELL AND GENE THERAPY PRODUCTS
HFP	HUMAN DERIVED FRACTIONATION PRODUCTS
LBI	LABORATORY, BIOLOGICAL TESTING
RBD	RECOMBINANT ANALOGUES OF BLOOD DERIVATIVE PRODUCTS
TIS	HUMAN TISSUE REGULATED BY FDA
VBP	VACCINE BULK PRODUCT
VFP	VACCINE FINISHED PRODUCT
VIV	IN VIVO DIAGNOSTICS
VTK	VIRAL MARKER TEST KIT

**Table 5-14.7.1.2 Devices**

DEVICES	
Profile Class Code	Definitions
AMP	ADDITIVE MANUFACTURING PROCESS (incl. 3D printing, additive manufacturing medical products)
CCR	CLINICAL CHEMISTRY REAGENTS (including diagnostic tapes, sticks, etc.)
COH	COMPUTER HARDWARE
COS	COMPUTER SOFTWARE (Devices only)
CSP	CHEMICAL STERILIZATION
CTD	CONTROL TESTING LABORATORIES "ALSO"

	(Device manufacturer that is also a contract testing lab.)
DKA	DEVICE KIT ASSEMBLER (Ex: lumbar puncture kit, anesthesiology kit, suture removal kit)
ELE	ELECTRICAL ASSEMBLY
FSP	FILTRATION STERILIZATION
GLA	GLASS OR CERAMIC FABRICATION AND ASSEMBLY
GSP	GAS (ETO, PROPYLENE OXIDE STERILIZATION )
HCP	HEMATOLOGY AND COAGULATION PRODUCTS
HSP	DRY HEAT STERILIZATION
HTD	HUMAN TISSUE DEVICES
IDD	INJECTABLE DELIVERY DEVICE (syringes, auto injectors/pens)
MED	MEDIA (including microbiological and tissue culture, growth media and accessories, and ingredients)
MIS	NOT ELSEWHERE CLASSIFIED (Note specific product(s) in <i>Remarks</i> field)
MSO	METERED SPRAY OTHER (incl. nasal sprays, sublingual sprays)
MTL	METAL FABRICATION AND ASSEMBLY
OID	ORALLY INHALED DELIVERY (incl. MDIs, DPIs, sprays)
OPT	OPTIC FABRICATION AND ASSEMBLY (Optical products or parts, e.g., eye glass lenses, intraocular lenses, contact lenses, lens portion of a laser, etc.)
PAT	PATCH (incl. conventional patches, micro needles)
PBM	PROCESSED BIOLOGIC MATERIAL (Only animal or plant material used as a device)
PRF	PLASTIC OR RUBBER FABRICATION AND ASSEMBLY
RIP	RADIOIMMUNOASSAY PRODUCTS
RSP	RADIATION STERILIZATION
SIP	SEROLOGICAL AND IMMUNOLOGICAL PRODUCTS (Including bacterial typing, rheumatoid factors, pregnancy kits, IVD other than VIRAL marker test kits, etc.)
SOL	DEVICE SOLUTIONS AND GELS (Including contact gels, dialysis solutions, dental pastes, adhesives, etc.)
SPD	SPECIFICATION DEVELOPERS (Note in <i>Remarks</i> field where finished product testing is conducted.)
SSP	STEAM STERILIZATION
TSP	FRACTIONAL TYNDALLIZATION STERILIZATION
TXT	TEXTILE FABRICATION AND ASSEMBLY
WOD	WOOD FABRICATION AND ASSEMBLY
WSP	WATER STERILIZATION

AMT	ADVANCED MANUFACTURING TECHNOLOGIES (including 3D printing, continuous drug manufacturing)
CBI	RECOMBINANT/NON-RECOMBINANT PROTEIN DS OF BIOLOGIC ORIGIN
CEX	STARTING/INTERMEDIATE DERIVED FROM PLANT/ANIMAL EXTRACTION
CFN	NON-STERILE API BY FERMENTATION
CFS	STERILE API BY FERMENTATION
CHG	CAPSULES, PROMPT RELEASE
CRU	NON-STERILE STARTING/INTERMEDIATE/NEC (not Plant/Animal)
CRX	STERILE STARTING/INTERMEDIATE/NEC (not Plant/Animal)
CSG	CAPSULES, SOFT GELATIN
CSN	NON-STERILE API BY CHEMICAL SYNTHESIS
CSS	STERILE API BY CHEMICAL SYNTHESIS
CTR	CAPSULES, MODIFIED RELEASE
CXA	PURIFIED API DERIVED FROM PLANT/ANIMAL EXTRACTION
EXC	EXCIPIENT (also referred to as inactive ingredient)
GAS	MEDICAL GAS (includes liquid oxygen)
HMA	HOMEOPATHIC API/drug substance/tinctures
HMF	HOMEOPATHIC FINISHED DRUG PRODUCTS
LCP	LABORATORY, CHEMICAL/physical testing
LIQ	NON-STERILE LIQUID (other than suspensions & emulsions)
LMN	LABORATORY, MICROBIOLOGICAL-non-sterility testing
LMS	LABORATORY, MICROBIOLOGICAL-sterility testing
LVP	LARGE VOLUME PARENTERALS
PTC	PATCH (incl. conventional patches, no micro needles)
NEC	NOT ELSEWHERE CLASSIFIED FINISHED DRUG
OIN	OINTMENT, NON-STERILE (includes cream, jelly, paste)
PET	POSITRON EMISSION TOMOGRAPHY
POW	NON-STERILE POWDERS (Includes oral and topical)
SES	SUSPENSIONS AND EMULSIONS (NON PARENTERALS)
SLQ	STERILE LIQUID (other than suspensions & emulsions)
SON	STERILE OINTMENT
SPW	STERILE POWDER
SUP	SUPPOSITORIES
SVL	SMALL VOLUME PARENTERALS (Lyophilized)
SVS	STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS
SVT	TERMINALLY STERILIZED SMALL VOLUME PARENTERALS
TCM	TABLETS, PROMPT RELEASE
TCT	TABLETS, DELAYED RELEASE
TDP	TRANSDERMAL PATCHES
TTR	TABLETS, EXTENDED RELEASE

Table 5-14.7.1.3 Drugs and Veterinary

DRUGS	
Profile Class Code	Definitions
ADM	AEROSOL DISPENSED MEDICATION

NOTE: API - Active Pharmaceutical Ingredient is sometimes referred to as Drug Substance.

**Table 5-14.7.1.4 Special Veterinary**

<b>Profile Class Code</b>	<b>Definitions</b>
IMN	IMPLANT NON-STERILE
IMS	IMPLANT STERILE
TAM	TYPE A MEDICATED ARTICLE

### 5-15 COMPLIANCE ACHIEVEMENT REPORT

**FACTS Version 4.9.01 - [Compliance Achievements]**

Action Edit Navigate Tracing Window Help

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**Compliance Achievements**

**Firm**

Firm:  Organization:  Home District:

Address:  Home District:

**Reported By**

Organization:  Employee:  Home District:

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**Corrective Actions**

Product Code	PAC	Problem Type	Corrective Action	Verification Date	Reporting Organization	Correcting Organization
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Reason for Correction:  Remarks:  Description:

---

**Linked Operations**

Op ID	Type of Operation	Unique ID	Accomplishing Organization	Performing Organization	Status	Status Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

### 5-16 FACTS REIMBURSABLE CHECK BOX

Screenshot showing location of Reimbursable check box:

**Inspection Accomplishment Hours**

**Operation**

Operation Code: 12 - Domestic Inspection      Work Subject / Title: MN Seafood FY 05

Assignment Status: In Progress      Status Date: 07/27/2005      Reimbursable:

Performing Org.: MIN-GRP6

**Assignees Accomplishment Hours**

Lead	Employee	Position	Hours	PAC	Est	Process	Hours
Invstgr	Name	Class	Credited To		Type		
<input checked="" type="checkbox"/>	Rogers, Sidney H	INV	MIN-DO				
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							

Total Hours:

Add  
Delete  
Duplicate

5-17 FORM FDA 4056 - PRODUCE FARM INSPECTION OBSERVATIONS



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration



PRODUCE FARM INSPECTION OBSERVATIONS

Name of State and Department (if acting under commission with FDA)		DISTRICT OFFICE ADDRESS	
DISTRICT OFFICE PHONE NUMBER	DATE(S) OF INSPECTION	FEI NUMBER	
LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED (Most responsible individual present) TO:			
FARM NAME (include business name, if different)			
OWNER/OPERATOR			
FARM MAILING ADDRESS		FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS (e.g., location identifiers such as GPS coordinates)	
TYPE OF INSPECTION: <input type="checkbox"/> Initial <input type="checkbox"/> Routine <input type="checkbox"/> Follow-up <input type="checkbox"/> For-cause <input type="checkbox"/> Other (please specify) _____		CROPS OBSERVED DURING INSPECTION	

This form lists factual observations made by the FDA representative(s) during the inspection of the farm's operation.

**This is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule (21 CFR Part 112) or any other legal requirement.**

Representatives of the regulatory agency should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. Representatives of the regulatory agency should record observations in the topic area listed below that, in the representatives' judgment, is the most appropriate topic. Not all topic areas may be applicable in every situation. In addition, representatives of the regulatory agency may not examine every aspect of the farm's operation during an inspection, so a topic area left blank should not be interpreted to mean the farm is in compliance, or not in compliance, with requirements related to that topic area.

Representatives of the regulatory agency should discuss all observations with the management of the farm or their representative as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when this form is issued. Discussion should include those observations which may be written on the form and those that will only be discussed with management during the closeout meeting. This form should be issued during the exit conference of all produce inspections, including when no observations have been recorded.

The farm may use this opportunity to ask questions about the observations or to request clarification. If the farm has implemented, or plans to implement, corrective action in response to an observation, this may be discussed with the representatives of the regulatory agency during the inspection. Representatives of the regulatory agency should annotate the form, as applicable, with any completed or promised corrections discussed during the inspection. FDA representatives are encouraged to verify the farm's completed corrective actions during the inspection as long as the verification does not unreasonably extend the duration of the inspection. Inclusion of annotations regarding corrective actions does not signify any conclusion by the regulatory agency regarding the sufficiency of the actions.

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION

FEI NUMBER

If you have any questions, please contact the regulatory agency at the phone number and address above.

Representatives of the regulatory agency should record observations consistent with procedures established for conduct of inspections, including additional instructions that appear in Chapter 5 of the IOM, available at <https://www.fda.gov/ICECI/Inspections/IOM>.

**REPORTABLE OBSERVATIONS MADE DURING THE INSPECTION**

Representatives of the regulatory agency should check one of the following options. As noted above, this is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule (21 CFR Part 112) or any other legal requirement.

- During an inspection of the operation (I) (we) did not observe any conditions and/or practices to be reported on this form.
- During an inspection of the operation (I) (we) observed the following conditions and/or practices as described below.

**Personnel Qualifications and Training (21 CFR Part 112, Subpart C)**

1. §§ 112.21 and 112.22: Qualifications and training for personnel who handle (contact) covered produce or food contact surfaces

- Observation     Corrective action taken

Description:

2. § 112.23: Assignment or identification of supervisors

- Observation     Corrective action taken

Description:

3. § 112.30: Record-keeping

- Observation     Corrective action taken

Description:

**Health and Hygiene (21 CFR Part 112, Subpart D)**

4. § 112.31: Measures to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance

- Observation     Corrective action taken

Description:

5. § 112.32: Hygienic practices of personnel

- Observation     Corrective action taken

Description:



FARM NAME (include business name, if different)

DATE(S) OF INSPECTION

FEI NUMBER

6. § 112.33: Measures to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance

Observation  Corrective action taken

Description:

[Redacted description area]

**Agricultural Water (21 CFR Part 112, Subpart E)**

7. § 112.41: Quality of agricultural water

Observation  Corrective action taken

Description:

[Redacted description area]

8. § 112.42: Agricultural water sources, water distribution system, and pooling of water

Observation  Corrective action taken

Description:

[Redacted description area]

9. § 112.43: Treating agricultural water

Observation  Corrective action taken

Description:

[Redacted description area]

10. § 112.44: Microbial quality criteria applicable to agricultural water used for certain intended uses

Observation  Corrective action taken

Description:

[Redacted description area]

11. § 112.45: Corrective measures if agricultural water does not meet requirements of § 112.41 or § 112.44.

Observation  Corrective action taken

Description:

[Redacted description area]

12. §§ 112.46 and 112.47: Testing agricultural water that is subject to the requirements of § 112.44.

Observation  Corrective action taken

Description:

[Redacted description area]

13. § 112.48: Water that is used during harvest, packing, and holding activities

Observation  Corrective action taken

Description:

[Redacted description area]

14. § 112.50: Record-keeping

Observation  Corrective action taken

Description:

[Redacted description area]

FARM NAME (include business name, if different)

DATE(S) OF INSPECTION

FEI NUMBER

**Biological Soil Amendments of Animal Origin and Human Waste (21 CFR Part 112, Subpart F)**

15. § 112.52: Handling, conveyance, and storage of biological soil amendments of animal origin

Observation  Corrective action taken

Description:

[Description area]

16. § 112.53: Use of human waste

Observation  Corrective action taken

Description:

[Description area]

17. §§ 112.51, 112.54, 112.55, and 112.56: Determining status of biological soil amendment of animal origin; acceptable treatment processes; applicable microbial standards for such treatment processes; and, application requirements and minimum application intervals for biological soil amendments of animal origin

Observation  Corrective action taken

Description:

[Description area]

18. § 112.60: Record-keeping

Observation  Corrective action taken

Description:

[Description area]

**Domesticated and Wild Animals (21 CFR Part 112, Subpart I)**

19. § 112.83: Measures related to grazing animals, working animals, or animal intrusion

Observation  Corrective action taken

Description:

[Description area]

**Growing, Harvesting, Packing, and Holding Activities (21 CFR Part 112, Subpart K)**

20. § 112.111: Measures related to growing, harvesting, packing, or holding both covered and excluded produce

Observation  Corrective action taken

Description:

[Description area]

21. § 112.112: Measures to be taken immediately prior to and during harvest activities

Observation  Corrective action taken

Description:

[Description area]

22. § 112.113: Handling harvested covered produce

Observation  Corrective action taken

Description:

[Description area]

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER
-----------------------	------------

23. § 112.114: Disposition of dropped covered produce

Observation     Corrective action taken

Description:

[Redacted description area]

24. § 112.115: Measures related to packaging covered produce

Observation     Corrective action taken

Description:

[Redacted description area]

25. § 112.116: Measures related to food-packing (including food-packaging) material

Observation     Corrective action taken

Description:

[Redacted description area]

**Equipment, Tools, Buildings, and Sanitation (21 CFR Part 112, Subpart L)**

26. § 112.123: Equipment and tools

Observation     Corrective action taken

Description:

[Redacted description area]

27. § 112.124: Instruments and controls used to measure, regulate, or record

Observation     Corrective action taken

Description:

[Redacted description area]

28. § 112.125: Equipment used in the transport of covered produce

Observation     Corrective action taken

Description:

[Redacted description area]

29. § 112.126: Buildings

Observation     Corrective action taken

Description:

[Redacted description area]

30. § 112.127: Domesticated animals in and around a fully-enclosed building

Observation     Corrective action taken

Description:

[Redacted description area]

31. § 112.128: Pest control in buildings

Observation     Corrective action taken

Description:

[Redacted description area]

FARM NAME (include business name, if different)

DATE(S) OF INSPECTION	FEI NUMBER
-----------------------	------------

32. § 112.129: Toilet facilities

Observation     Corrective action taken

Description:

[Description area]

33. § 112.130: Hand-washing facilities

Observation     Corrective action taken

Description:

[Description area]

34. § 112.131: Control and disposal of sewage

Observation     Corrective action taken

Description:

[Description area]

35. § 112.132: Control and disposal of trash, litter, and waste

Observation     Corrective action taken

Description:

[Description area]

36. § 112.133: Plumbing

Observation     Corrective action taken

Description:

[Description area]

37. § 112.134: Control of animal excreta and litter from domesticated animals

Observation     Corrective action taken

Description:

[Description area]

38. § 112.140: Record-keeping

Observation     Corrective action taken

Description:

[Description area]

**Sprouts (21 CFR Part 112, Subpart M)**  
 Check here if entity does not engage in growing, harvesting, packing, and/or holding of sprouts

39. § 112.142: Seeds or beans used to grow sprouts

Observation     Corrective action taken

Description:

[Description area]

40. § 112.143(a): Fully-enclosed buildings

Observation     Corrective action taken

Description:

[Description area]

FARM NAME (include business name, if different)

DATE(S) OF INSPECTION

FEI NUMBER

41. § 112.143(b): Cleaning and sanitizing food-contact surfaces

Observation  Corrective action taken

Description:

[Redacted description area]

42. §§ 112.144(a), 112.145, and 112.148: Environmental monitoring for *Listeria* species or *L. monocytogenes* (written environmental monitoring plan, collection and testing, corrective actions)

Observation  Corrective action taken

Description:

[Redacted description area]

43. §§ 112.144(b) and (c), 112.147 and 112.148: Testing spent irrigation water or in-process sprouts for pathogens (written sampling plan, collection and testing, corrective actions)

Observation  Corrective action taken

Description:

[Redacted description area]

44. § 112.150: Record-keeping

Observation  Corrective action taken

Description:

[Redacted description area]

**Records (21 CFR Part 112, Subpart O)**

45. § 112.161 - 112.167: General record-keeping

Observation  Corrective action taken

Description:

[Redacted description area]

**Other Observations**

46. Other

Observation  Corrective action taken

Description:

[Redacted description area]

FDA REPRESENTATIVE SIGNATURE

FDA REPRESENTATIVE(S) NAME AND TITLE (Print or Type)

DATE ISSUED

[Redacted signature]

[Redacted name and title]

[Redacted date]

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION

FEI NUMBER

**Continuation Sheet**

Additional Observations and/or Comments

Large light blue rectangular area for entering additional observations and/or comments.

Continue

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION

FEI NUMBER

The observations of conditions and practices listed on this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug, and Cosmetic Act, or
2. To assist firms inspected in complying with applicable laws and regulations.

Any reference to this report in labeling, advertising, or other sales promotion by any person is prohibited under Section 301(n) of the Federal Food, Drug and Cosmetic Act.

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# CHAPTER 6 - IMPORTS

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## SUBCHAPTER 6.1 - IMPORTS

### 6.1.1 - AUTHORITY

Section 801 of the FD&C Act [21 U.S.C. 381] authorizes FDA examination of foods, drugs, cosmetics, devices, and tobacco products offered for entry into the United States. Section 536 of the FD&C Act [21 U.S.C. 360mm] authorizes refusal of radiation emitting products which fail to comply with the requirements of Section 534 (h) of the FD&C Act [21 U.S.C. 360kk (h)]. 19 CFR 151.4 of the U.S. Customs and Border Protection (CBP) regulations authorizes employees of FDA to examine or take samples of entry goods released under immediate delivery.

The procedures outlined in this chapter cover imported goods subject to, but not limited to, the following Acts/Regulations:

1. Federal Food, Drug, and Cosmetic Act (FD&C)
2. Fair Packaging and Labeling Act (FPLA)
3. Nutrition Labeling and Education Act (NLEA)
4. Import Milk Act/ Filled Milk Act
5. Federal Caustic Poison Act Bioterrorism Act
6. Public Health Service Act, Part, Part F, Subpart 1, Biologic Products
7. Title 21 CFR Subpart E - Imports and Exports (1.83), etc.
8. Title 19 CFR Customs Duties (authority to sample delegated by CBP Regulations, etc.)
9. Federal Cigarette Labeling and Advertising Act Comprehensive Smokeless Tobacco Health Education Act
10. Family Smoking Prevention and Tobacco Control Act

**6.1.2 – IMPORT INVESTIGATIONS**

Import operations, normally focus on entry review, field examinations, and sample collections. However, investigations are an essential tool in uncovering and developing evidence documenting violations such as entry misdeclaration, product substitutions, and “port shopping.” Invaluable sources of information include: Import Alerts, assignments from headquarters or other districts, interagency cooperation and local intelligence.

When documenting these situations, your supervisor may request a memo of investigation or an Establishment Inspection Report (EIR) to be sent to the compliance branch. Follow your district procedures, IOM Chapter 5 for preparation of the EIR and IOM Subchapter 8.1.9. for preparation of memorandums.

When examining, sampling, or following up on refused imported products you may use an affidavit to document the facts surrounding the situation. Refer to IOM 4.4.8 and Exhibit 6-5 for guidance on preparation of an affidavit.

**6.1.3 - INVESTIGATIONS INVOLVING THE IMPORTATION PROCESS**

During the importation process, FDA personnel encounter attempts to bypass proper FDA record review, inspection and/or sampling as well as the willful attempt to import goods known to violate the Act. In addition to FDA detention, refusal, and placement onto an Import Alert, FDA performs investigations and forwards the evidence collected to support a recommendation for CBP sanction under Title 19 which include administrative seizures, civil money penalties, revocation of conditional release privileges, and bond actions (liquidated damages, increases to bond amount, requirement of single-transaction bond).

**6.1.3.1 - Import Violation Patterns**

The below investigational points should be covered to promote a thorough investigation. Any given situation may overlap into more than one pattern. While not an exhaustive list, the following four patterns may be encountered:

- 1. Failure to hold (See IOM 6.1.3.2)
- 2. Substitution (See IOM 6.1.3.5)
- 3. Importer misdeclaration (See IOM 6.1.3.6)
- 4. Filer misdeclaration (See IOM 6.1.3.7)

**6.1.3.2 - Failure To Hold**

‘Failure to hold’ means that the goods have been distributed by the importer/consignee without an FDA release from import status. Please note that this is defined as distribution without a release, not merely moving the goods outside of the port area. FDA personnel may encounter this situation at various points in the importation process including initial exam/inspection, sample collection, audit sample collection, reconciliation examination after a health hazard finding, verification of a reconditioning, and refusal verification. The following steps should be taken on all failure to hold cases:

1. Collect entry documentation (CBP form 3461 or 7501, invoice, packing list, bill of lading).
2. Determine distribution - collect and analyze pertinent distribution records.
3. Determine who authorized the distribution. (There may be more than one responsible party.)
4. Determine if the importer was aware of the health hazard associated with the product.
5. Obtain the authorizing person’s explanation as to why the goods were distributed. Items (1), (2), (3), (4), and (5) should be covered in one or more affidavits.
6. Perform a data search via ORADSS or other means to determine the importer’s history and discuss relevant findings with supervisory and compliance staff.
7. Coordinate with CBP the issuance of a Demand for Redelivery (form 4647) if one has not already issued per a refusal. Form 4647 can be issued for the purposes of examination/sampling, not merely as a result of an FDA refusal. In such circumstances, the deadline for redelivery is 30 days instead of the 90 days post-refusal.
8. Determine the importer’s bond type and amount.

**6.1.3.3 - Failure To Hold – Health Hazards – Direct FDA Evidence**

Distribution of goods where there is direct evidence of a significant health hazard, such as an FDA finding of *Salmonella* contamination in a ready-to-eat food entry, should be regarded as a concern of the highest priority. In addition to the eight common elements listed above, the following additional step should be taken:

- Consult with supervisory staff, compliance staff, and the district’s Recall and Emergency Coordinator as needed to address retrieval from and/or notification to the consignees, as well as consideration for any public warning.

**6.1.3.4 - Failure To Hold - Health Hazards – Detention Without Physical Examination (DWPE)**

Distribution of goods where there is evidence of a significant health hazard which only meets the appearance of a violation evidentiary standard (the standard under the 801(a) admissibility process) such as an entry of a ready-to-eat food detained without physical examination (DWPE) due to a history of *Salmonella* contamination, should be regarded as a concern of high priority. In addition to the eight common elements listed above, the following additional steps should be taken:

1. Consult with supervisory staff and compliance staff as needed to determine if the FDA should collect samples for analysis.
2. Consult with supervisory staff, compliance staff, and the district’s Recall and Emergency Coordinator as needed to address retrieval from and/or notification to the consignees, as well as consideration for any public warning.

**6.1.3.5 - Substitution**

Substitution is an attempt by the importer or importer’s agent to present goods to FDA as corresponding to a particular entry when they are in fact not the goods from

that entry. FDA personnel may encounter this situation at various points in the importation process including initial exam/inspection, sample collection, audit sample collection, reconciliation examination after a health hazard finding, verification of a reconditioning, and redelivery examination. Substitution may occur as an attempt to hide distribution without FDA release (Failure to Hold). The investigation may reveal negligence, gross negligence or fraud. The following steps should be taken when evidence of substitution is encountered:

1. Confirm that the goods are being presented to FDA as corresponding to a particular entry. In some situations, you may only be able to show associated entry documents to the importer or importer's agent and request confirmation that the goods presented correspond to that entry. Confirmation can be accomplished by performing the following steps:
  - a. Collect all available evidence supporting the presented goods were substituted. This may include labeling, lot codes, and the condition of the goods themselves. Photos are invaluable. Examination of the entire shipment would minimize the possibility the importer will be able to successfully claim that the portion not examined was in fact not substituted.
  - b. Collect all available evidence to show any attempt to conceal the substitution. For example, in a partially substituted entry the substituted goods are in the center, bottom position on a pallet, or placement of the substituted goods is in the front position of the trailer.
2. Determine the importer's or importer's agent's explanation for the discrepancies. Collect this in an affidavit along with a description of the declared/actual goods and the substituted goods.
3. Until it is determined otherwise, consider all substitution cases to involve distribution of the actual goods without FDA release. See IOM 6.1.3.2 FAILURE TO HOLD.

### 6.1.3.6 - Importer Mideclaration

Importer mideclaration refers to the importer's provision of incorrect and/or incomplete information to FDA and CBP, usually via the filer. When FDA personnel encounter this situation, it is usually during the initial examination or sampling of the entry. It may be the case that the investigation reveals negligence, gross negligence or fraud. The following examples may apply:

1. The importer provides information to the filer that does NOT include a product that is actually present in the entry and as a result that product is not included in the declaration (undeclared goods).
2. The importer provides the filer information that a product is manufactured by firm X, when it is in fact manufactured by firm Y. As a result, the filer declares the product as manufactured by firm X (mis declared goods).

### 6.1.3.7 - Filer Mideclaration

Although this section is oriented to filer interventions, it must always be recognized the filer is the agent of the importer and the importer is ultimately responsible. Filer mideclaration refers to the importer's provision of correct

information to the filer who then files an erroneous entry to (CBP). The following examples may apply:

1. The filer omits a product properly listed on the entry invoice from the declaration (undeclared goods).
2. The importer provides the filer information that a product is manufactured by firm X, but the filer declares it as manufactured by firm Y (mis declared goods).
3. The importer provides an invoice to the filer that lists product X, but the filer declares product Y. When FDA personnel encounter this situation, it is usually during the initial examination or sampling of the entry (mis declared goods).
4. The filer selects a food Process Identification Code (PIC) for packaged food (which should only be selected when no other PIC applies, per the instructions of the FDA's Product Code Builder on the Web) when the broker does not have sufficient information to determine if any other PIC applies (mis declared goods).

### 6.1.3.7.1 - REPEATED FILER MISDECLARATION

In the event a filer continues to mis-declare a product to CBP or FDA and/or continues to introduce or present to CBP or FDA any erroneous types of documentation which may violate the FD&C Act; the following steps should be taken:

1. Document what information was available to the filer to file the entry. Collect any relevant records not already obtained.
2. Document the undeclared or mis declared products through the collection of labeling and/or photos.
3. Obtain the filer's explanation for the discrepancies. Collect this in an affidavit along with (1).
4. It may be necessary to also collect an affidavit from the importer in some fact patterns. For example, if a filer declares a cosmetic product code for fluoridated toothpaste because the importer failed to provide the filer information about whether the toothpaste did or did not contain fluoride, it may be necessary to collect that information via an affidavit from the importer.
5. A Filer Evaluation should be conducted to examine records and to determine the extent of the problem. FDA should gather enough evidence to support a possible broker penalty and the following should be considered:
  - a. If the filer has no history of filing erroneous entries to FDA, Districts should consider further training and or placing the filer back to phase 1 filing status and withhold a request to assess a broker penalty against the filer.
  - b. If the filer has a history of filing erroneous entries to FDA and the filer continues to disregard FDA's attempts to provide guidance, train, and document guidance provided of filing entries through the Automated Broker Interface (ABI), FDA should contact (CBP) to request a broker penalty be assessed against the filer.

### 6.1.3.8 - Reporting Investigations Involving the Importation Process

An investigational memo with supervisory endorsement should be generated for all instances described under IOM 6.1.3.1 (import violation patterns), IOM 6.1.3.7 (filer

misdeclaration), IOM 6.1.3.5 (substitution) and IOM 6.1.2 (import investigations). The memo should normally be provided to supervisory staff for endorsement within ten business days of the last investigational activity. The memo should normally be endorsed by supervisory staff within five business days. Memos that are endorsed for regulatory consideration should then be forwarded to Compliance for further follow-up. If no memo is generated, then the importer and/or broker should be advised, and that advisement should be documented in accordance with district policy.

## SUBCHAPTER 6.2 - IMPORT PROCEDURES

### 6.2.1 - SCOPE

The procedures in this section cover imported goods. Your personal safety during any import procedures outlined in this subchapter is important. For more information concerning personal safety, see IOM 5.2.1.2.

### 6.2.2 - DIVISION OF AUTHORITY

FDA determines if an article is in compliance with the Acts it enforces. It also determines whether or not the article can be brought into compliance with the appropriate statute and authorizes reconditioning for that purpose.

Supervision over the reconditioning is exercised by either FDA or CBP as mutually arranged. At ports in reasonably close proximity to an FDA office, supervision is ordinarily exercised by FDA. At remote ports supervision may be exercised by CBP.

The refusal of admission, exportation, or destruction of goods is carried out under the direction of Customs. However, at some ports the actual supervision of the destruction of violative goods may be conducted by FDA pursuant to a local FDA/Customs agreement.

### 6.2.3 - ENTRIES

#### 6.2.3.1 - Formal Entries

All articles offered for entry into the U.S. and subject to the Acts enforced by FDA, with a value greater than \$2,500 (current), are considered formal entries. They are subject to bond requirements, which include a condition for the redelivery of the goods, or any part of it, upon demand by CBP at any time, as prescribed for in the CBP regulations in force on the date of entry. (section 801(b) of the FD&C Act [21 U.S.C. 381(b)], 19 CFR Part 113) The bond is filed with CBP which, in case of default, takes appropriate action to effect the collection of liquidated damages provided for in the bond after consultation with FDA. (19 CFR Section 113.62 and 21 CFR Section 1.97).

Notification of the CBP entry is generally accomplished by electronic submission through the CBP Automated Commercial Environment (ACE). Non-electronic entries are

submitted directly to FDA. Electronic entries received by FDA may be subject to on screen review (OSR) to determine if further action is needed, or if full documentation must be submitted. For entries requiring further review, FDA will be provided the appropriate CBP Entry documents (CF 3461/3461ALT, commercial invoice, bill of lading and any other relevant documents to aid in making an admissibility decision), which also document interstate commerce. If an entry is not filed electronically, these documents will be submitted to FDA at the time CBP entry is made, in accordance with local port operations.

#### 6.2.3.2 - Informal Entries

Normally, informal entries (value less than \$2,500 currently) do not require posting a redelivery bond. All informal entries of articles subject to FDA jurisdiction, entered electronically, are forwarded to FDA through the CBP/FDA ACE interface. When FDA takes action on an informal entry not filed electronically by the filer, FDA personnel will input the informal entry into FDA import systems (ER, SERIO, OASIS) as a manual entry. When taking FDA action with an informal entry, CBP will be requested to convert it into a formal consumption entry.

#### 6.2.3.3 - Mail/Personal Baggage

In the case of imports by mail or personal baggage, FDA districts should arrange for coverage with their local CBP International Mail Office or border crossing office. This should include agreements designating who is responsible for coverage, when (how often), etc. CBP is responsible for examination of personal baggage. If an article subject to FDA review is encountered, the CBP officer will determine if it should be brought to the attention of the local FDA office. Personal importations meeting the criteria of a formal entry will be processed in accordance with normal non-electronic entries. Generally, since most personal importations are small in size and value, guidance has been developed for evaluating these importations. (See RPM Chapter 9-2"Coverage of Personal Importations".)

"Section 321 entries" for CBP are those entries with a value of \$800 or less. Generally, this form of entry applies to articles which pass free of duty and tax, and are imported by one person, on one day (19 C.F.R. 101.1 (o)). CBP and FDA may conduct periodic "blitzes" to determine the volume and type of FDA-regulated goods admitted under "Section 321 entries." The use of the 321 entry process should not apply to multiple shipments covered by a single order or contract, sent separately for the express purpose of securing free entry and avoiding compliance with pertinent law or regulation.

#### 6.2.3.4 – Import for Export (IFE) Entries

PRODUCTS IMPORTED UNDER THE PROVISIONS OF SECTION 801(d)(3) OF THE FD&C Act [21 U.S.C. 381 (d)(3)]: Import For Export (IFE) Processing and Follow-Up

**PURPOSE:** To establish procedures facilitating the uniform review of Import for Export (IFE) at the time of entry and domestic follow up to insure articles entered as Import for Export are either exported or destroyed but not distributed domestically.

**REFERENCES:** Regulatory Procedures Manual Chapter 9-15, Federal Food, Drug, and Cosmetic Act

**BACKGROUND:** Section 801(d)(3) of the FD&C Act [21 U.S.C. 381 (d)(3)] allows the importation of certain violative FDA-regulated articles into the U.S. on a conditional basis that they are not for domestic distribution. Those articles include human and veterinary drugs (or their components); device components or accessories, or other devices requiring further processing for health-related purposes; and food additives, color additives and dietary supplements including in bulk form. They must be explicitly intended for further processing or incorporation into other products and subsequent export.

Documentation required at the time of importation under section 801(d)(3) of the Act [21 U.S.C. 381 (d)(3)] includes:

1. A statement that article is intended to be further processed or incorporated into a drug, biologics product, device, food, food additive, color additive or dietary supplement that will be exported under sections 801(e) or 802 of the FD&C Act [21 U.S.C. 381 (e) or 382] or section 351(h) of the Public Health Service Act (PHSA);
2. Information to identify the manufacturer of the article and each processor, packer, distributor, or other entity in chain of possession from manufacturer to importer;
3. Such certificates of analysis as necessary to identify the article, unless it is a device or falls under section 801 (d)(4) of the FD&C Act [21 U.S.C. 381 (d)(4)] - blood and blood components;

In addition, an IFE applicable bond must be executed providing for payment of liquidated damages in accordance with CBP requirements.

### 6.2.3.4.1 – IFE ENTRY REVIEW

Import for Export entry procedures are as follows:

1. If electronic submission is made, it is unlikely all of the information required under section 801(d)(3) FD&C Act [21 U.S.C. 381 (d)(3)] will be provided electronically. Divisions should request the supporting documents (if not already received from the broker or importer) by setting an entry option of Documents Requested (DRQ) and/or Entry Incomplete (DEF) on all entries with IFE in the Affirmation of Compliance (AOC) field, or those suspected to be IFE, which lack complete supporting documents.
2. If the entry is indeed an IFE entry and the AOC was not included in the original entry, the entry reviewer should modify the AOC field to indicate "IFE".

If the required documentation is not provided after a DRQ, entry reviewers should take the appropriate compliance follow-up, under the basis the required IFE documentation was not provided to FDA at the time of initial importation.

Divisions should determine the appropriate time frame for receiving the required IFE documents in particular circumstances. It is anticipated three (3) days from the DRQ or DEF notice will usually be adequate for the required IFE documentation to be submitted. This is because the broker may need to communicate FDA's requirement for documents to an importer. If all required documentation is provided, the entry should be given a "May Proceed". NOTE: All documentation supporting the IFE entry should be processed in accordance with step 4 below.

If documentation is not adequate, the district should issue a detention after review of the documentation, in accordance with normal procedures outlined in the RPM Chapter 9.

3. If the entry is marked IFE but review of the entry information or supporting documents indicates the AOC was entered inappropriately, the entry reviewer should note this in the entry remarks section.
4. Copy and attach all entry documentation and forward to the FDA home district of the initial owner or consignee, identifying the following:
  - a. FOREIGN MANUFACTURER/SHIPPER
  - b. ENTRY NO.
  - c. U.S. IMPORTER OF RECORD
  - d. INITIAL OWNER/CONSIGNEE
  - e. ARTICLE/PRODUCT

### 6.2.3.4.2 – DOMESTIC Follow-up of IFE entries

The FDA home district of the initial owner or consignee should:

1. Ensure the IFE Entry is copied from the list of IFE shipments for the last 30 days which is generated by the Division of Import Operations (DIO).
2. Ensure supporting documents are sent to the establishment file of the initial owner or consignee.
3. Ensure follow-up inspections are conducted within 6 - 9 months of the initial notification the firm is receiving an IFE entry. All existing IFE entries for the firm should be investigated during the initial IFE inspection. If the product has not been "further processed" or "incorporated" into product for export, the home district should monitor the firm's practices to ensure there is no violation of the IFE provisions of the Act.

### 6.2.3.4.3 – IFE DOMESTIC INSPECTION GUIDANCE

When a firm is scheduled for inspection, you should:

1. Review the IFE entry documentation and/or follow-up inspection information from the establishment file prior to conducting the inspection.

2. Verify during the inspection if the IFE article:
  - a. Was used to produce an exported product,
  - b. Was destroyed, or
  - c. Still under the firm's control pending disposition. If the article is pending disposition, verify that a current and valid customs bond covering the article exists, and the article is the same article that was offered for entry.

If the article was exported or destroyed, you should request the manufacturer's import, export, and/or destruction records to verify the imported article was further processed or incorporated into another product and was exported in accordance with sections 801 (e) or 802 of the FD&C Act [21 U.S.C. 381 (e) or 382] or section 351(h) of the PHSA, or destroyed. Please note, for drug products, an initial owner or consignee may be allowed to retain a sample of the imported article in order to comply with good manufacturing practices (GMP) regulations concerning sample retention.

Include in the Establishment Inspection Report or a memo the status of the IFE product and if further follow-up is required.

Following review and determination of the necessity of further follow-up, forward the completed EIR or memo and supporting documents to the District which initiated the IFE follow-up.

Upon receipt of the completed IFE Follow-up, ensure the following actions are taken:

1. Verify if further follow-up is needed. If so, schedule a follow-up inspection. If further follow-up is NOT needed, document the completed follow-up.
2. Any inspections identifying a prohibited act under section 301(w) of the FD&C Act [21 U.S.C. 331 (w)] should be forwarded immediately to the district compliance branch for regulatory action. See RPM Chapter 9. In addition, a copy of the violative inspection findings should be forwarded to DIO immediately.

### 6.2.3.5 - Prior Notice of Importation of Food and Animal Feed

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires that FDA receive prior notice of food imported into the United States. Most of the prior notice information required by the final rule is data usually provided by importers or brokers to CBP when foods arrive in the United States. The Bioterrorism Act requires that this information also be provided to FDA prior to an imported article of food's arrival to the United States. FDA uses this data in advance of the arrival of the article of food to review and assess the prior notice data and determine whether to examine the imported food for potential contamination by bioterrorism act or significant public health risks. Prior notice can be submitted either through ABI/ACE or FDA's Prior Notice System Interface (PNSI).

#### 6.2.3.5.1 - PRIOR NOTICE RECEPTION

Prior notice for food articles subject to the rule must be received and confirmed electronically by FDA no more than 15 calendar days before the anticipated date of arrival for submission made through the PNSI and no more than 30 calendar days before the anticipated date of arrival for submission made through ABI/ACE, and as specified by the mode of transportation below, no fewer than:

1. 2 hours before arrival by land by road
2. 4 hours before arrival by air or by land by rail
3. 8 hours before arrival by water

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. (The parcel must be accompanied by confirmation of FDA receipt of prior notice.)

#### 6.2.3.5.2 - PRODUCTS REQUIRING PRIOR NOTICE

Prior notice applies to food for humans and other animals that is imported or offered for import into the United States. For purposes of prior notice requirements, "food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles.

Examples of "food" include:

1. Dietary supplements and dietary ingredients
2. Infant formula
3. Beverages (including alcoholic beverages and bottled water)
4. Fruits and vegetables
5. Seafood
6. Dairy products and eggs
7. Raw agricultural commodities for use as food or components of food
8. Canned and frozen foods
9. Bakery goods, snack food, and candy (including chewing gum)
10. Live food animals
11. Animal feeds and pet food

#### 6.2.3.5.3 - PRODUCTS EXCLUDED FROM PRIOR NOTICE

Foods that are excluded from the prior notice requirement are:

1. Food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution);
2. Food that is exported without leaving the port of arrival until export;
3. Meat food products, poultry products and egg products that are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal

Meat Inspection Act (21 USC 601), (21 USC 601), the Poultry Products Inspection Act, or the Egg Products Inspection Act;

4. Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; and
5. Articles of food subject to Art. 27 (3) of the Vienna Convention on Diplomatic Relations (1961), (1961), i.e. shipped as baggage or cargo constituting the diplomatic bag.

#### 6.2.3.5.4 - PRIOR NOTICE SUBMISSION

The prior notice must be submitted electronically and contain the following information in accordance with 21 CFR 1.281:

1. Identification of the submitter, including name, telephone number, email address, and firm name and address
2. Identification of the transmitter (if different from the submitter), including name, telephone number, email address, and firm name and address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address
3. Entry type and CBP entry identifier, if available
4. The identification of the article of food, including complete FDA product code, the common or usual name or market name, the estimated quantity described from the largest container size to the smallest package, and the lot or code numbers or other identifier (if applicable)
5. If the food is no longer in its natural state (21 CFR 1.276(b)(10)), name of the manufacturer and either (1) The registration number, city and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided
6. If the food is in its natural state, the name of grower, if known, and growing location
7. The FDA Country of Production
8. The identification of the shipper, express consignment operators, carriers, other private delivery service or sender's if the food is mailed. This is to include the name and full address of the shipper, if the shipper is different from the manufacturer. If the address of the shipper is a registered facility, the submitter may submit the registration number of the shipper's registered facility city and country instead of the facility's full address
9. The country from which the article of food is shipped. If the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed
10. The anticipated arrival information (location, date, and time). If the food is imported by international mail, the U.S. recipient (name and address). If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is

- submitted via PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the anticipated arrival information. For post-refusal submissions, actual date the article arrived is required
11. The identification and full address of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States. If the business address of the importer, owner, or ultimate consignee is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address
12. The identification of the carrier and mode of transportation, except for food imported by international mail
13. Planned shipment information is applicable by mode of transportation and when it exists. For food arriving by express consignment operator or carrier, when neither the submitter nor transmitter is the express consignment operator or carrier, the tracking number can be submitted in lieu of the Bill of Lading or Airway Bill number and the flight number for prior notices submitted via PNSI
14. The name of any country to which the article of food has been refused entry.

#### 6.2.3.5.5 - INADEQUATE PRIOR NOTICE SUBMISSION

Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in secure storage facility. FDA provided guidance to its stakeholders and CBP staff on enforcing the prior notice requirements in a Compliance Policy Guide, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 at <https://www.fda.gov/food/importing-food-products-united-states/prior-notice-imported-foods>. This guidance, however, does not affect FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns or taking any other action under the Federal Food, Drug, and Cosmetic Act. This policy will also not affect the ability of CBP to assess penalties under 19 U.S.C. 1595a (b) or to take enforcement action under any other authority.

#### 6.2.3.5.6 - PRIOR NOTICE PROCESS

The prior notice process begins with an automated screening process. If additional evaluation of the prior notice information is necessary, all review of prior notice information is performed by the Division of Food Defense Targeting (DFDT); FDA headquarters staff, operating 24 hours a day, 7 days a week. The review process is a manual review by the DFDT. It is designed to identify food products that may pose serious risks to public health so that appropriate action can be taken upon arrival of article of food in the United States. The review process is not impacted by the method of electronic submission. The results of this process are transmitted to CBP.



The DFDT reviews and assesses the prior notice information and may initiate an examination or other action by FDA or CBP of the article of food at the port of arrival or elsewhere, or in the case of rail shipments, within the confines of the closest appropriate examination site. The DFDT will advise the FDA field offices and/or CBP of the inspection requirements. The DFDT is also responsible for communication with submitters regarding the compliance of prior notice, the initiation of refusal or hold due to inadequate prior notices, the response to requests for review of refusals or holds, and the completion of the prior notice process.

In addition to the prior notice process, the OASIS system review will determine if further staff evaluation of the article of food is necessary for admissibility determinations under section 801(a) of the FD&C Act (e.g., subject to the guidance in an import alert). If the food meets the prior notice requirements; the food will be subject to further review by FDA staff for determination of admissibility under section 801(a) of the FD&C Act.

This admissibility examination may take place at the border but may also take place at an examination site, a public warehouse, or other appropriate locations. If FDA determines that refusal under section 801(a) of the FD&C Act is appropriate, the appropriate refusal procedures will be used.

### 6.2.3.6 - Entry Processing

FDA division offices generally receive notification of all formal and informal entries subject to FDA's jurisdiction. Management for each port of entry determines coverage, hours of operation and resource allocation for any office closures impacting normal working hours. In addition, FDA's import systems allow for entries to be reviewed remotely by off-site personnel.

Entries submitted electronically to FDA are screened against criteria established by FDA. Filers submitting entries via the Automated Broker Interface (ABI) to Customs for cargo release are required to provide FDA information on entries subject to its jurisdiction submitted through ACE. The means of receiving notification for non-ABI entries can be arranged through local Customs/FDA division agreements.

#### 6.2.3.6.1 - U.S. CUSTOMS AND BORDER PROTECTION

CBP's ACE uses guides established by each Federal agency to identify which commodities are subject to their jurisdiction. These guides are known as Other Government Agency (OGA) flags. FDA flags are identified as FD1, FD2, FD3 and FD4.

For entries flagged FD1 the commodity may or may not be subject to FDA regulation. Electronic entries for the filer may, based on information received from the importer

regarding the intended use of the commodity, specify the entry is not subject to FDA regulation and "Disclaim" the entry. Otherwise, FDA required information must be submitted. FDA review of "Disclaimed" entries is performed periodically to confirm the accuracy of the declaration.

Entries covered by an FD2 flag must include FDA required information.

FD3 indicates that the article may be subject to prior notice under section 801 (m) of the FD&C Act and 21 CFR Part 1, subpart I, subpart I, e.g. the article has both food and non-food uses. The filer may, based on information received from the importer regarding the intended use of the commodity, specify the entry is not subject to prior notice and "Disclaim" the entry. If the product is an FDA regulated product, but not a food, the entry can be disclaimed from prior notice by using the affirmation of compliance code "PND" in the entry.

FD4 indicates that the article is "food" for which prior notice is required under section 801(m) of the FD&C Act and 21 CFR Part 1, subpart 1. Entries covered by FD4 flag must include prior notice required information.

Electronic entries for CBP review include all mandatory CBP entry required information, i.e., entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff System (HTS) code for product description, information on foreign shipper, country of origin, etc. Through the screening process in ACE, CBP determines if the article is subject to FDA examination (see OGA flag identifications above).

#### 6.2.3.6.2 - FDA

In collaboration with the U.S. Customs and Border Protection (CBP) and 46 partner government agencies, the Food and Drug Administration has been working to modernize business processes through the implementation of the Automated Commercial Environment/International Trade Data System (ACE/ITDS). ACE/ITDS is a single access point whereby industry can electronically submit all data required by various government agencies involved in international trade. ACE replaced the Automated Commercial System (ACE) in 2016.

FDA has established Intended Use Codes (IUC) to assist FDA reviewers in determining the end use of the imported product. Some commodities require the use of IUC, some commodities have optional IUC, and IUC are not applicable for some commodities.

Affirmation of Compliance (A of C) codes provide FDA reviewers with information concerning the imported article. They are also used by filers to affirm that the firm and/or product identified in an FDA line meets the requirements specific to the product being imported. A of C code requirements are dependent on the commodity being imported and can be impacted by the IUC.

To review the specifications and requirements for filing in ACE as per the final rule, refer to 81 FR 85854

Submission of Food and Drug Administration Import Data in the Automated Commercial Environment, and the FDA's Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) Version 2.5.

OASIS generates a "Notice of FDA Action" providing information on the actions taken regarding a particular entry line e.g. "Notice of Sampling", "Release Notice", "Notice of Detention and Hearing", and "Notice of Refusal of Admission" The Notice identifies the specific line(s) of the entry, where appropriate, with the description of the sample collected or intended for sampling, specific line(s) identified as detained, and/or the specific line(s) identified as released, refused, etc. As the status changes for any line, a new "Notice of FDA Action" is issued to advise the appropriate individuals of the changes. The use of the designation "Product Collected by FDA," "Detained," "Released," "Refused," etc., or similar wording on the "Notice of FDA Action," meet the requirements of the wording of the law and regulation when applied to "giving notice thereof to the owner or consignee." See Exhibit 6-1.

Notices are designed to be electronically or physically distributed to the addressees. Those who hold an approved ITACS account may opt to receive Notices via email or as a download within ITACS. A copy of each Notice is produced with the filer, importer of record, and consignee and delivered to the party on the addressee line. (If the same firm acts in one or more of those functions, only one copy is produced for the firm.) Notices are official documents which provide notification of a change in the status for an FDA regulated entry/line. The distribution of the Notices is made by FDA, not the filer, to ensure proper notification to the parties involved (i.e., FAX, express pick-up services, postal service, etc.). The intention is for FDA to distribute to the responsible firm without an intermediary.

### 6.2.3.7 – VQIP Entry Processing

FDA will work with CBP to expedite entry into the United States for VQIP foods. FDA sets screening in its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening system to recognize shipments of food which are the subject of an approved VQIP application. The system is designed to recognize the information and release the shipment immediately after the receipt of entry information, unless examination and/or sampling are necessary for public health reasons. FDA will limit examination and/or sampling of VQIP food entries to "for cause" situations (i.e., when the food is or may be associated with a risk to the public health), to obtain statistically necessary risk-based microbiological samples, and to audit VQIP.

## 6.2.4 - SAMPLING

### 6.2.4.1 - Ports Covered by FDA

For electronic entry submissions, if the filer receives a message indicating FDA review, the filer will provide appropriate entry information to the FDA office having jurisdiction over the port of entry. The filer can also submit the entry documents electronically to FDA via the Import Trade Auxiliary Communications System (ITACS). For those entries submitted by paper, all appropriate entry documents should be included with the package sent to the local FDA office.

After evaluating the entry, if FDA decides to collect a sample, the appropriate individuals/firms will be provided with a Notice for Sampling and advised:

1. If the entry is to be held intact for FDA examination or sampling;
2. Only those designated items need be held; etc.

### 6.2.4.2 - Ports not Covered by FDA

For those ports where CBP does not maintain its ACE electronic entry process, and FDA does not generally cover the port under its normal operating schedule, the responsible FDA district office will coordinate coverage with the responsible CBP Port manager to assure FDA notification. If FDA decides to examine or sample articles being entered through such a port, CBP, the importer, and broker will be notified.

Generally, for these entries, examination and/or sampling can take place at the point of destination. Under certain conditions, however, FDA may ask CBP to collect a sample at the point of entry for forwarding to the FDA servicing laboratory. Appropriate information on the entry, sample requirement, and requirements for holding the entry will be provided to the CBP officials and importer by the responsible district.

### 6.2.4.3 - Entry Sampling

If no examination or sample is requested, FDA will notify CBP and the filer (who is responsible for notifying the importer, or other designated parties). This electronic notification is called a "May Proceed Notice". It indicates the shipment may proceed without further FDA examination. This may occur as a result of the initial FDA import systems screening or after the division performs an "On-Screen-Review".

NOTE: Since the article is allowed entry without FDA examination, should the article, at a later time, be found in violation of the law, the Agency is not prevented from taking legal action because the article was allowed admission by FDA without examination at the time of importation. (See section 304(d) of the FD&C Act [21 USC 334(d)])

If an examination or sample is requested, FDA notifies CBP, broker or filer, importer, or other designated parties. Notification is either through the electronic entry system or other form of notification (Notice of FDA Action), to hold the entry and will identify the specific product(s) to be sampled, etc.

#### 6.2.4.4 - Notice of Sampling

When a sample is collected by FDA, a Notice of FDA Action is issued to the importer of record, consignee, and filer. If CBP collects the sample for FDA, the division will enter the entry information into FDA Import systems and issue the Notice of FDA Action.

For those entries where specific lines (items) of an entry are not sampled or examined, the Notice of FDA Action will be amended to indicate which lines (items) have been issued a "May Proceed." (See RPM Chapter 9-19"Notice of Sampling" for detailed guidance.)

#### 6.2.4.5 - Payment for Samples

The FDA will pay for all physical samples collected by FDA and found to be in compliance (See 21 CFR 1.91). In addition, FDA will pay for physical samples collected by FDA as an audit of private laboratory analytical results submitted to FDA when the FDA audit sample is found to be in compliance. (NOTE: FDA does not pay for samples found to be non-compliant (violative) or for samples taken in connection with the supervision of a reconditioning.) See IOM 4.2.8.2 for guidance on sample costs.

Billing for reimbursement should be made to the FDA district office in whose territory the shipment was offered for import. FDA will not pay for a sample if the article is initially found to be in violation, even though it is subsequently released. For this reason, do not pay for samples at the time of collection.

Samples taken in connection with the supervision of a reconditioning are not paid for by FDA.

#### 6.2.5 - PROCEDURE WHEN PRODUCTS CANNOT BE SAMPLED OR EXAMINED

If the entry is still under control of the district inspection operations, and the sample collection cannot be completed, the district may annotate the notice to the filer and importer no product was collected and return the entry to the filer designating the entry "May Proceed." If the designated product was part of a multi-line entry where other products were collected, the notice issued for the other items sampled will be appropriately updated with the release of the product not sampled.

In the OASIS system, when a notice is issued for the collection or examination of a product, and neither operation is accomplished, the filer will be advised through a revised Notice indicating the article is given a "May

Proceed" status. The system will print a status of "May Proceed" in the Line Summary and also print a detail section "Lines Which May Proceed."

In OASIS, the following are definitions used to describe "May Proceed" or "Release" actions:

May Proceed: "Product may proceed without FDA examination. FDA has made no determination the product complies with all provisions of the Food, Drug, and Cosmetic Act, or other related acts. This message does not preclude action should the products later be found violative." (No compliance decision has been made.)

Release: "The product is released after FDA examination. This message does not constitute assurance the product complies with all provisions of the Food, Drug and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative." (A compliance decision has been made.)

Districts will follow the appropriate guidance under each of the above procedures, according to their import operations.

#### 6.2.6 - PROCEDURE WHEN NO VIOLATION IS FOUND

If the shipment is found in compliance after examination, the importer of record, consignee (where applicable), filer, and CBP are notified with a Notice of Release. The shipment may be admitted. (See RPM Chapter 9-5 "Release Notices" for detailed guidance).

#### 6.2.7 - PROCEDURE WHEN VIOLATION IS FOUND

##### 6.2.7.1 - "Notice of Detention & Hearing"

If examination of the sample or other evidence indicates the article appears to be in violation, and detention is the course of action chosen by the district, the filer, owner and consignee, where applicable, are advised of such action by "Notice of Detention and Hearing." The Notice will specify the nature of the violation charged and designate a site for the owner or consignee (or authorized representative) to appear at a hearing. These hearings are informal meetings with the district, designed to provide the respondents an opportunity to present evidence supporting admissibility of the article. Ordinarily the respondents are allowed 10 working days to appear. However, if for some compelling reason the district determines ten (10) working days are insufficient; this time period may be extended. On the OASIS generated "Notice of FDA Action", this date is identified under the caption "Respond By". A copy of this Notice is also sent to CBP. (See RPM Chapter 9-10 "Response (Hearing) to Notice of FDA Action – Detained.")

### **6.2.7.2 - Response to "Notice of Detention & Hearing"**

Response to the Notice of Detention and Hearing may be made personally, by representative or by mail. The importer may present evidence supporting the admissibility of the article, request refusal of admission, propose an effective manner of reconditioning, or a method to remove the product from the authority of the FD&C Act.

### **6.2.7.3 - Request for Authorization to Relabel or Recondition Non-compliant Articles**

FDA may authorize relabeling or other remedial action upon the timely submission of an "Application for Authorization to Relabel or To Recondition Non-Compliant Articles," (Form FDA 766 - See Exhibit 6-2). This form is also available in fillable formats online at <http://www.fda.gov/media/71537/download>.

Application may also be made by letter and the execution of a good and sufficient bond by the owner or consignee (See section 801(b) of the FD&C Act [21 U.S.C. 381(b)]). The redelivery bond on file with the Port Director of CBP for the particular importation applies to any relabeling or other action authorized, a new bond will not have to be filed.

After review of the application, FDA will notify the importer of its approval or disapproval. If approved the original application will be returned outlining the conditions to be fulfilled and the time limit within which to fulfill them will be noted. Notification to other parties will be made where appropriate. A copy will be retained in the district files. (See RPM Chapter 9, subchapter 9-10 "Response (Hearing) to Notice of FDA Action - Detained", and subchapter 9-12, "Reconditioning" for detailed guidance).

### **6.2.7.4 - Inspection after Approved Reconditioning has been Completed**

After the relabeling or reconditioning operation has been completed, the applicant will submit the "Importer's Certificate" (page 2 of Form FDA 766, Exhibit 6-2) or advise the district that reconditioning is complete. At this point, FDA may conduct a follow-up inspection and/or sampling to determine compliance with the terms of the approved reconditioning application, or it may accept the statement from the importer with no further follow-up. The follow-up inspection and/or sampling may be made by FDA or CBP, depending on agreements between the division and local CBP. The "Report of Investigator/Inspector" (section 4, page 2 of Form FDA 766, Exhibit 6-2), or other appropriately completed summary of reconditioning, should be forwarded to the appropriate FDA office.

### **6.2.7.5 - Procedure when Conditions of the Approved Reconditioning Application Have Been Fulfilled**

If the conditions of the approved reconditioning application have been fulfilled, the district will notify the owner or consignee by Notice of Release. This notice is usually identified as "Released after reconditioning." A copy is also sent to CBP and the filer. Where there is a non-admissible portion (rejects), they must be destroyed or re-exported under FDA or CBP supervision. A Notice of Refusal of Admission should be issued for the rejected portion. FDA may include in its approval of the reconditioning a provision for the non-admissible portions (rejects) of the reconditioning to be destroyed and not exported.

### **6.2.7.6 - Procedure when Conditions of the Approved Reconditioning Application Have Not Been Fulfilled**

If the initial attempt at reconditioning is unsuccessful, a second attempt should not be considered unless a revised method of reconditioning shows reasonable assurance of success.

If the conditions of the approved reconditioning application have not been fulfilled, a "Notice of Refusal of Admission" is issued to the importer, consignee (where applicable) to the filer, and to CBP.

### **6.2.7.7 - Procedure after Hearing - "Notice of Release"**

If, after presentation of testimony, the division determines the article should be released, the importer of record and consignee are issued a "Notice of Release". The Notice will declare the detained goods may be admitted. The Notice will also be identified "Originally Detained and Now Released" and, where appropriate, explain the reason for the change of action. A copy of the Notice is sent to CBP, and all parties receiving the Notice of Sampling/Notice of Detention. (See RPM Chapter 9-7 "Release Notices" for detailed guidance.)

### **6.2.7.8 - Procedure after Hearing - "Refusal of Admission"**

When the importer requests the district issue a "Notice of Refusal of Admission", or the district decides the shipment still appears to be in violation, the importer, owner, and consignee where applicable, are issued a "Notice of Refusal of Admission". On this Notice, the charge(s) is stated exactly as shown on the original (or amended) "Notice of Detention and Hearing". A copy of the Notice is also sent to CBP. (See RPM Chapter 9-11 "Notice of Refusal of Admission" for detailed guidance.)

The "Notice of Refusal" provides for the exportation or destruction of the shipment, under CBP supervision, within 90 days of the date of the notice, or within such additional time as specified by CBP Regulation. Under OASIS, the Notice will also contain language which includes reference to the requirement for redelivery and contain all the above required information concerning the product and charge(s). The FDA file remains open until the district receives notification indicating the goods were either destroyed or exported.

FDA is responsible for the protection of the U.S. public regarding foods, drugs, cosmetics, tobacco products, etc. until the violative article is either destroyed or exported.

### 6.2.7.9 - Payment of Costs of Supervision of Relabeling and/or Other Action

After completion of the authorized relabeling or other action, FDA will submit a detailed statement of expenses incurred, including travel, per diem or subsistence, and supervisory charges, on a Form FDA 790 (See IOM Exhibit 6-3, Charges for Supervision). This is completed by FDA employees regarding the supervision of the authorized relabeling or other action to U.S. Customs and Border Protection – Revenue Division. The expenses shall be computed on the following basis:

1. Supervising Officer's time
2. Analyst's time
3. Per diem allowance
4. Travel other than by auto - actual cost of such travel
5. Travel by auto (mileage, toll fees, etc.)
6. Administrative support

Future enhancements to FDA import system may result in electronic processing of the supervisory charges submitted to CBP, in which case the Form FDA 790 will no longer be used. (See [RPM Chapter 9-13](#) "Supervisory Charges" for detailed guidance.)

CBP, upon receipt of the charges for supervision, will send a notice for payment to the identified importer of record. The expenses shall include charges for supervision of destruction of the article or rejects. The remittance by the owner or consignee shall be to CBP. Payment of supervisory charges should not be accepted by FDA district offices.

### 6.2.7.10 - Exportation of Goods Refused Admission

Exportation of refused goods is done under CBP supervision. However, if after a reasonable time, FDA has not received notification of exportation or destruction, the district should investigate the status of disposition. Districts should also consider, under certain conditions, verifying the refused goods have been held intact pending exportation or destruction, or that re-export actually occurred. Guidance on refusals to be verified may change, based on the reason for detention. Each District involved in performing Import

Operations has been assigned a set number of import exams of refused entries as part of ORA's Performance Goals.

### 6.2.7.11 - Bond Action

Under the provisions of the FD&C Act ([section 801\(b\) of the FD&C Act \[21 U.S.C. 381\(b\)\]](#)) and CBP regulations ([19 CFR 113.62](#)) a bond is required for all conditionally released articles offered for importation. This bond provides relief to the government on the default of the conditions of the bond and the payment of liquidated damages in the amount specified in CBP notice of assessment of liquidated damages for failure to redeliver such goods.

Bond actions are taken when an entry is distributed prior to FDA release and cannot be redelivered, or when an article has been detained and refused and the article is not destroyed or exported in accordance with the requirements of the law.

If district has evidence the entry, or any portion of an entry subject to FDA jurisdiction, was disposed of in violation of the terms of the appropriate Act, or its regulations, or of the terms of the bond, (see [19 CFR Section 113.62 \(l\)\(1\)](#)) they should immediately contact the appropriate Customs office.

The district, upon receiving evidence the refused article was not exported or destroyed should immediately investigate the matter. See Section 6.1.3 of the IOM, Investigations Involving the Import Process. Send a detailed statement showing the importer's liability under the redelivery bond or other applicable customs bond to the responsible CBP office. If the facts warrant, and the article was under detention, and the Notice of Refusal of Admission has not been issued, immediately issue a Notice of Refusal to the owner or consignee, with a copy to CBP.

Upon the receipt of an application for relief (appeal for Mitigation or Cancellation of Assessed Liquidated Damages), CBP may agree to mitigate the amount of damages. However, in cases involving FDA goods, CBP does not usually mitigate unless FDA is in full agreement with the action [see [21 CFR section 1.97 \(b\)](#)]. (See RPM Chapter 9-12 "Bond Actions" for detailed guidance.)

### 6.2.8 – PHOTOGRAPHS: IDENTIFICATION AND STORAGE

Photographs are evidence documented during import field work and are a crucial element in case development. They should be clear and capture evidence needed to support the appearance of a violation and the proposed charges. The photographs should capture, at a minimum, all sides of the product packaging, labeling, (i.e. top, bottom, and sides; including blank sides), all labeling (e.g. package inserts and any labeling that provides the intended use of the product, product value, directions for use, daily intake, and firm information) any available production (lot) codes and/or dates, an overall view of the lot(s) examined, and any adverse conditions observed.

Photographs must be collected and uploaded electronically to the entry/line via FDA import systems (ER, OASIS, SERIO) for all sample collections, Class 2 and Class 3 field/label exams, detention requests (when warranted), destructions, reconditioning, refusal verification discrepancies, and other situations as warranted.

All photographic evidence (including photographs of labeling) must be identified with the following required information: entry/line number, collection date, investigator's initials, a brief description of the photo, and must be numbered in a manner that allows future reviewers to determine if any pages or photos are missing (e.g., 123-456789-1/11/1; 8/10/20; RS, information panel, right side, 1 of 4).

Photographs may be uploaded directly from a government issued mobile device or computer file to an entry/line via FDA import systems. The system records the date/time and investigators initials at the time of upload. The required information described above must be included within the file name and/or using the Document Remarks section (See [SERIO manual](#) instructions) specific to each photograph during the document upload process. However, there is no need to include the entry/line number when uploading from a mobile device or computer file as the photograph(s) will be directly associated to the entry/line. For example, the file name or Document Remarks would include "information panel/right side, 1 of 4".

Photographs may also be downloaded and combined into a single document (e.g., Word or PDF document) for each entry/line with the required information included within the document.

If photographic evidence is printed, it should be documented in one's regulatory notes and the required information must be permanently affixed to the printed photos so that there is never any loss of association between the photographic evidence and the entry/line. This information must be recorded immediately above or below the photograph(s) (not directly on the photos) so that the integrity of the evidence is not compromised.

Note: If additional enforcement or legal actions including but not limited to seizure, injunction, debarment or prosecution are contemplated with respect to an import case, the procedures for preparing and maintaining digital photographs and video as evidence, as described in IOM 5.3.4.2.5 and IOM 5.3.8.3, must be followed.

## SUBCHAPTER 6.3 – ENTRY REVIEW

### 6.3.1 - GENERAL

Entry review consists of the examination of any electronic data and/or hard-copy entry documentation received by FDA for an FDA regulated entry line. The information received is reviewed to determine if entry admissibility criteria for the commodity are met, and if additional actions,

such as examination sampling, or detention request, are applicable and/or necessary.

An investigator may be assigned the role of an import entry reviewer. Entry reviewers use sound judgment based on their experience and training when performing entry review. All import entry reviewers receive both formal training and on-the-job training to ensure they are familiar with admissibility requirements and can effectively use FDA databases. Along with attending national import courses, on-the-job training should result in the ability to conduct entry review independently with minimal supervision.

An entry reviewer is expected to possess the knowledge to:

- Utilize the electronic Imports Entry Review (ER) system.
- Access and reference appropriate FDA databases.
- Reference initial admissibility job aids and other FDA work instructions to ensure accurate and consistent entry processing.
- Use the internet to access and review regulatory requirements not included in an FDA database (e.g. the Interstate Certified Shellfish Shippers List).
- Make the appropriate initial admissibility entry decision (e.g. "May Proceed", request field work, recommend detention) and provide remarks/justification as appropriate.
- Understand ORA Field Work Plan and Sample Collection Operation Planning Effort (SCOPE) obligations to assure that center-prioritized work is completed.
- Refer entries to OCI and Partner Government Agencies (PGA) when warranted.
- Refer entries to a supervisor and/or Compliance Branch (CB) when information is uncovered during ER that may require a national screening criteria recommendation by CB.

The entry reviewer takes one of three final entry review actions:

1. "May Proceed",
2. Detention Request (DER/DTR), or
3. Request Field Examination (FEX), Label Examination (LEX), and/or Sample Collection (SAM).

Entry review actions can be supported by:

1. Electronic and/or hard-copy entry documentation including declarations of intended use
2. Electronic systems screening of entry information
3. Affirmations of Compliance (AofC) such as Registration and Listing.
4. Database Query
5. Import Alerts (IA)/Import Bulletins (IB)
6. Past compliance history
7. Compliance Program Guidance Manuals (CPGM)
8. Import Assignments, DIO Field Advisories and Notices, and SCOPE
9. Intelligence from PGAs
10. Management directives

**NOTE:**

The Automated Commercial Environment (ACE) requires filers to submit certain data elements for FDA regulated products. For specific ACE requirements, refer to the most current [FDA Supplemental Guide](#). If inaccuracies are found with the transmitted manufacturer, shipper, product code, or country data elements that could affect entry screening, correct the information, assign fault, save, and rescreen the entry/line

- If information exists to support the appearance of a violation or if compliance with the regulations cannot be confirmed (e.g., Registration, Listing, Approval), forward a Detention Request to the Compliance Branch.
- The reviewer may, at any time, assign or set up a work request for examination or sample collection (e.g. LEX, FEX, or SAM).

See Regulatory Procedure Manual (RPM) Chapter 9 and Initial Admissibility Job Aids for additional information concerning the review/processing of entries of specific types of commodities, including products under detention without physical examination.

Entry review activity is reported as Import Investigation Time in OASIS.

**6.3.2 – INITIAL ENTRY REVIEW**

Lines submitted electronically to FDA are received with the initial work types of Quantity and Value (QAV) or No Quantity and Value (NQV). In addition to receiving electronic entries, FDA receives non-ABI (paper) entries. For non-ABI entries, follow the same decision-making criteria as electronic entry filing, but electronically transmitted entries will be given review priority. NOTE: If setting up work on a non-ABI entry, refer to the Entry Review Job Aid for specific instructions on creating a manual entry in ER.

Use the actual arrival date/time (for truck ports of entry) and submission date/time (for air, rail and sea ports of entry) when prioritizing entry review lines. In general:

- Lines with a QAV work type take priority over lines with an NQV work type.
- Lines with documents sent via Import Trade Auxiliary Communications System (ITACS) take priority over lines with documents sent via alternative means of transmission.

The quantity and value for each line are typically provided electronically for FDA review to aid in the admissibility process. Quantity and value are required to setup a work request.

**6.3.2.1 –Emergency and Perishable Shipments**

Emergency or perishable shipments take priority over non-perishable shipments.

An emergency shipment consists of one or more lines that require immediate review based on a demonstrated and

urgent need or situation. Emergency entries are to be handled per import division discretion to control and prevent abuse by regulated industry and individuals.

Perishable products are articles not otherwise preserved in a manner so as to prevent the quality, safety and/or effectiveness of the article from being adversely affected if held for an extended period of time under normal shipping and storage conditions. Perishable products are raw and fresh products stored in ambient or refrigerated conditions. These products typically consist of raw/fresh seafood, raw/fresh produce (fruits and vegetables), and temperature and/or time sensitive drugs, vaccinations, lab reagents, or biologics.

Device shipments may be released if the entry documents include documentation verifying approval by CDRH. If unable to verify the authenticity of the approved document, please contact the center at [cdrhimport@fda.hha.gov](mailto:cdrhimport@fda.hha.gov).

**6.3.2.2 – Reviewing Entry Data and Information**

Electronically submitted entry lines that are not issued a “May Proceed” by the system are manually reviewed by entry reviewers.

Review of entry lines submitted electronically is conducted using the ER system. ER incorporates PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting), a screening tool that uses automated data mining, pattern discovery, and automated queries of FDA databases to determine the potential risk of a shipment. It takes into consideration the inherent risk of certain commodities and information about the previous history of importers, manufacturers, and shippers. Those lines with the highest risk are flagged for additional review. ER system recommendations should be reviewed and considered before taking any action. For specific instructions on navigating through and using ER, refer to the [Entry Review Job Aid](#).

When an entry reviewer issues a “May Proceed” for a line flagged for an IA that is indicated as Priority Review, record a remark in the Priority Review “Remarks” field that provides a clear justification as to why the line is not subject to detention without physical examination (DWPE). NOTE: The firm taking a corrective action is not a sufficient reason to issue a “May Proceed” for the line. If the firm has taken corrective action, they should request to be removed from the IA, and the request will be reviewed by the appropriate center and DIO. The following are some examples of acceptable remarks:

- “The product brand submitted for entry is not a brand name subject to DWPE.”
- “Product is in powdered rather than liquid form.”
- “Specific manufacturer and/or product is exempt from IA XX-XX”
- “Documentation shows imported item does not contain heparin”

The Admissibility requirements that need to be verified when performing entry review for electronic and non-ABI (paper) entries are depended upon the commodity being offered for import (e.g. food, medical, devices, drugs, radiological health products, cosmetics, biologics, and tobacco products). Commodity specific requirements are outlined in the Initial Admissibility Job Aids.

The following are some activities performed by entry reviewers prior to making an initial entry admissibility decision:

- Review the commodity-based PREDICT cumulative percentile rank and mashup in ER which shows the risk score. Request the most recent copy of the PREDICT Guide for Rules and Scoring
- Review all entry line flags in ER. For example:
  - If you observe an IA flag in ER, determine if the firm and/or product combination is subject to DWPE
  - If you suspect that the firm/product should have an IA flag in ER but is not flagged, conduct follow-up investigative work to determine if the firm and/or product combination is subject to DWPE.
  - Report problems and provide feedback using the ER feedback functionality when a PREDICT rule does not fire or fires in error. For additional instructions on this functionality, refer to the [Entry Review Job Aid](#).
- Perform firm/product searches on applicable center databases. Review entry documents when necessary.
- Request field work that aligns with the ORA Field Work Plan, SCOPE, obligations, and center assignments.
- Use applicable guidance and instructional documents to determine compliance with regulatory requirements.

The following is a list of resources that an entry reviewer should be familiar with when performing entry review functions:

- Commodity-Specific Resources, which provide center-specific Import resources that include links to additional information (e.g. center contact information and case routing, initial admissibility resources, field and label examination work instructions and additional resources).
- FDA Affirmations of Compliance (AofC) for the Automated Commercial Environment, which provides definitions of required AofCs for articles offered for entry.
- Compliance Program Guidance Manuals which provide instructions to assist FDA personnel in evaluating compliance with the FD&C Act and other laws administered by FDA.

- Internal documents such as the ORA Field Work Plan, SCOPE, active import assignments, internal notices, advisories, bulletins, and Standard Operating Procedures (SOP).
- RPM Chapter 9 "Import Operations and Actions".
- PREDICT Guide for Rules and Scoring

### 6.3.2.2.1 – Manual “May Proceed”

If compliance with regulatory requirements can be confirmed using information transmitted electronically and/or information provided in entry documents, and there is no indication that a detention recommendation or request for field work is appropriate, the entry reviewer should issue a “May Proceed” for the entry line.

NOTE: No further manual verification of AofC data is needed if the line passes the automated database look-up.

### 6.3.2.2.2 – Rescinding a “May Proceed” or IB Release

Rescinding a “May Proceed” or IB Release should only occur for articles that are subject to a compliance action or in exceptional cases and must be accomplished immediately. This action should not be used for routine or work plan examination or sampling purposes.

When an entry receives a “May Proceed” or IB Release, the conditional release period of the entry ends (Section 6.3.4) and does not re-open when the “May Proceed” or IB Release is rescinded.

If an entry line inadvertently receives a “May Proceed” or IB Release or additional information is received that warrants further review for admissibility:

- Obtain supervisory approval prior to rescinding the “May Proceed” or IB Release.
- Notify import filer immediately the FDA MAY Proceed or IB release has been rescinded pending an FDA Admissibility decision.
- Generate an updated Notice of FDA Action and forward it to the filer, importer, and consignee within 24 hours of rescinding the “May Proceed” or IB Release. Manually generating the notice is necessary because rescinding a “May Proceed” or IB Release does not generate electronic messaging back to the filer via ABI.
- Request CBP within 24 hours of rescinding the May Proceed or IB Release to Unset/Hold the CBP Bond from liquidating in case Compliance Branch needs to pursue a liquidated damages case against the bond for cargo FDA refuse and not redelivered for export or destruction.
- If the shipment has been distributed, notify CBP and request that they issue a demand for redelivery. (See IOM 6.2.3.2 for information regarding informal entries.) CBP has 30 days to demand redelivery from the date the conditional release period ended (i.e. the “May Proceed” was



issued.) Any delays compromise FDA's ability to request CBP issue a Notice to Redeliver.

- This process and communication with CBP shall be recorded in OASIS to document FDA follow-up when FDA issues a May Process or IB Release inadvertently.

### 6.3.2.2.3 – Recommend Detention (DER/DTR)

The detention recommendation process is described in IOM section 6.3.5 – Detention Recommendations by Entry Reviewers.

### 6.3.2.2.4 – Request Examination and/or Sampling (LEX/FEX/SAM)

When requesting field work, the entry reviewer should:

- Update transmitted data in line details if inaccuracies are found that would affect an admissibility decision or would result in inaccurate information being populated on a Notice of FDA Action. Record reason for update, save, and rescreen the data.
- Set the entry up for examination and/or sample collection by choosing the correct work type/Problem Area Flag (PAF) combination. Work should be set up in accordance with agency priorities, work plans, SCOPE, and assignments.
- Enter instructions in the "Instruction Text" field for the investigator to reference when work is set up for any reason other than routine surveillance. Instructions might be necessary, for example, when:
  - ORA Assignments may require specific remarks;
  - Specifying if exam instructions should be used during the examination (e.g. "further instructions, follow DOPG-Device-05 for Glucose Meters and Glucose Strips, Field Examinations.");
  - A specific discrepancy is found during the entry review process that should be evaluated during the examination and/or sampling;
  - Referencing the results of previous violative examinations/samples (include the previous entry/sample numbers for reference);
  - Indicated in an Import Bulletin;
  - Special notes are applicable (e.g. any known safety precautions, or specifics about the product itself).

#### NOTES:

- Do not routinely set up work on a line that is confirmed to be subject to an IA. However, there could be special situations when a line subject to IA may need to be examined for a reason unrelated to the IA. In these situations, work may be set up under a PAF that is not related to the IA.
- The Entry Review Job Aid includes specific instructions on updating and re-screening

electronic data, setting up work, and entering work instructions in the "Instruction Text" field.

### 6.3.2.2.5 – Notices

When the entry reviewer recommends detention or requests field work, the filer is notified through ABI (Automated Broker Interface) and a Notice of FDA Action generated in OASIS. Notices of FDA Action are to be distributed as described in IOM 6.2.3.6.2. – FDA.

### 6.3.2.2.6 – Cancelled Entries

Entry reviewers should be able to identify CBP cancelled entries in ER. Entries that have been cancelled by CBP will display static text at the top of multiple creens indicating "This Entry is Cancelled". The Entry Review Grab Bag (ERGB) will display a "Y" in the "Cncl'd" column and the Current Entry Status field will display "ACS/ACE Entry Cancelled".

### 6.3.2.2.7 - Partner/Other Government Agency (OGA) Referral

The purpose of OGI (Other Government Agency - Investigations Branch) and OGC (Other Government Agency - Compliance Branch) work types are to close a line without an admissibility decision being recorded by FDA. Selecting OGI/OGA from Possible Actions allows Investigations Branch (IB) to close a line with no further action after OGA referral from the OGA Entry Review Grab Bag. Selecting OGC/OGA from Possible Actions will route the line to Compliance Branch (CB) and allow CB to close the line with no further action after OGA referral from the OGA Compliance Grab Bag.

Note: In some areas, OGAs are referred to as PGAs (Partnering Government Agencies).

One situation IB may use OGA referral to close a line without an FDA admissibility decision is when an entry has been refused or seized by another government agency (i.e., APHIS or CBP) and FDA did not have the opportunity to examine the entry. Therefore, FDA does not have adequate information to make an initial entry admissibility decision. The line(s) within the entry may be closed with no further FDA action after referral to an OGA has been recorded. When this occurs, documentation showing evidence of the final disposition of the product should be obtained and uploaded to the entry/line prior to closure with OGA referral.

An Ad-Hoc OGA referral, found under the Action menu, allows the field to record an OGA referral but does not allow closure of the line with no further action after OGA referral. Ad-Hoc OGA Referrals differ from the use of OGI/OGC work types in that they are used strictly to provide information to the OGA without deferring FDA's responsibility to make an admissibility decision. If an Ad-Hoc OGA referral is recorded the line will still need to be processed with an entry admissibility decision.

Regardless of whether FDA did or did not have the opportunity to examine the goods but has adequate information to make an initial entry admissibility decision, the entry should be processed according to established procedure. This includes May Proceed or detention recommendation (DTR or DER). The OGA referral can still be recorded using an Ad-Hoc OGA Referral if needed.

If an entry has been acted on by an OGA and the entry has been cancelled by CBP, the entry will be automatically closed by the system if no work has been assigned. If work has been assigned, the field can send a request to close the cancelled entry to the ORA OISM DSS ISB Import Systems Problem Reports group at [ORAOISMDSSISBImportSysProblemRpts@fda.hhs.gov](mailto:ORAOISMDSSISBImportSysProblemRpts@fda.hhs.gov).

If there is a need to refer a line to an OGA that is not found in the system, please contact the [Division DIALs](#) who will then work with DSS to have the OGA added.

### 6.3.3 – ENTRY DOCUMENTATION

The admissibility of an article may depend on the submission of entry documentation, which may include the following: Bill of Lading (BOL) or Airway Bill (AWB), invoice, purchase order, certificates of analysis, copies of labeling, intended use statement, or other related documentation.

The 3461 and 7501 have been eliminated for electronic transmission of entries in ACE. Reviewers should not be holding up admissibility of lines to review these documents. They are still used for Non-ABI or paper entries.

#### 6.3.3.1 – Request of Entry Documents (DRQ)

If during the initial review of an entry, the reviewer determines that additional information is necessary to make an admissibility decision, request documents via the “Documents Required” Entry Option (DRQ). In the “Remarks” field of the “Issue Entry Option” page enter:

- The reason the documents were requested to assist in the future review of the entry or line.
  - NOTE: Do not routinely request documents solely for the purpose of verifying the accuracy of submitted data.
- A summary of the data elements reviewed and admissibility requirements needed for review.

This information will expedite review of the documents once they are received and will avoid a duplication of efforts. For example:

The DRQ entry option sends an electronic message to the filer via the FDA-CBP Interface, but does NOT generate a Notice of FDA Action.

#### 6.3.3.2 – Receipt of Entry Documents

Entry documents may be submitted to FDA in several ways. Documents received via ITACS, are given priority over documents received via other means. Documents can be submitted prior to or at the time of a DRQ.

If documents are not received, refer to Section 6.3.3.4 Failure to Submit Entry Documents and Follow-up Requests.

#### 6.3.3.2.1 – Uploading documents received outside of ITACS

When work has been set up on an entry and documents have subsequently been received from the filer or importer outside of ITACS (e.g. email, mail, fax), upload the documents using ER. Instructions for uploading documents can be found in the [Entry Review Job Aid](#). Examples of documents that should be uploaded by the entry reviewer include:

- Product labeling
- Email correspondence that contains information that might affect admissibility
- Entry documentation such as invoices, packing slips, FDA forms, or CBP forms

NOTES: Electronically viewed material such as web pages can also be uploaded via ER. Ensure that for all records, the record retention policy is adhered to.

#### 6.3.3.3 – Review of Entry Documents

When documents are received, review entries in chronological order (e.g. by earliest submission date in Imports Entry Review, by email receipt date). Documents received via ITACS are given priority over documents received via other means.

If, after review of the entry documents, sufficient information exists to support the appearance of a violation or if compliance with the regulations cannot be confirmed (e.g., Registration, Listing, Approval), forward a Detention Request to the Compliance Branch (See IOM 6.3.5).

If examination or sample collection is indicated, assign or set up a work request (e.g., LEX, FEX, or SAM).

If the documents submitted do not provide sufficient information to make an entry admissibility decision, the reviewer may follow-up by using:

- Direct communication (i.e. email, phone call) with the filer or importer
- Entry Incomplete – Return, Deficient Entry (DEF) Entry Option
- Request Information (INF) Activity

In the follow-up communication, indicate to the importer/filer the specific additional information needed, and that if the information is not provided, FDA may take other action to continue the admissibility review.

Record direct communications with the filer or importer in the “Remarks” field of the Entry Details page or via the “Log Miscellaneous information received” (MIB) function. Include the date, method of communication (i.e. email, phone), content requested, point of contact and reviewer name or initials in the remarks.

Please note that neither the DEF Entry Option nor the INF Activity sends an electronic message to the filer via the FDA-CBP interface, however, they do generate a Notice of FDA Action. Specify the information requested in the “Narrative” field of the DEF Entry Option and the “Information Requested” field of the INF Activity. In addition, if the INF Activity is used, it will display as a status in ITACS, advising the user to view the narrative for details via the Notice of FDA Action.

**NOTE:** Information entered in the “Remarks” field is for internal use only. Information entered in the “Narrative” field appears in the Notice of FDA action.

### 6.3.3.4 – Failure to Submit Entry Documents and Follow-up Requests

If entry documents were not received, the reviewer can send a follow-up request to the filer. The review may follow-up by using any of the following options available:

- Direct communication (i.e. email, phone call) with the filer or importer
- Deficient Entry (DEF) Option
- Request Information (INF) Activity

In the follow-up request to the filer/importer, indicate the specific additional information needed, and that if additional information is not received, FDA will continue its admissibility review without the benefit of the additional information.

Record direct communications with the filer or importer in the “Remarks” field of the Entry Details page or via the “MIB function”. Include the date, method of communication (i.e. email, phone), content requested, and reviewer name or initials.

If additional information is received after follow-up communication, make an entry decision.

If the information is not received, take appropriate action (e.g. setup field work or request detention). If detention is requested, refer to IOM 6.3.5.

## 6.3.4 – ENTRY DECISION

Under the conditions of the entry bond, articles may receive a conditional release by CBP pending a final admissibility decision by FDA. An FDA entry decision must be made prior to the end of the conditional release period (within 30 calendar days after CBP has conditionally released the product), unless otherwise extended. If FDA does not take an action to extend the conditional release period, it will terminate upon the earliest occurring of the following events:

- The date that FDA issues a notice of refusal of admission;
- The date that FDA issues a notice that the merchandise may proceed;
- Upon the end of the 30-day period following the date of release.

As indicated in 19 CFR 141.113(c), to extend the conditional release period, FDA must issue a written or electronic notice (within 30 days of the conditional release of the merchandise), informing the bond principal (i.e., importer of record) that the product will be examined, sampled or has been detained. The DRQ, DEF and INF functions do not extend the conditional release period.

## 6.3.5 - DETENTION RECOMMENDATIONS BY ENTRY REVIEWERS

Importers introduce goods through multiple ports of entry and work with a variety of districts. FDA personnel review these import entries utilizing data submitted by filers/brokers to make an initial admissibility decision. FDA regulated products which appear to be non-compliant and/or subject to an Import Alert or Import Bulletin should be considered for field work or submission to the Compliance Branch (CB) with a detention recommendation. Since filers have interactions with multiple FDA districts, it is vital that entries be handled by a uniform procedure regardless of the port of entry.

### 6.3.5.1 - Submission of Detention Recommendations to the Compliance Branch at the Entry Review Step

Entry reviewers recommend detention using one of two work types: DER or DTR.

1. DER refers to a detention recommendation based on Detention without Physical Examination (DWPE), and is utilized when a product is subject to DWPE and is either listed on an Import Alert (IA) or meets the criteria found in Direct Reference Authority for DWPE (6.3.5.4.2.1, below).
2. DTR refers to all other detention recommendations for products with the appearance of a violation, either because administrative requirements cannot be verified or

other evidence supports the appearance of a violation.

**NOTE:** If additional entry documentation is needed to support the detention recommendation, collect prior to submitting a recommendation. Include comments for all detention recommendations articulating the reason why the entry is being sent to the CB for review.

### 6.3.5.2 - General Procedures Pertaining to all Detention Recommendations (DER and DTR)

Entry Reviewers ensure detention recommendations are aligned with center specific requirements. To promote consistency across districts, refer to the Center Specific *Initial Admissibility Job Aids* for instructions on commodity-specific requirements and center database use. The entry reviewer is responsible for searching all applicable center databases prior to a detention recommendation. Ensure research conducted in the FDA database systems is documented in the remarks section of the detention recommendation.

Prior to submitting a detention recommendation, verify accuracy for all Line Details in the entry.

1. If at any time data is found to be incorrect, correct the inaccuracies. **NOTE:** Quantity and Value are required to take a "Next Step" and for CB to take action.
2. Split lines if necessary.
3. Rescreen updated lines.
  - a. If data has been changed, click on "Save", then enter a brief description in the pop-up box, and assign fault to any errors as appropriate.

**NOTE:** Some firms or products may be subject to multiple import alerts or compliance with multiple regulations cannot be verified at the time of entry. In these situations, the entry reviewer should recommend detention for all applicable import alerts and/or problem area flags (PAFs).

#### 6.3.5.2.1 - Entry Documents

Entry documents are not required for all detention recommendations made by an entry reviewer, as indicated below in sections 6.3.5.3, 6.3.5.4, and 6.3.5.5. However, the CO does require entry documents for case review. For detention recommendations made by the entry reviewer without having the entry documents, the entry documents should be requested for CO use per the instructions below.

1. If entry documents were not obtained prior to making the detention recommendation (DER or DTR), ensure the "Entry Option" selected in the drop-down menu includes a document request, e.g. "Hold Designated, Others Go, Docs Required". This designation alerts the filer to submit entry documents to FDA.
2. Entry documents received by the investigations branch outside of ITACS are to be uploaded via FDA import systems (ER, SERIO).

- a. JA-000038 - Job Aid for the Entry Review Application contains instructions for uploading entry documents via ER.
- b. OASIS Mail/Baggage Procedures contains instructions for attaching entry documents via OASIS.
- c. MAN-000091 - System for Entry Review and Import Operations (SERIO) User Manual contains instructions for uploading documents via SERIO.

### 6.3.5.3 - DER - Import Alert (IA)

A Detention without Exam Recommendation or DER is utilized in Entry Review for entries/lines that are subject to an Import Alert (IA).

Entry documents and additional evidence are not required prior to submission to the CB if all the following requirements are met:

- The elements in the electronic submission match the criteria found in the IA (e.g. Country of Origin ("CofO"), declared manufacturer, product description).
- The IA does not specify that entry documents be submitted
- No additional information is necessary to make an initial admissibility decision
- No additional line information is required

**NOTE:** Request entry documents and/or additional evidence prior to a DER submission when the IA specifies that the shipment may be detained if it is not accompanied by certain additional entry documents and/or evidence. Example: IA 28-02 for Indian Black Pepper states that Districts may detain all shipments of black pepper from India not accompanied by a certificate, containing certain information, from the Indian EIC.

When submitting a DER:

1. Ensure that you follow the instructions for each applicable IA (more than one IA may apply to a line).
  - a. Verify electronic entry information matches the IA prior to submitting the DER to CB. This includes:
    - CofO
    - Firm Name and Address (for the manufacturer, shipper, consignee, or importer, as applicable to the import alert)
    - Importer Description/Product Description (Some IAs are very general - ensure the specific product is subject to the IA)
2. Update and rescreen as appropriate.
3. Enter the following comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen:
  - a. Example: "Manufacturer/Product is subject to IA XX-XX" or "CofO/Product combination is subject to IA XX-XX"
  - b. If required by the IA, ensure that any research conducted in the FDA database systems are documented in the remarks section. Example:

“Per IA XX-XX (Database Name) was reviewed and (Manf/Supplier) was issued a W/L”.

4. If it is suspected that an entry/line may be subject to an IA but cannot be confirmed from the electronic entry data, request and/or review entry documents. This may occur when a manufacturer name is listed on an IA, but the address differs from what was electronically transmitted.
  - a. If the entry documents show that the electronic information submitted was incorrect, update and rescreen the entry/line. If the updated entry/line is subject to an IA follow the DER procedures above.
  - b. If review of the entry documents show that the entry/lines are not subject to the IA, the reviewer can determine the appropriate next step (MPro, FEX/LEX, SAM, DTR).

### 6.3.5.4 - DTR

A Detention Recommendation (DTR) is utilized at the entry review step when the reviewer cannot confirm that products being offered for import meet FDA’s admissibility criteria. Prior to recommending a DTR, the reviewer may utilize the electronic submission, internal FDA databases, and any entry documentation submitted by the filer to make a determination. A field/label exam or sample collection may be assigned to aid in determining admissibility.

#### 6.3.5.4.1 - Similar to Import Alert

If the product appears to be similar to a product/manufacturer/CofO combination on IA and additional information is needed to determine if the product is subject to IA:

1. Request and review the entry documents.
2. Update and rescreen inaccurate data.
3. If the entry is subject to IA, follow procedures for DER (See IOM Section 6.3.5.3).
4. If the product does not match the IA, determine the next step, which could include any of the following:
  - a. May Proceed
 

If the entry flagged for the IA, and is subsequently released:

    - Provide feedback to the Import Compliance Systems Branch (ICSB) using ER if the line flagged incorrectly for an IA. (PREDICT Guide: Rules and Scoring)
    - Include a comment as to why the product was not subject to the IA. Example: “Firm flagged for IA XX-XX but product is not subject to IA (include reason why product is not subject to IA)”.
  - b. Request Field Work (SAM/FEX/LEX):
    - Include pertinent instructions in the “Instruction Text” field located in the “Work Details” section of the “Work Request and Work Request Details” screen. Example: “Firm/product may be subject to IA XX-XX, collect pertinent evidence (labeling, photographs, entry documents, sample)”.
  - c. If a violation (different from the IA) has been determined, submit a DTR to CB.

- Include pertinent comments in the “Instruction Text” field located in the “Work Details” section of the “Work Request and Work Request Details” screen. Example: “No (Listing) found in (database searched) for (manf/product)”.

#### 6.3.5.4.2 - Previous Violative Results (pending IA addition)

At times the Entry Reviewer may come across entries/lines that contain the same product and manufacturer as a previous entry/line that was found violative and is pending addition to Import Alert. Depending on the screening criteria and whether or not ORA has direct reference will impact the reviewer’s next step.

**NOTE:** In these situations, a screening criteria may have been implemented by the CO to ensure reviewers are aware of the violative findings.

##### 6.3.5.4.2.1 Direct Reference Authority for DWPE

When ORA has direct reference authority (DIO Advisory #1) and the electronic entry is an exact match to the previously found violative shipment, additional entry documents and/or evidence may not be necessary.

**NOTE:** Ensure any additional requirements included within an assignment are met.

When you encounter one of these shipments and ORA has direct reference authority:

- a. Recommend Detention (DER).
- b. Include pertinent comments in the “Instruction Text” field located in the “Work Details” section of the “Work Request and Work Request Details” screen:
  - a. Previous violative findings, CMS/work activity number and/or entry number, Reference to the IA, any evidence collected. Example: “Previous violative findings (issue found, CMS/work activity number and/or entry number) firm/product awaiting addition to IA XX-XX. Direct reference authority for (product) for addition to DWPE. No physical exam conducted.”

##### 6.3.5.4.2.2 - No Direct Reference Authority for DWPE

When ORA does not have direct reference authority, the entry must stand on its own. There are many factors to consider in these types of situations such as risk and pending cases. Discuss the next steps with your supervisor and CB. Possible next steps could include the following:

1. Request and/or review entry documents.
2. Request Field Work (SAM/FEX/LEX)
  - a. Include pertinent instructions in the “Instruction Text” field located in the “Work Details” section of the “Work Request and Work Request Details” screen. This includes: Previous findings, CMS/work activity number and/or entry number,

- instruction for field work. Example: “Previous violative findings (issue found and entry number) firm/product awaiting addition to IA XX-XX. Review labeling for ephedrine alkaloids.”
3. If a violation is determined for the current shipment, submit to CB under the applicable Problem Area Flag (PAF).
  4. May Proceed the entry if no violation is found with the current shipment.

### 6.3.5.5 - Registration/Listing/Approval

Some products may require registration, listing, and/or approval. The steps below describe how to recommend detention when compliance with these requirements cannot be verified.

#### Registration and Listing

1. When registration and/or listing is required, review the electronic submission. For those entries where compliance cannot be confirmed using the electronic data transmitted and internal FDA databases, request and review entry documentation.
2. Recommend detention (DTR) if the necessary registration or listing cannot be verified after reviewing the entry documents and the appropriate center database.

**NOTE:** Failure to submit Affirmation of Compliance data or a look-up failure is not sufficient to recommend detention. Prior to recommending detention, make a reasonable effort to verify compliance with registration and listing requirements in the center databases using the manufacturer and product information provided.

- a. Include pertinent comments in the “Instruction Text” field located in the “Work Details” section of the “Work Request and Work Request Details” screen. Such as, the database reviewed, findings, any evidence collected.  
Example: “No registration or listing found in (database) for manufacturing company (Provide specifics as to what does not match (i.e. name, street address, city))”.
3. If additional information is not submitted in the electronic or paper entry and is required to make an initial admissibility decision (e.g. drop ball test or can size), request that specific information from the filer.

#### Approval

1. When the required approval cannot be verified after reviewing the entry documents and searching the appropriate database, collecting additional product labeling is not required to recommend detention, unless specifically noted by additional guidance. If the entry reviewer is unable to determine if the product requires approval, collect the product labeling. Legible copies or photos of the labeling from the current shipment should accompany the detention recommendation.
  - a. Reference the pertinent *Initial Admissibility Job Aids* for center requirements, e.g., intended use, end use, and annual reports (IOM Section 6.3.5.2).

- b. Include pertinent comments in the “Instruction Text” field located in the “Work Details” section of the “Work Request and Work Request Details” screen. Such as the database reviewed, findings, and any evidence collected.  
Example: “No (approval e.g. NDA, ANDA, 510(k), PMA, etc.) found in (database) for manufacturing/product combination. Labeling, end use letter, and intended use included in submission.”

### 6.3.5.6 - IFE

Follow current procedures for reviewing IFE (Import for Export) entries (IOM 6.2.3.4 and RPM 9-15).

## SUBCHAPTER 6.4 - FIELD EXAMINATION

### 6.4.1 - GENERAL

A field examination is a physical inspection of products subject to FDA jurisdiction. Examinations may take place at the port of entry, warehouse, cold storage facility, or other designated examination site. Additional information about performing field examinations, specific to product and program area, may be addressed in the [Compliance Program Guidance Manuals \(CPGMs\)](#) and the [Compliance Policy Guides \(CPGs\)](#)

A field examination involves actual physical examination of the product for such things as:

1. Confirming that product and quantity present corresponds to product and quantity declared on shipping documents,
2. In transit or storage damage,
3. Inadequate storage temperature conditions,
4. Rodent, bird or insect activity,
5. Lead in ceramic ware (Quick Color Test – QCT and Rapid Abrasion Test - RAT),
6. Odors uncharacteristic for the product or of spoilage,
7. Non-permitted food and/or color additives, and
8. General label compliance (label examinations)

A label examination (LEX) is used when the investigations branch conducts a label review (LBL) of the physical product in the field to determine labeling compliance. The remarks entered and exam class selected can be used by compliance to make an admissibility decision for the product. A Label exam should be recorded as LEX. All other field examinations should be recorded as a FEX along with the appropriate problem area flag (PAF) When conducting a field examination, compare documents provided by the filer/importer, to what is physically available during your inspection and to the information that was electronically submitted. Record your observations in your regulatory notebook at the time of the field exam. Information to record includes:

- Date
- Entry number

- Name and address of the location where the exam is taking place
- Name and title of the persons providing information about the entry/lot being examined
- Information from the product labeling including the name of the product and any lot numbers or codes identified
- Number of units examined
- Documentation of any photos or labels collected
- Any abnormalities or discrepancies observed
- A record of the quantity of any product that was destroyed in the field as part of the field examination process, if any

Note: Additional instructions on regulatory notes can be found in IOM Subchapter 2.1  
REGULATORY NOTES.

A field examination does not have the same level of confidence as a laboratory examination. Consequently, more rigorous standards of acceptance are applied than those used for formal regulatory levels. For example, if the formal action guideline for whole insects is 10 per 100 gm in product X, you may sample product X when your field examination shows only one or two insects per 100 gm. The decision to sample is, to some degree, left to your discretion. In most instances, it should be based on findings significantly lower than specified by the formal guideline.

See IOM 5.1.4.3 for suggestions on what to do when conducting a field examination when the firm responsible for the products invites individuals who are not directly employed by the firm to observe the examination. See IOM 6.4.10 for instructions on recording field/label examination results in OASIS.

### 6.4.2 - FIELD EXAMINATION SCHEDULE

A field examination should include a physical examination of a minimum of five containers (cases, cans, bags, etc.) of a product, or as directed by Compliance Programs, specific product examination schedules (e.g., LACF), or other guidance. All containers opened for exam should be identified with FDA, division abbreviation, the date of the examination, and the lead investigator's initials.

When you conduct any field examination, in addition to specific items discussed in the following sections, be alert for any over labeling where a product name or identity may have been changed; different manufacturer than that transmitted or provided in the entry documents; product without mandatory English labeling; changes in expiration date or lot numbers; product quantity differences; product integrity; country of origin (under CBP authority 19 CFR 134) or similar questionable practices. If you encounter any of these items, document your findings and discuss the appropriate action with your Supervisor.

## 6.4.3 - FIELD AND LABEL EXAMINATIONS – FOODS AND COSMETICS

See IOM 5.4.1.4.2 for information on performing reconciliation examinations during import field examinations.

### 6.4.3.1 - Food Sanitation

Microbiological - field examinations cannot be used for suspected microbiological contamination.

Filth and Foreign Objects - field examine only those product/container combinations in which you can physically view and examine the product, e.g., products which can be probed, products in see-through containers, etc. See 5.1.5, for additional instructions on performing field examinations.

Canned and Acidified Foods – See IOM Chapter 4 SAMPLE SCHEDULE CHART 2.

Decomposition in Non-sealed Foods - This can include organoleptic examination for fish, seafood, frozen eggs, etc.

### 6.4.3.2 - Pesticides, Industrial Chemicals, Aflatoxins, & Toxic Elements

Field examinations cannot be performed for most pesticides, chemical contaminants, natural toxins and metals, except for metals in dinnerware and the side seam solders of cans.

NOTE: Divisions should use commercial versions of the Quick Color Test (QCT) and the Rapid Abrasion Test for lead, e.g. Lead Check Swabs, while conducting field examination of dinnerware and food cans to determine if follow-up sampling is required. The testing scheme for dinnerware can be found in CP 7304.019. Specific information regarding the techniques of testing dinnerware and can side seam solder can be found in Lab Information Bulletins (LIB) 4127 and LIB 4041, respectively on the Office of Regulatory Science (ORS) intranet site.

### 6.4.3.3 - Food and Color Additives

Perform a visual examination of the container and a label review for the mandatory labeling requirements. Determine if a color additive is declared for a product to which it appears coloring has been added. Determine if a declared color additive is acceptable for use in the product.

The use of a color additive must conform with the requirements stated in the color additive's listing regulation. These requirements are outlined in the "Color Additive Status List" and the "Summary of Color Additives Listed for Use in the United States in Food, Drugs, Cosmetics, and

Medical Devices.” These lists provide the current status and use limitations of color additives permitted in food, drug, cosmetic, and medical device products.

Requirements for declaring color additives on food labels are provided in 21 CFR 101.22 (k). Color additives subject to certification may be declared by the names listed in 21 CFR parts 74 and 82 or by abbreviated names that omit “FD&C” and “No.” The term “Lake” must be included in the names of color additive lakes. FD&C Yellow No. 5 is specifically required to be declared on food labels under 21 CFR 101.22 (k) and 21 CFR 74.705. Cochineal extract and carmine are specifically required to be declared on food labels under 21 CFR 101.22(k) and 21 CFR 73.100. Other color additives not subject to certification may be declared by the names listed in 21 CFR part 73 or in general terms such as “Artificial Color,” “Artificial Color Added,” or “Color Added.”

Determine if a preservative declaration includes its purpose; for example, “Sodium Benzoate as a preservative.”

#### 6.4.3.4 – Nutrition Labeling and Food Allergen Labeling

The only valid field examination which can be performed for this type of problem is a label examination for the mandatory labeling requirements. Refer to the [“Industry Resources on the Changes to the Nutrition Facts Label”](#) and [Food Allergen Labeling and Consumer Protection Act of 2004 \(FALCPA\)](#) requirements for guidance.

Note that there are requirements for voluntary Gluten-Free label claims. Such claims must meet the requirements in the Gluten-Free labeling of foods regulation (21 CFR 101.91). This is an important public health issue for persons suffering from Celiac disease. For products that bear gluten-free claims, refer to [“Gluten- Free Labeling of Foods”](#) page for guidance.

Also see the [“Food Labeling & Nutrition”](#) website for the most up-to-date information regarding claims in labeling. Also, see CP 7321.005 to determine areas as emphasis for food labeling violations.

#### 6.4.3.5 - Food Economics (On Consumer Size Containers only)

Label Examination - Review labels for all aspects of the labeling requirements.

Net weight - See IOM 4.3.8.1

Food Standards - The only valid field examination which can be performed for Food Standards is a label examination for the mandatory labeling requirements of a particular Food Standard.

#### 6.4.3.6 - Cosmetics

Valid cosmetic field examinations include a reconciliation examination for security purposes and/or a label examination for the mandatory labeling requirements. The most important labeling considerations are:

1. Ingredient Labeling (21 CFR 701.3)
2. Prohibited ingredients (21 CFR 700.11 through 700.27 and 21 CFR 250.250)
3. Non-permitted color additives (see Color Additives Status Lists)
4. Warning Statements (21 CFR 740.11, 740.12, 740.17, and 740.19)
5. Cautionary/Other Required Statements (for example, required caution statement and directions for patch test for coal-tar hair dyes - FD&C Act sec. 601(a); required caution statement for the color additive lead acetate - 21 CFR 73.2396; required label information for the color additive bismuth citrate – 21 CFR 73.2110; and required label information for the color additive henna – 21 CFR 73.2190)
6. Tamper Resistant Packaging Requirements (21 CFR 700.25)
7. Other Labeling Requirements (21 CFR 701.10 through 701.13)

For further questions contact the Office of Cosmetics and Colors.

#### 6.4.4 - FIELD AND LABEL EXAMINATION – DRUGS

A field examination involves actual physical examination of the product (minimum of five containers or as directed by Compliance Programs).

- Confirm that product and quantity present corresponds to product and quantity declared on shipping documents.
- Examine security and integrity of the container including tamper resistant packaging requirements.
- Examine for in-transit or storage damage or inadequate storage temperature conditions.
- Examine for any over labeling where a product name or identity may have been changed.
- Examine if the manufacturer is the same as the one transmitted or provided in the entry documents.

A label exam involves an examination of the product label and accompanying labeling. The drug products must comply with the general labeling requirements found in 21 CFR 201.1 – 201.328. Product labeling should bear all required information in English. If product labeling includes a language other than English, it should contain all required information in both languages. Exception: Labels in Spanish for distribution in the Commonwealth of Puerto Rico is authorized under 201.15 (c). For bulk drugs verify that product labeling complies with the requirement(s) in 21 CFR 201.122. Section 201.125 does not apply to bulk drugs only to finished dosage prescription drug products.



#### 6.4.4.1 - Labeling

Bulk drugs and finished dosage forms should be evaluated for compliance with the drug listing and drug establishment registration requirements.

#### 6.4.4.2 - Contamination

Drugs should be examined for container integrity, e.g., cracked vials, ampoules, bottles, etc.

#### 6.4.4.3 - Samples

A decision to collect samples should be made in accordance with relevant CPs and any applicable assignments. Samples collected from lots where the drug substance or finished product has been subjected to actual or suspected contamination should be decided on a case-by-case basis.

#### 6.4.4.4 - Special Instructions

Field examinations may be performed on drug lots to obtain information to determine the new drug status of a given shipment. Divisions should contact the CDER Office of Compliance, Office of Drug Security, Integrity and Response, Division of Imports Exports and Recalls, Import Export Compliance Branch for guidance.

### 6.4.5 - FIELD AND LABEL EXAMINATIONS – DEVICES

Field and label examination instructions issued by CDRH for specific devices are located on the [Import Program](#) intranet site under commodity specific resources.

At a minimum, the label should include the name and place of business of the manufacturer, packer or distributor and product identity. Be aware of mis declared devices, for example, TENS (transcutaneous electrical nerve stimulation) devices are often declared as therapeutic massagers but in fact should be declared as neurological therapeutic device. Products declared as destined for veterinary use only must include such a statement on the packaging and product. CAUTION: If the sealed packaging, such as an outer crate, of a medical device indicates that the manufacturer's warranty will be violated should it be opened by someone other than a factory representative, DO NOT open the packaging. Consult with your supervisor regarding any further action. For further information refer to [21 CFR Part 801](#).

It is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization. During a field exam of "sterile" devices offered for entry, which are destined for sterilization, per [21 CFR 801.150](#), each pallet, carton, or other designated unit must be conspicuously marked to show its non-sterile nature when it is introduced into and

moving in interstate commerce, and while it is being held prior to sterilization.

FDA will not support import action against the device as misbranded or adulterated when the non-sterile device as labeled sterile if the lot is marked appropriately as noted previously. [21 CFR 801.150i](#) also requires a written agreement between the foreign firm and the importer of record. Specifically, there is in effect a written agreement which: (i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization.(ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized.(iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and(iv) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act. This should be verified upon import.

### 6.4.6 – FIELD AND LABEL EXAMINATIONS - BIOLOGICS

Review applicable import alerts regarding biologics prior to conducting any field examinations of biological products subject to import alert.

In general, products regulated by Center for Biologics Evaluation and Research (CBER) do not warrant a field examination, because they are licensed under Section 351 of the PHS Act. In addition, lot release procedures pursuant to [21 CFR 610.2](#) apply to many products, such as vaccines.

If it is determined that a field examination is warranted for licensed or unlicensed CBER-regulated products, labeling for the product and its intended use should be examined. Any questions should be sent to CBER Import Inquiry at [CBERImportInquiry@fda.hhs.gov](mailto:CBERImportInquiry@fda.hhs.gov)

### 6.4.7 - LABEL EXAMINATIONS - ANIMAL PRODUCTS

Contact the CVM mailbox [CVMImportRequests@fda.hhs.gov](mailto:CVMImportRequests@fda.hhs.gov) with questions on the importation of animal food, drugs, devices, and other animal products. You should be aware of various import alerts, Compliance Policy Guides or guidance documents as they affect individual import situations. See the commodity specific resources section in the Import Program intranet site for additional information or notifications on current import situations

### 6.4.7.1 – Animal Drugs

Label examinations of animal drugs are visual examinations that are sometimes needed to determine product admissibility. A label examination may be necessary if:

- the product is an unapproved new animal drug, especially one for use in food animals;
- the product is sterile;
- the manufacturer is not registered with FDA or differs from the firm in the foreign drug manufacturer registration;
- the drug is not listed with CVM; or
- discrepancies between the information on the product label and the import documentation exist.

Bulk New Animal Drug substances and Active Pharmaceutical Ingredients (APIs) may be legally imported if the firm is registered with FDA and it is destined to the holder of an approved New Animal Drug Application (NADA), Abbreviated New Animal Drug Application (ANADA), index listing or a Generic Investigational New Animal Drug Number (JINAD) or Investigational New Animal Drug Number (INAD) exemption. For bulk drugs for use in compounding for animals, confirm the registration and listing status of the firm and product and consult with the Center for the current status of the bulk drug substance presented for import.

Type A Medicated Articles are animal drugs and must meet the appropriate drug requirements listed above.

FDA personnel may allow veterinarians and animal owners to import unapproved drugs under the Personal Importation Policy (PIP). For more information, refer to the Regulatory Procedures Manual, section 9-2 Coverage of Personal Importations.

### 6.4.7.2 – Animal Devices

Devices intended for animals do not require premarket approval. However, they are still subject to examination for adulteration and misbranding violations. When conducting your label exam, verify that labeling is not false or misleading and bears adequate instruction for use in each target animal group. When conducting your label exam, ensure the following:

- Devices for animal use are clearly marked for animal use only
- Prescription animal medical devices are labeled in the following manner: “Caution Federal law

restricts this device to sale by or on the order of a licensed veterinarian.”

- Non-prescription animal medical device labeling bears adequate directions for use by the lay user.

In addition to being regulated by CVM, animal devices that are radiation emitting products are also regulated by CDRH. Import coverage for radiation emitting products is provided for in [CPGM 7386.007](#) Imported Electronic Product.

Animal devices that include a drug component should be referred to [CVMImportRequests@fda.hhs.gov](mailto:CVMImportRequests@fda.hhs.gov)

### 6.4.7.3 - Animal Food

Animal food and food components, including pet food should be examined for conformance with all applicable and appropriate food labeling requirements listed in [21 CFR 501](#), be acceptable for animal food (e.g. not contain drug claims, be an approved food additive, generally recognized as safe (GRAS) for an intended use, or otherwise found acceptable as an animal food ingredient, and not contain hazardous levels of contaminants). For example, determine if a preservative declaration includes its function, such as “Sodium Propionate (preservative).”

A list of approved food additives for use in animal food is found in [21 CFR 573](#) and a partial list of GRAS substances for use in animal food is found in [21 CFR 582](#). Substances affirmed as GRAS for use in animal foods are listed under [21 CFR 584](#). Irradiation is considered a food additive and approvals for the use of irradiation for animal food are found in [21 CFR 579](#). Additionally, animal food GRAS substances that have been notified to the FDA can be found in the [Animal Food GRAS Notices Inventory](#).

Ensure the use of a color additive conforms with the requirements stated in the color additive’s listing regulation. For further questions, contact [CVMImportRequests@fda.hhs.gov](mailto:CVMImportRequests@fda.hhs.gov).

### 6.4.7.4 – Animal Grooming Aids

FDA does not regulate products intended solely to cleanse or beautify animals, commonly referred to as grooming aids. Cosmetic regulations outlined in the FD&C Act do not apply to products intended for animal use. Products purporting to be animal grooming aids that are labeled as or otherwise intended for therapeutic purposes may be considered animal drugs. This may occur when a grooming aid is labeled to contain an active drug ingredient or to suggest or imply a therapeutic benefit. Refer to CPG Sec. 653.100 Animal Grooming Aids.

NOTE: Medicated shampoos are not animal grooming aids and are regulated by FDA as animal drugs. Consult CVM before detaining these products.

### 6.4.7.5 – Animal Biological Products

Although animal biological products are “drugs” within the meaning of the FD&C Act, animal drugs produced and distributed in full conformance with the Virus, Serum, Toxin Act (VSTA) and its implementing regulations administered by the United States Department of Agriculture Animal Health Inspection Service (USDA-APHIS) are not subject to the animal drug approval requirements in section 512 of the FD&C Act.

Under the regulations implementing the VSTA, 9 CFR part 101, animal biological products are defined, in part, as “all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.” (9CFR 101.2)

A MOU between APHIS and FDA (APHIS Agreement #04-9100-0859-MU, FDA Serial #225-05-7000) addresses jurisdictional issues concerning the regulation of certain animal products as biological products. Examples of products listed in the MOU as products generally regulated as animal biological products by USDA-APHIS include vaccines, viruses, bacterins, bacterial extracts, allergens, antiserums, antitoxins, toxoids, immunomodulators, immunoglobulins, and serum and plasma for passive transfer. Examples of products listed in the MOU as products generally regulated as animal drugs by FDA include antibiotics, antimicrobial peptides, anti-inflammatories, anthelmintic, antiprotozoal, competitive exclusion products, genetic constructs (non-vaccine), stem cell therapies, gene and somatic cell therapies, hormones, growth factors, growth promotants, whole blood, transfusions, and clotting products (except serum and plasma for passive immunity).

For questions regarding whether a product is regulated as a drug by FDA or an animal biological product by USDA-APHIS, contact [CVMimportrequests@fda.hhs.gov](mailto:CVMimportrequests@fda.hhs.gov).

### 6.4.8 - FIELD AND LABEL EXAMINATIONS -RADIOLOGICAL HEALTH

Import coverage for radiation emitting products is provided for in [CPGM 7386.007](#), Imported Electronic Product.

When conducting fieldwork on radiation emitting products refer to the field and label examination work instructions issued by CDRH and located on the [Import Program](#) intranet site under commodity specific resources. Additionally, field and label examinations for imported electronic products should include of entry documents and [FDA-2877](#), Declaration for Imported Electronic Products Subject to Radiation Control Standards, to determine if

they are properly completed and accurate. This applies to each shipment of electronic products for which performance standards exist. Performance standards, covering [ionizing](#), [optical](#), [microwave](#) and [acoustic](#) radiation-emitting products, are specified in 21 CFR 1020 through 1050.

### 6.4.9 - FIELD EXAMINATIONS – TOBACCO PRODUCTS

Contact the Center for Tobacco Products (CTP) Office of Compliance and Enforcement, Division of Enforcement and Manufacturing, at [CTP-ComplianceImports@fda.hhs.gov](mailto:CTP-ComplianceImports@fda.hhs.gov) with general questions on the importation of tobacco products. Label examination instructions issued by CTP are located on the Import Program intranet site under commodity specific resources.

### 6.4.10 – FIELD/LABEL EXAMINATION RESULTS

Examination results should be reported via FDA import systems for those lines that have been physically examined. Results should reflect the findings within the limitations of an examination for the specified problem area. An examination should not be reported on lines that were not physically examined. If adverse findings are encountered, examination work type(s) should be added to the line, if needed, to record the adverse findings under the appropriate problem area.

Review the Line Details screen prior to completing the OASIS Field Exam Results Screen.

1. Access the Line details by double clicking the work type field, i.e. “FEX”. This will open the “Entry/Line Summary” screen. Click the “Line Details” button.
2. Review all the data and verify that it is complete and correct. For example, make sure the product code matches the product, and that the manufacturer, country of origin, quantity and value are correct. Add any lot codes if applicable and update the Line Availability information if needed. If there is a build button on the line you need to correct, you must use the build function to make corrections. All fields that are white or highlighted in purple can be updated.
3. If data has been changed, click the “Save” button. Then enter a brief description in the pop-up box of corrections made. Assign fault to any errors as appropriate.
4. After any changes are made, save the changes and “Rescreen” the line to see if changing the data caused the line to hit on any other criteria or alerts.

Complete the examination results by navigating to Work Results:

The system auto fills the following fields: entry number, Lead Initials, Date Completed, Product Code, Product Description, Importer/Corrected Description, PAF, PAC, and Reference.

Enter data in the following fields:

### 6.4.10.1 – Date Completed

The Date Completed field will default to the current date. If necessary, update the Date Completed field to the date the examination was completed.

### 6.4.10.2 – Location of goods

Enter the location where the examination was conducted if availability and location of goods have not been entered or if the exam location has changed. Include location name and address or resident post location.

### 6.4.10.3 – Remarks

Enter the type of examination performed, describe how the examination was performed, and note any samples collected or photos taken, or product and quantity destroyed in the field as part of the examination process. If the examination was performed due to an assignment, import bulletin, or import alert, then enter pertinent information as instructed.

Example Remarks text: “Conducted food filth exam under CP03819A. Viewed outer cases under a black light. Opened 5 of 10 cases and viewed contents through transparent packaging. Collected a sample for micro analysis under CP03819C.”

Or, “Exam was conducted according to DOPG-XXXX-XX. Examined 200 units and found 6 devices with integrity issues. A sample was collected for integrity analysis and 7 photos documenting the exam were uploaded.”

Note – Text entered in the Remarks Field does not appear on the Notice of FDA Action.

### 6.4.10.4 – Summary

Enter the findings of the examination. Be as specific as possible in the allowed space. If the examination will be reported as Class 2 provide specific remarks detailing why Class 2 was chosen.

Example Summary text: “All cartons are accounted for. No macro filth observed during examination. Exam Class 2 as this line to be held for analysis of line 1/4.”

Or,  
“Observations include no ingredients statement, no serving size and incomplete nutrition info. Label submitted to CB for review.”

Note – Text entered in the Summary Field does not appear on the Notice of FDA Action.

### 6.4.10.5 – Exam Class

Select the appropriate Exam Class.

Class 1 – No Adverse Findings within Problem Area: No adverse findings were noted within the limitations of the examination for the specified problem area. The entry line may be IB Released, sampled for a different problem area, referred to Compliance Branch for a

different problem area or have additional work types added to it as appropriate. Additional action should not be taken within the specified problem area that was deemed Class 1

Class 2 – Other Findings: Class 2 is intended to be used only for those situations that do not meet the definitions of Class 1 or Class 3. Some examples of when to use Class 2 include the following (this list is not intended to be all-inclusive):

1. Potential adverse findings were observed. Observations lead to the collection of a sample or referral to compliance branch in the specified problem area for final admissibility determination.
2. The product appears to be in violation within the limitations of a field examination for the specified problem area; however, investigations branch is using discretionary authority to release the product. If this option is used, describe in detail in the Summary field the reason(s) why this violative product is being released, such as, “This product meets the criteria for release under the Personal Importation Policy (PIP) as stated in the Regulatory Procedures Manual (RPM).” Note: The exemption for releasing a personal importation with a class 2 field exam findings, only applies to the mail environment.
3. No adverse findings were observed within the limitations of an examination for the specified problem area; however, the line is sampled within the same problem area due to the firm/product having a violative history in that problem area or as directed by an assignment, import bulletin or other guidance.
4. No adverse findings were noted within the limitations of an examination for the specified problem area; however, the line is being held and referred to compliance branch pending sample analysis of another line. (Note: it is inappropriate to record a field examination if no physical examination occurred. The “Same Action As” function allows for the holding of lines where no examination occurred pending the analytical results of another sampled line)

Class 3 – Adverse Findings within Problem Area: The product appears to be in violation within the limitations of an examination for the specified problem area.

Further action must be taken under the specified problem area, i.e. sampled or referred to the compliance branch for final admissibility determination.

NOTE: If a LEX is conducted and the examination identifies labeling claims that may warrant marketing clearance and/or approval, record the findings as a Class 3 LEX and submit to compliance as a DTR/AAP.

Click "OK" to save the examination results.

#### 6.4.10.6 – Record Time

Select the correct PAC from the drop-down menu. Enter your time. If more than one person worked on the examination, click on the "Add" button. A box will come up; select the person's name from the drop down menu, and select the correct PAC from the drop down menu. Enter that person's time. Repeat for each person who worked on the examination. Click "OK". Note: time is entered in decimal format in tenths of an hour (6-minute increments).

#### 6.4.10.7 – Next Steps

Once the work has been submitted, if no other work was set up on the line, you will be prompted to Next Steps.

If the exam was classified as Class 1 you will have the option to IB Release or Add Work.

If no other work needs to be added to the line, the line will be released by selecting "IB Release" and entering Remarks including an appropriate summary of all remarks entered in the Exam Results. If product was destroyed in the field as part of the field examination process, record what was destroyed in the Remarks field. Text entered in the Remarks field does not appear on the Notice of FDA Action.

If work needs to be added to the line select "Add Work". The system will take you to the Work Request and Work Request Details page to add work as appropriate.

If the exam was classified as Class 2 with No Adverse Findings, but the line is to be held pending sample analysis of another line, follow Division procedures for notifying Compliance Branch.

If the exam was classified as Class 3 you will have the option to Refer to CB or Add Work IB Release Remarks should include a detailed description of why the product was released if Adverse Findings were found.

If "Yes" is chosen, the system will prompt you to return to the Possible Actions page to add work as appropriate.

If "No" is chosen, the system will display the message: "Performing Hold Designated/Others Go!" Click "OK". The line will move to the Compliance Branch Grab Bag. Follow Division procedures for notifying the compliance branch.

## SUBCHAPTER 6.5 - IMPORT SAMPLE COLLECTION

### 6.5.1 - GENERAL

In general, the difference between official domestic and import samples is that import samples do not require official seals or collection of a 702(b) reserve portion. However, these are division options. See Chapter 4 for sampling instructions and guidelines. There are instances when the collection of a reserve portion and an official seal is warranted, i.e., when enforcement action (e.g., seizure, injunction, prosecution) is contemplated. Some sample sizes are provided in the Sample Schedule Section (Chapter 4). When using the sample sizes furnished elsewhere in this manual, do not collect the duplicate portion of the sample unless directed by your division. In addition, when preparing to collect import samples, you should be aware of your personal safety. Refer to IOM 5.2.1.2.

Import sub samples should be identified in accordance with IOM 4.5.2.1. However, if the sample number is not available at the time of shipment or sample delivery (e.g. a situation arises where the investigator collects the sample and must deliver it to a servicing lab prior to completing the collection report.) the entry/line number may be used in lieu of the sample number for identification. In these cases, complete the collection report as soon as possible and notify the sample custodian of the sample number. The collection report should clearly indicate how the sub samples are identified and provide reasoning as to why the sample number was not used.

Collect, prepare, handle, and ship import samples in a manner which assures the samples integrity. It is important that samples are packaged properly and labeled completely and legibly on the outside of the immediate sample container before delivery to the laboratory. This allows the sample custodian to properly store the samples and expedite delivery to the appropriate laboratory branch.

Attaching a Form FDA 525, Sample Package Identification, is not required; however, if a Form FDA 525 is not used, the outside of the immediate sample package should be identified with the following:

- Sample number, if available at time of shipment
- Entry/Line number if sample number not available at the time of shipment or sample delivery
- PAC/PAF (include all if multiple PAC/PAFs going to the same lab) see IOM 6.5.5
- Date of collection
- Storage Condition (ambient/frozen/refrigerated)
- Lead CSO's initials
- The number of bags/cartons in sample if more than 1 and the sub numbers in each container, i.e. bag/box 1 of 3, subs 1-10, etc.

Note: If an FDA 525 is used, do not affix it on the outside of the shipping container.

Including a copy of the Collection Report (CR) is not required unless specifically requested by a lab.

FDA does not pay for import samples at the time of collection. The Importer should be advised they may bill the responsible division. FDA will not pay for violative import samples, per 21 CFR Part 1.91, see IOM 6.2.4.5.

When collecting IMPORT "ADDITIONAL Samples", the original Import Collection Report (CR) number should be used. Under OASIS, this will be the entry number with appropriate line information, etc.

Import Samples are compliance samples, except for those collected for pesticide analysis. See IOM Sample Schedule Chart 3 (Chapter 4) for guidance.

## 6.5.2 - PROCEDURES

Review the submitted entry (electronic or hard copy documentation) to assure the location of the product(s) is known and the lots are available for FDA examination/sampling before initiating action. The general description of the shipment in the entry documentation submitted to FDA should match the description of the product(s) in the invoice from the broker.

## 6.5.3 - TECHNIQUES

Follow guidance furnished in IOM Subchapter 4.3 - Collection Technique.

## 6.5.4 - IMPORT FORMS PROCEDURES

Because forms are now generated electronically by OASIS, individuals performing field examination or sample collections should follow guidance provided in the OASIS Training Manual, or consult their lead OASIS personnel.

## 6.5.5 - SAMPLE COLLECTION REPORTS

See IOM 1.1 English language requirement. For every sample collected, a corresponding electronic collection report must be completed in OASIS. (See IOM Exhibit 6-4.)

Prior to completing the collection report, review the Line Details for the product sampled. You are responsible for making sure all fields in the Line Details screen are complete and correct. The Line Details screen is the only place you can make corrections to the entered data.

NOTE: If you start a collection report and need to exit at any time to make a correction in the Line Details you will lose the original collection report and a new lab number will be assigned when you return to the Collection Report screen.

To review the Line Details:

1. Access the Line Details screen by double clicking the work type field, i.e. "SAM". This will open the Entry/Line Summary screen. Click the "Line Details" button.
2. Review all data and verify that it is complete and correct. For example, make sure the product code matches actual product, and that the manufacturer, country of origin, quantity and value are correct. Add any lot codes if applicable and update the Line Availability information if needed. If there is a build button on the line you need to correct, you must use the build function to make corrections. All fields that are white or highlighted in purple can be updated.
3. If data has been changed, click the "Save" button, then enter a brief description in the pop-up box of corrections made. Assign fault to any errors as appropriate.
4. After any changes are saved, click on "Rescreen" in the Application Tool bar to see if changing the data caused the line to hit on any other criteria or alerts.

Complete the OASIS Collection Report:

1. Highlight the line sampled in your Personal In Box and click on "Wk Detail" in the Application Toolbar.
2. If the line was sampled for more than one PAF, and analysis will be performed at the same laboratory, only one collection report should be generated; unless otherwise directed. Use Ctrl+Click to highlight all PAFs going to the same laboratory.
3. If the sample will be split and sent to more than one laboratory, highlight the PAF(s) for each laboratory individually and complete a separate collection report for each laboratory.
4. Click the "Work Result" button near the top right of the screen to access the Product Collection screen.

OASIS completes the following fields for you: **Entry number, Investigator initials, Date Collected, Product Code, Product Code Description, Importers Corrected Description, Location of Goods**, and the **Lab Number**. The **Date Collected, and Location of Goods** can be corrected on this screen if needed.

Enter data in the following fields:

### 6.5.5.1 - Collection Date

The Date Collected should reflect the date the sample was collected, not the date the sample was entered into OASIS. Only one date can be entered. If the sample collection was accomplished over several days use the last date of collection. Be consistent. This date should also be used to identify the physical sample.

### 6.5.5.2 - Episode

An "episode" is defined as a violative pesticide (or other chemical contaminant) finding and all samples collected in follow-up to that finding. All samples must be associated with one responsible firm (grower, pesticide applicator, etc.) and one specific time period (e.g. growing season). For example, samples of cantaloupes from Mexico reveal

violative residues. Any destination point samples or subsequent compliance samples from the same shipper or grower would along with the original sample be considered an episode. Enter the episode number. See IOM 4.4.10.1.8.

**6.5.5.3 - Submitted To**

To select the appropriate servicing laboratory, click the “Get Lab” button. The National Sample Distributor (NSD) is currently inactive. All lab capabilities have been set to “0”. Districts are instructed to submit samples utilizing the Servicing Laboratory Table (SLT) located in the ORA Workplan. If the servicing laboratory presented by the NSD does not match the specific assignment instructions or the SLT, override the NSD. (See IOM 4.4.10.4.) The NSD-assigned laboratory can be overridden by choosing another laboratory from the drop-down menu. Override Reason must also be selected from the dropdown menu. Click “Proceed” to return to the collection report. The chosen laboratory should be displayed in the Submitted To field.

**6.5.5.4 - Quantity Collected**

Enter the number of sampled units you collected.

**6.5.5.5 - Units**

Select the appropriate units from the pull-down menu. The Calculated Cost will automatically populate based on the Value submitted in the Line Details, Quantity Collected and Units selected.

**6.5.5.6 - DescText**

Enter a description of the sample. The description should include:

1. Number of subs collected
2. Weight/volume of each sub
3. Brief product description
4. Type of container the subs were collected in
5. Lot sampled

Describe how you collected the sample:

Specify any special sampling techniques; if the sample was collected randomly, aseptically, selectively, etc. and the number of master cases collected from.

For example: “Sample consists of 12 subs /16 oz. (1lb) each of IQF Cod Fillets collected at random from lot B129A1. Sample was collected aseptically from 12 master cases and packed in 12 whirl-pak bags.”

Any text you enter in this field will be printed on the “Notice of FDA Action”. This field transfers to the “Sample Description” field in FACTS.

**6.5.5.7 - Hand Ship**

Enter the method of shipping and describe how sample integrity is maintained including sample chain of custody.

1. Describe how the sample was held and stored until shipment.
2. Include how the sample was prepared for shipping and
3. Method of shipment

For example: “Transported from firm in a closed cooler with gel packs, sample was then transferred to freezer #1 in the locked sample room until shipped via UPS to PRL-NW in a cooler with Gel packs.”

NOTE: This field does not transfer to FACTS for the laboratory to view. **Please enter any special handling instructions in the Remarks field.**

**6.5.5.8 - Remarks**

Enter any additional information that is pertinent to the sample collection such as:

1. Special handling instructions or storage condition requirements as necessary;
2. When applicable, note the use of guidance documents used for the collection such as Compliance Program Guidance Manuals, Assignment, or field examination guidance document.
3. Additional information your District, Laboratory, Compliance Program, Assignment, or Import Alert/Bulletin requires;
4. Any specific analysis instructions needed (i.e. any specific pathogen or mycotoxin screen needed.)
5. Any controls or photos collected

For example: “Store frozen. Master case code: PRODUCTION DATE 1319. Open and closed controls submitted with the sample. Analyze for milk protein per IB XX-BXX”

Or, “Store Ambient. Sample collected per DOPG-XXXX-XXXX. Examined 200 units from lot 1234 for defects and identified 6 with pitting. Analyze for device integrity”

This field transfers to the “Collection Remarks” field in FACTS.

NOTE: Be sure to review the entire screen before clicking “OK.” The sample will be transferred immediately in FACTS to the respective laboratory once the OK button is clicked, (unless your supervisor has set up a supervisory review of your work).

**6.5.5.9 - Record Time Screen**

The Record Time Screen will appear. Enter your time. If more than one person worked on the sample, click on “add” button to the right. A box will pop-up; enter the person’s initials and the tab key. Highlight the person’s name, click on OK. Enter other person’s time. Repeat for each person that worked on the sample. Click on OK Note: time is entered in decimal format for OASIS.

## 6.5.6 – Updating a Sample Collection Report

OASIS will allow users to make corrections to collection reports until the laboratory has set the sample to “In Progress” in FACTS. Note that a collection report may only be corrected once. To update a collection report, query the entry by clicking on “Query” and then “Entry”. From the Entry Query screen enter the entry number and click on “Execute Query”. Once you are at the Entry Details screen, select the line you want to update and click “All Activities”. Finally, double click on the “Product Collect Comp” field under the Pending text column to open the collection report and click the “Update” button. The updatable fields will become enabled for modification. They are Quantity Collected, Units, Desc Text, Hand/Ship and Remarks. Once all necessary changes have been made, click “Save”. At that point, the “View Update” button will become enabled. If a change was made to the Quantity Collected, Units, or Desc Text the “Print Notices” button will also be enabled. It is very important to generate and send the Notice that notifies the parties that changes were made to the collection data.

NOTE: If a change was made to Hand/Ship or Remarks fields ONLY, then no new Notice is needed and the “Print Notices” button will not be enabled.

## 6.5.7- Special Domestic Import Samples (SDI)

The SDI sample work type should only be used when directed by a special sampling assignment, for certain perishable products collected for metal (MET) analysis or for products collected for nutritional analysis (NIS). It should not be used when collecting samples for multiple PAFs or if the product appears to be violative or has a history of being violative.

If a product is identified for collection as an SDI under a special sampling assignment, or other directive, follow the instructions outlined in the assignment or directive. SDI samples should be recorded per IOM 6.5.5 – Sample Collection Reports. Additionally, SDI samples require the following:

- A description of the product label as per IOM 4.4.10.3.40 - Product Label in the “Remarks” section.
  - Include brand names and size of lot if not already recorded in the “Line Details” screen.
- An official seal (Form FDA 415a) on the sample container(s).
  - Follow instructions in IOM 4.5.4.3-4.5.4.5.
- Collectors ID on the seal as per [IOM 4.4.10.3.12 Collector’s ID on Seal](#).

- Include collectors ID on the seal in the “Remarks” section.

Note: This information is required for FDA to utilize its domestic authority if the sample analysis results are violative.

After sample collection time is recorded, the user will be prompted to “Add Work” or “IB Release”. The collector should select “IB Release” after any necessary work is completed. After the “SDI” sample work type has been recorded, additional work that would hold the line cannot be added. Once the line is released, the user should generate the Notice of FDA Action (NOA). The NOA will contain a section labeled “SAMPLES COLLECTED AND RELEASED” with additional language pertaining to the release of those lines. When the SDI line is released, the line will be closed. If all lines in the entry have been closed, the entry will be closed.

The import compliance branch will be notified of and responsible for any necessary follow up (such as submitting a screening criteria request and/or coordinating with the appropriate domestic division and program for follow-up actions) on SDI samples found to be violative.

## SUBCHAPTER 6.6 - FILER EVALUATIONS

### 6.6.1 - GENERAL

The FDA makes admissibility decisions based on the electronic entry data transmitted to the FDA by the filers. The admissibility process is reliant upon data provided by parties outside of the FDA, most notably, the entry filers transmitting import entry information to the FDA on behalf of importers. As such, the FDA is dependent on entry filers to submit the most accurate data to make sound, risk-based admissibility decisions.

The FDA conducts periodic filer evaluations to monitor the accuracy of entry data transmitted electronically to the FDA. Filer evaluations are conducted based on the physical location within an import division and may include entry lines transmitted by filers that are physically located within a different import division. Follow [SOP-000217 “Import Filer Evaluation”](#) when conducting import filer evaluations.

## SUBCHAPTER 6.7 - GLOSSARY OF IMPORT TERMS

Refer to the “Glossary” for a more complete listing of import terms. Below is some common import language:

### 6.7.1 - American Goods Returned

Goods produced in the U.S. which are exported, and then returned to the U.S. They are considered imports. (See [Sec. 801\(d\)\(1\) of the FD&C Act \[21 U.S.C. 381\]](#)).



## 6.7.2 - Bonded Warehouse

One of several classes of CBP Warehouses authorized to receive goods that have not been entered into the commerce of the US. Goods are entered into a Customs Bonded Warehouse (CBW) by a "formal entry" or "warehouse entry" requiring complete documentation for the entry, and payment of a fee, but not payment of duty and taxes. Goods in the warehouse can be held for up to 5 years. After 5 years the goods must be entered, exported, or destroyed. Goods in a CBW can be manipulated, but except in certain smelting operations, cannot be manufactured into something else. If the CBW is located in the US, the goods are in interstate commerce and subject to the FD&C Act. See CPG Sec. 110.600 FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers

## 6.7.3 - Break-Bulk Cargo

Cargo transported in individual units, such as bags or cartons, which are not containerized.

## 6.7.4 - Consumption Entry (CE)

"Entered for Consumption" means an entry summary for consumption has been filed with CBP in proper form, with estimated duties attached. The duty can be submitted electronically at the same time as the entry is transmitted or on a 15-day schedule when approved by CBP.

## 6.7.5 – Container Freight Station (CFS)

Another location authorized to receive goods under customs Bond for the purpose of breaking bulk and redelivery of cargo. Containerized cargo can be moved from the place of unloading to a designated container station or may be received directly at the container station from a bonded carrier after transportation in-bond, before the filing of an entry of goods.

## 6.7.6 - Date Collected

The date an import sample is collected.

## 6.7.7 - Date of Arrival

The date a carrier transporting imported cargo arrives in the U.S.

## 6.7.8 - Date of Availability

The date imported cargo is available/accessible for sampling by FDA. Goods may not be available for sampling as soon as they arrive in the U.S., due to the way the items were shipped/stored.

## 6.7.9 - Detention

A temporary administrative action taken by FDA against articles offered for entry which are not or appears not to be in-compliance with the laws FDA administers. Detained articles can be released if brought into compliance, or are refused entry or seized, if not brought into compliance.

## 6.7.10 - Detention Without Physical Examination (DWPE)

An action directed against specific products manufactured or shipped by specific foreign firms. "Import Alerts" list products which may be detained without physical examination due to their violative history or potential.

## 6.7.11 - Domestic Import (DI) Sample

A sample of an imported article collected after it has been released from import status. See IOM 4.1.4.8.

## 6.7.12 - ENTRY

Delivery or offer for delivery of merchandise into the Customs Territory of the U.S. from an outside point.

## 6.7.13 – ENTRY ADMISSIBILITY FILE

Entry admissibility file refers to the file, hard copy and/or electronic, as appropriate, maintained by the District, which contains relevant documentation to support the District's admissibility decision.

## 6.7.14 - Entry Documents (Entry Package)

Information submitted to CBP to determine the goods quantity, its contents, and the parties of interest. Actual documentation for an individual entry can vary greatly, but it generally, consists of an invoice, purchase order, AWB and/or BOL. Entry documents can be submitted electronically to FDA, preferably through the Import Trade Auxiliary Communications System (ITACS) or via paper submission.

## 6.7.15 – FAILURE TO HOLD

Failure to hold means that the goods have been distributed by the importer/consignee without an FDA release from import status. Such goods are usually subject to CBP's redelivery provisions. See IOM 6.7.31 – REDELIVERY BOND.

## 6.7.16 - FILER

A CBP term used to identify the individual or firm responsible for filing an entry. Also known as a Customs House Broker.

### 6.7.17 - Formal Entry

The entry type required for shipments valued over \$2500 or for shipments containing specific commodities designated by CBP. Formal entry is usually a three-step process, "Entry" – which gains the release of the goods from CBP control, "Entry Summary" – which includes determination of the classification and collection of the duty/taxes owed, and "Liquidation" – which is the finalization of the entry process and the completion of an CBP changes to classification and monies owed.

### 6.7.18 - Foreign Trade Zones

Foreign Trade Zones (FTZ) are established under the Foreign Trade Zones Act. Goods properly admitted into an FTZ is considered outside the territory of the US for the purposes of duty and taxes. Several classes of goods are present in an FTZ at any one time. Some of these classes provide duty advantages when the goods are eventually entered into the commerce of the US. Other classes of goods are prohibited by law from entering the commerce and must be exported or destroyed. There is no time limit on how long goods can remain in an FTZ without entry or export. If the FTZ is located in the US, the goods are in interstate commerce and subject to the FD&C Act See CPG Sec. 110.200 Export of FDA Regulated Products from U.S. Foreign Trade Zones

### 6.7.19 - Immediate Delivery (ID)/ Conditional Release

Entry/Immediate Delivery (CF 3461) must be filed within 15 calendar days of arrival of goods in the U.S. Goods may be released for immediate delivery if it is arriving by land from Canada and Mexico. Products may be released for immediate delivery pending entry process completion. Even though CBP has allowed the immediate delivery, FDA regulated products are conditionally released until FDA makes an admissibility decision. The conditional release period ends when FDA May Proceeds the entry or issues a refusal.

### 6.7.20 - Import Alerts

Import Alerts are guidance documents concerning significant re-occurring, new, or unusual problems affecting import coverage. They are available on the internet at <https://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm>

### 6.7.21 - Importer of Record

The party in whose name the entry is made. For example, a Customs House Broker might make an entry and become the "importer of record" by using his importer ID and bond on behalf of his client, the true "importer" of the goods. For FDA purposes, the "importer of record" is the person or company filing the redelivery bond under Sections 802(b) and 536(b) of the FD&C Act [21 U.S.C. 382(b) and 360mm(b)].

### 6.7.22 - Import Sections

Import Sections (536, 801 and 802) are those sections of the FD&C Act containing the Import/Export Provisions

### 6.7.23 - Import Status

Import Status is the standing of an article in the import database system which has not yet been released.

### 6.7.24 – IMPORTER MISDECLARATION

Importer misdeclaration refers to the importer's providing incorrect and/or incomplete information to FDA and CBP, usually via the filer. This may include incorrect product codes and/or product descriptions; incorrect/incomplete manufacturer/shipper name/address; incorrect quantity and value. It may occur as an attempt to avoid FDA and/or CBP actions/regulations such as DWPE, sampling, duties, etc.

### 6.7.25 - Informal Entry

A simplified import entry procedure accepted at the option of CBP for any shipment not exceeding a specified value. Informal entries are filed with complete paperwork and any duties and taxes are paid at the time of filing. The entry liquidates at time of filing.

### 6.7.26 – Immediate Transportation (IT)

An entry document filed with CBP by the importer. It allows the immediate transport of goods without a determination of admissibility, from the port of unloading under CBP bond. In general, the importer must file a consumption entry within 6 months of the date of importation or export the goods. FDA typically examines these goods at an inland port of entry.

### 6.7.27 - Line (Line Item)

A line is each portion of an entry which is listed as a separate item on an entry document. An importer may identify goods in an entry in as many portions as he chooses, except each item in the entry having a different tariff description and rate must be listed separately.

### 6.7.28 - LOT

A lot is an entry, group of entries, or a portion of an entry of goods which can clearly be defined as appropriate for FDA sampling and examination purposes.

### 6.7.29 - MARKS

Words or symbols, usually including the country of origin, marked on cartons, bags, and other containers of imported goods for identification purposes. Marks are a CBP requirement.

### 6.7.30 - Port (Point) of Entry

A port is the CBP location where the Consumption Entry is made. This may or may not be at the Port of Unloading (the point of physical entry into the U.S.)

### 6.7.31 - Redelivery Bond (AKA Entry Bond)

A bond posted by the importer of record with CBP. For FDA regulated products, this is currently in the amount of three times the value of the imported product, to insure redelivery of the product for examination, reconditioning, export, or destruction.

### 6.7.32 - Stripping (Of Containers)

Stripping is the removal of articles from transportation "Container" for examination or sampling.

### 6.7.33 – SUBSTITUTION

Substitution is an attempt by the importer/consignee to present goods to the FDA as corresponding to a particular entry when they are in fact not the goods from that entry. May occur as an attempt to hide distribution without an FDA release and avoid CBP bond actions. See IOM 6.7.15, FAILURE TO HOLD.

### 6.7.34 - Supervisory Charges

Supervisory charges are the charges for FDA supervision of the reconditioning and examination of articles after detention. (See 21 CFR 1.99).

### 6.7.35 - Warehouse Entry (WE)

An entry document filed with CBP by the importer which allows the goods to go immediately into a bonded warehouse.

### 6.7.36 – VQIP QUALITY ASSURANCE PROGRAM

VQIP Quality Assurance Program (QAP) is a compilation of the written policies and procedures used to ensure adequate control over the safety and security of the foods being imported by the VQIP importer. Any format can be used to organize the QAP to include all foods and all of the written policies and procedures under VQIP.

### 6.7.37 – FSVP AND/OR HACCP IMPORTER

The importer who, for a specific food, is subject to the importer requirements in FDA's FSVP regulation, (21 CFR part 1, subpart L) or the requirements applicable to importers in the juice or seafood HACCP regulations (21 CFR 120.14 and 123.12, respectively). Under both the FSVP and the HACCP importer regulations, the importer is

the U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States (21 CFR 1.500 (FSVP)); 21 CFR 120.3(h) (juice HACCP); and 21 CFR 123.3(g) (seafood HACCP)). An FSVP or HACCP importer must be physically located in the United States. When the FSVP or HACCP importer for a food is a U.S. agent or representative for the foreign owner or consignee, the U.S. agent or representative is responsible for meeting the FSVP or HACCP requirements with respect to that food.

### 6.7.38 – DATA UNIVERSAL NUMBER SYSTEM (DUNS)

A DUNS number is a unique nine-digit business identification number provided by the company Dun & Bradstreet (D&B). Upon request, D&B will assign a DUNS number for each physical location of a business.

### 6.7.39 – FOOD SAFETY MODERNIZATION ACT (FSMA)

The FDA Food Safety Modernization Act (Pub. L. 111-353) enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities.

### 6.7.40 – FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

FSVP is a program that importers covered by the rule must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the U.S. safety standards, including the preventive controls or produce safety regulations as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

## SUBCHAPTER 6.8 FOREIGN SUPPLIER VERIFICATION PROGRAM

### 6.8.1 - FSVP INSPECTIONS

FSVP inspections are conducted to verify human and animal food imported into the United States is as safe as food produced and sold within the United States. The [FSVP website](#) contains resources for legal, regulatory, guidance, and policy issues for the FSVP regulation.

### 6.8.1.1 - Pre-Inspection Activities

Prior to conducting an FSVP inspection, contact the person identified at entry as the FSVP importer by phone. During the pre-inspection phone call, you should:

1. Identify yourself and inform the importer that FDA will be conducting an FSVP inspection.
2. Verify the firm or person identified at entry is the "importer" as defined in 21 CFR 1.500 and the imported food is subject to the FSVP regulation.
3. Verify the importer's contact information (e.g., name, email address, phone number, and physical address).
4. Determine whether the importer of the food is a manufacturer/processor or re-packer and should be inspected under other programs, such as the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods Regulation \(Preventive Controls for Human Foods Rule\)](#) or [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Foods Regulation \(Preventive Controls for Animal Food Rule\)](#).
5. Determine whether the importer of produce is a grower, and should be inspected under the [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption \(Produce Safety Rule\)](#).
6. Verify the FSVP records are available onsite. If the records are offsite, advise the importer that he/she will need to retrieve the records.
7. Determine if any FSVP records need to be translated.

### 6.8.1.2 - Preparation and References

Before undertaking an inspection:

1. Review the firm's FSVP inspection history, the compliance history of the products, and the foreign supplier associated with the products targeted for FSVP review. Ensure the highest risk products are covered.
2. Prepare a list of the foods imported by the importer and the foreign supplier for each food.
3. Review the entry date of the assigned products and the associated foreign suppliers to ensure the compliance date has passed.
4. Conduct the pre-inspectional hazard analysis to determine the known or reasonably foreseeable hazards that should be addressed in the importer's hazard analysis, if applicable.
5. Review and become familiar with the appropriate parts of the FSVP regulation [21 CFR Part 1, subpart L](#).

6. Ensure that you have received all necessary training that may be required. Consult your supervisor with questions.

### 6.8.1.3 - Inspectional Authority

Authority to review records required of FSVP importers falls under the statutory provisions of section 805 of the FD&C Act, 21 CFR 1.510(b)(1), 21 CFR 1.510(b)(3), 21 CFR 1.512(b)(5)(ii)(A), and/or 21 CFR 1.512(b)(5)(ii)(C). See IOM subchapter 2.2 for broader information on inspectional authority.

### 6.8.1.4 - FSVP Inspectional Activities

Upon arrival at the firm locate the person identified at entry as the FSVP importer. Introduce yourself by name, title and organization. Show your credentials, explain the purpose of the inspection, and issue a properly signed, completed original of the Form FDA 482d, Request for FSVP Records (the division office address should be the pre-alignment district office associated with the importer's geographical location).

If this is an initial inspection, provide FSVP education materials. Briefly explain the fact sheets and refer the importer to additional documents that can be found on the FDA.gov FSVP website.

See IOM subchapter 5.2.2 for general information on issuing the Notice of Inspection.

#### 6.8.1.4.1 - CONDUCTING THE FSVP RECORDS REVIEW

Review the importer's required FSVP records for the products and foreign suppliers as assigned or as needed to ensure appropriate coverage of the firm's FSVP programs. When following up on an inspection during which an FDA 483a was issued, review the FSVP records for the observations documented on the FDA 483a during the previous inspection. Determine whether the importer corrected the observations that were identified during the previous inspection and what corrective actions were taken. Verify that those actions corrected the observations.

For each FSVP product reviewed during the inspection, review documentation that the importer meets the definition of "importer" as defined in 21 CFR 1.500. Review the prepared list of the imported foods with the importer and document which foods do not have an FSVP plan.

If the importer is required to comply with the requirements in section 1.504, request to review the importer's hazard analysis. It is important to determine if the importer identified any known or reasonably foreseeable hazards for each food. Compare your pre-inspection hazard analysis to the importer's hazard analysis. If there are discrepancies, discuss with the importer to determine their

reasoning behind the discrepancy. After reviewing the importer's hazard analysis, request to review the necessary records.

If the importer states that they do not have an FSVP, determine whether the importer maintains records that satisfy the FSVP requirements. Importers may not be aware of the specific requirements of the FSVP regulation, but upon further questioning, may be able to provide documents that fulfill FSVP requirements. Encourage the importer to take corrective actions for deviations observed during the inspection.

If the records review indicates there may be a public health concern relating to a food or foreign supplier (evidence that the food is adulterated or misbranded or that there are significant deficiencies at the foreign supplier), determine whether the importer took appropriate corrective actions and documented the corrective actions taken. For example, if an importer's sampling and testing records indicate that a sample was positive for *Salmonella*, determine whether the importer took appropriate corrective actions (e.g., importer did not import the food, imported food was recalled, importer worked with the foreign supplier to address the problem, importer discontinued use of the foreign supplier). In addition, document and collect available information relating to the food and foreign supplier, document FSVP observations on the Form FDA 483a, when applicable, and report the findings to your supervisor. Document all discussions with the importer as it relates to FSVP and the records review in the EIR.

## 6.8.2 - FSVP OBSERVATIONS

The FDA 483a, FSVP Observations is intended to assist firms inspected in complying with the laws and regulations enforced by the Food and Drug Administration. The FDA 483a notifies the inspected establishment's top management in writing of significant objectionable conditions relating to violations of the FD&C Act which were observed during the inspection. The issuance of written inspectional observations is mandated by law and ORA policy.

### 6.8.2.1 - Preparation of Form FDA 483a

The FDA 483a should be issued at the conclusion of the inspection and prior to leaving the premises. During the inspection, do not show the firm's management a draft, unsigned copy of the FDA 483a or an electronic copy of the FDA 483a on your computer screen. You should issue only a signed FDA 483a at the closeout discussion with management.

The FDA 483a should adhere to the following general principles:

1. Observations which are listed should be significant and correlate to regulated products being inspected.
2. Observations of questionable significance should not be listed on the FDA 483a, discuss these

observations with the firm's management so that they understand how uncorrected problems could become a violation. Detail this discussion in the EIR.

The FDA 483a should have the following characteristics:

1. Each observation should be clear and specific.
2. Each observation should be significant and ranked in order of significance.
3. All copies of the FDA-483a should be legible.

If an observation made during a prior inspection has not been corrected or is a recurring observation, it is appropriate to note this on the FDA 483a and document in the EIR. Corrective actions are not listed on the FDA 483a but are reported in the EIR.

The products and foreign supplier inspected must be identified on the FDA 483a when documenting an observation for the importer's lack of an FSVP.

Collect documentation to support observations. Do not copy records that do not support observations, unless otherwise directed. Contact your supervisor if unsure of the evidence required to support an observation.

Generate the FDA 483a in eNSpect. To generate the FDA 483a, complete the FSMA and FSVP Inspection Protocol (IP) for each FSVP product that is reviewed.

At the close of the inspection, provide the importer with a copy of the FDA 483a and discuss each observation. Also discuss non-significant observations not documented on the FDA 483a. Encourage the importer to make voluntarily corrective actions.

During the closeout discussion with the FSVP importer, inform the importer that they should respond to the FDA 483a within 15 business days after the end date of the inspection and that their response may impact FDA's determination of the need for follow-up action. Provide information to the importer on where to send their response according to their division's procedures (i.e., the address of the Division office associated with the importer's geographical location that is listed on the FDA 483a or FDA 483a response e-mail address associated with the applicable division). Hard copies of inspections records should be stored at the pre-alignment district office associated with the importer's geographical location.

#### 6.8.2.1.1 - INDIVIDUAL HEADINGS

**District Office Address and Phone Number** – Legibly print the District address. Include the district office commercial telephone number and area code.

**Name and Title of Individual to Whom Report Is Issued** - Enter legal first name, middle initial and last name and full title of the person to whom the form is issued.

**Firm Name** - Enter full, legal name of the firm, including any abbreviations, quotation marks, dashes, commas, etc.

**Street Address** - Enter street address (Not P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

**City, State and ZIP Code** - Enter city, state and ZIP Code.

**E-Mail Address** – Enter Email address for the FSVP contact at the firm.

**Date(s) of Review of your FSVP Records-** Enter actual or inclusive date(s) of inspection.

**FEI Number** - If the FDA Establishment Identifier is on the assignment, enter it here. If not readily available, leave blank.

**Employee(s) signature and Employee(s) name and title** - The names of everyone who participated in the inspection with the issuance of an FDA 482d should be listed on the FDA 483a even if they are not available to sign the FDA 483a. Each member of an inspection team should sign the FDA 483a. However, absence of a team member at the conclusion of an inspection need not prevent issuance of the FDA 483a. See IOM 5.1.2.5.1. If you use an eNSpect-generated FDA 483a, assure you have a copy for the program division files -- an unsigned photocopy or printed duplicate is unacceptable. See IOM 5.2.3.6.2.

### 6.8.2.1.2 - SIGNATURE POLICY

Everyone present at issuance signs the first and last pages of the FDA 483a and initials each intervening page in the signature block. The lead CSO's signature will appear on all pages of the FDA 483a and the remaining team members' signature will appear on the last page. See IOM 5.2.3 for more information on Reports of Observations.

## SUBCHAPTER 6.9– FSVP REPORTING

Following an inspection, you are required to prepare a report of your findings. Reporting includes the data and summary entered using eNSpect, a narrative report, attachments and exhibits. Your narrative report should be prepared to accurately and concisely communicate the findings of your inspection and be adequate for its intended use.

### 6.9.1– ESTABLISHMENT INSPECTION REPORT (EIR)

Based on the observations documented on the FDA 483a and other information captured on the IP in eNSpect, you will use the FSVP Establishment Inspection Report (EIR)

application in the eNSpect system to generate the EIR. The requirement to answer IP Question 1.5.1. replaces the requirement to complete the PRA “Memorandum to File”; document the reason for selecting the importer for inspection in the EIR. Write the EIR according to this subsection and IOM subchapter 5.11.

### 6.9.1.1- FSVP RECORDS REVIEW

Document the review of the importer's required FSVP records in the EIR. Identify the product and foreign supplier covered by each FSVP. Report the results of the comparison of your pre-inspection hazard analysis and the importer's hazard analysis, if conducted, and any resulting discussion with the importer. This information must be documented with sufficient detail to demonstrate the firm's compliance with FSVP or lack thereof.

For each product covered during the inspection, verify that the importer meets the definition of “importer” and document in the EIR as follows:

1. If the importer was the owner or consignee when the food was offered for entry into the U. S., attach a copy of a purchase order or some other documentary proof.
2. If the importer was the U. S. agent or representative when the food was offered for entry into the U.S., attach a copy of the written agreement to serve as the FSVP importer.
3. If the importer does not meet the definition of importer, explain this determination in the EIR and obtain information on the actual importer.

Document all corrective actions taken by the importer to correct the observations that were identified during the previous inspection. Describe what corrective actions were taken and whether those actions corrected the observations. Document any immediate corrective actions that the importer took during the inspection and any corrective actions promised for completion in the future, including when they expect to complete the corrective action. In addition, document any corrective actions taken during the inspection in the corrective action reporting system (CARS) within eNSpect

## 6-1 Notice of FDA Action

## EXAMPLE

**United States Food and Drug Administration**

DIVISION OF SOUTHWEST IMPORTS

**Notice of FDA Action**

Entry Number: ABC-0345241-2

Notice Number: 1  
July 11, 2017Importer:  
WARREN'S Produce  
PO Box 12345  
McAllen, TX 78502Port of Entry: 2305, Freer, TX  
Carrier: EXPRESS ServicesDate Received: July 11, 2017  
Arrival Date: July 11, 2017Filer of Record: Salinas Brothers Brokerage, Pharr, TX 78577-9499  
Consignee: WARREN'S PRODUCE CO., McAllen, TX 78502-4185**HOLD DESIGNATED**Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
11/1	FRESH JALAPENO PEPPERS	700 CT	May proceed 07-11-2017
* 11/2	FRESH SERRANO PEPPERS	200 CT	Pending Review By FDA Compliance Staff 07-11-2017
* 11/3	CALIFORNIA PEPPERS	196 CT	Product Collected by FDA 07-11-2017
* 11/4	FRESH AVOCADOS	1056 PCS	Released 07-11-2017

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Notice of FDA Action  
Entry Number: ABC-0345241-2

Notice Number 1  
Page: 2

### SAMPLES COLLECTED

Line ACS/FDA	Product Description	Est. Cost
11/3	CALIFORNIA PEPPERS	\$3.00

Sample : 12 KG - Sample consists of 12 subs /16 oz (1lb) each of fresh Anaheim peppers collected at random from lot B129A1. Sample was collected aseptically from 12 master cases and packed in 12 whirlpak bags.

### LINES RELEASED

Line ACS/FDA	Product Description
11/4	FRESH AVOCADOS

These products are released. This notice does not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Charles Dominguez, Investigator  
U.S. Food and Drug Administration  
222 West Avenue  
Freer, TX 78041

(956)225-1234  
(956) 225-2255 (FAX)  
CHARLES.DOMINGUEZ@FDA.HHS.GOV

Notice Prepared For: The District Director, U.S. Food and Drug Administration

Notice Prepared By: CD

<sup>1</sup>This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by districts from the Operational and Administrative System for Import Support (OASIS) may appear different.



## EXAMPLE

**United States Food and Drug Administration**

DIVISION OF SOUTHWEST IMPORTS

**Notice of FDA Action**

Entry Number: ABC-0345241-2

Notice Number: 2

July 15, 2017

Importer:  
 WARREN'S Produce  
 PO Box 12345  
 McAllen, TX 78502

Port of Entry: 2305, Freer, TX  
 Carrier: EXPRESS Services

Date Received: July 11, 2017  
 Arrival Date: July 11, 2017

Filer of Record: Salinas Brothers Brokerage, Pharr, TX 78577-9499  
 Consignee: WARREN'S PRODUCE CO., McAllen, TX 78502-4185

**HOLD DESIGNATED**Summary of Current Status of Individual Lines

Line	ACS/FDA	Product Description	Quantity	Current Status
*	11/2	FRESH SERRANO PEPPERS	200 CT	Detained 07-15-2017

\* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

**DETENTION WITHOUT EXAMINATION**

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Notice of FDA Action  
Entry Number: ABC-0345241-2

Notice Number 2  
Page: 2

Line ACS/FDA	Product Description	Respond by
11/2	FRESH SERRANO PEPPERS	August 10, 2017

**FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION**

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act.

Manuel Salinas, Compliance Officer  
(Region/District)  
U.S. Food and Drug Administration  
222 West Avenue  
Freer, TX 78041

(956)225-2255  
(956) 225-2256  
MANUEL.SALINAS@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration

Notice Prepared By: ES

<sup>1</sup>This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by districts from the Operational and Administrative System for Import Support (OASIS) may appear different.

6-2 FORM FDA 766- Application for Authorization to Relabel or Recondition Non-Compliant Articles

**APPLICATION FOR AUTHORIZATION TO RELABEL OR RECONDITION  
NON-COMPLIANT ARTICLES**

FORM APPROVED: OMB No. 0910-0048  
EXPIRATION DATE: 6/30/2023

Public reporting burden time for this collection of information is estimated to average .25 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right:

Department of Health and Human  
Services Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please do NOT send your completed form to the above PRA Staff email address.

**SECTION 1** Instructions for completing the FORM FDA-766 are found on pages 3 and 4.

1. TO: Director of _____ Division, Food and Drug Administration	2. APPLICATION DATE	3. ENTRY NO. AND LINE NO.
Application is hereby made for authorization to bring the article(s) below into compliance with the Federal Food, Drug, and Cosmetic Act and other related Act(s).	4. PRODUCT	
	5. QUANTITY	
6. QUANTITY TO BE RECONDITIONED	7. PRODUCTION CODES	

8. Redelivery bond has been posted by the applicant. The article(s) will be kept apart from all other article(s) and will be available for inspection at all reasonable times. The operations, if authorized, will be carried out at:

and will require about \_\_\_\_\_ days to complete. A detailed description of the method by which the article(s) will be brought into compliance is given in the space below:

We will pay all supervisory costs in accordance with current regulations.

9. APPLICANT AND FIRM NAME	10. ADDRESS OF FIRM
11. APPLICANT'S SIGNATURE	

**SECTION 2 - FDA ACTION ON APPLICATION**

12. TO: (Name and Address)	13. DATE
----------------------------	----------

14. Your application has been:  Denied because:  Approved with the following conditions:

Time limit within which to complete authorized operations: \_\_\_\_\_

When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.

15. SIGNATURE OF DIVISION DIRECTOR	16. DIVISION	17. DATE
------------------------------------	--------------	----------

**SECTION 3 - IMPORTER'S CERTIFICATE**

18. Location where reconditioning operation occurred	19. DATE
--	----------

20a. I certify that the work to be performed under the authorization has been completed and the article(s) are now ready for inspection at: \_\_\_\_\_

20b. Contact Information: \_\_\_\_\_

21. The rejected portion is ready for the approved disposition under FDA or CBP supervision and is held at: \_\_\_\_\_

22. APPLICANT AND FIRM NAME	23. APPLICANT'S SIGNATURE
-----------------------------	---------------------------

**SECTION 4 - REPORT OF INVESTIGATOR / INSPECTOR**

TO PORT DIRECTOR OR DIVISION DIRECTOR	24. DATE (MM/DD/YYYY)
--	-----------------------

25. I have examined the within-described article(s) and find them to be the identical article(s) described herein, and that they have been: \_\_\_\_\_ on: \_\_\_\_\_, 20 \_\_\_\_  
as authorized, except:

**SECTION 5 - DATA ON RECONDITIONED ARTICLE(S)**

26. Acceptable Portion: \_\_\_\_\_

27. Rejections: \_\_\_\_\_

28. Loss (if any): \_\_\_\_\_

29. Did importer recondition entire shipment? \_\_\_\_\_

30. Time and cost of supervision: \_\_\_\_\_

31. INSPECTING OFFICER NAME	32. DATE (MM/DD/YYYY)
-----------------------------	-----------------------

33. INSPECTING OFFICER SIGNATURE \_\_\_\_\_

**6-3 Form FDA 790 Charges for Supervision**

<b>CHARGES FOR SUPERVISION</b>					
<input type="checkbox"/> Federal Food, Drug, and Cosmetic Act, Section 801 (b) and (c) <input type="checkbox"/> 21 CFR 1005.24					
TO: <i>(Insert Address)</i> PORT DIRECTOR OF CUSTOMS			FROM: <i>(Insert Address)</i> DHHS FOOD AND DRUG ADMINISTRATION		
PRODUCT				FDA SAMPLE NO.	
CARRIER				CBP ENTRY NO.	
IMPORTER OF RECORD				ENTRY DATE	
CONSIGNEE					
<p>The following is a list of charges incurred by this Agency for supervision of operations performed in accordance with the above-designated Act or Regulation. You are requested to collect payment, including any expenses incurred by your Department, for deposit into Treasury Miscellaneous Receipts.</p> <p>Under Section 801(c), default of payment shall constitute a lien against any future importation made by the owner or consignee.</p>					
TYPE OF CHARGES	UNIT			CHARGE PER UNIT	TOTAL CHARGE
	HOURS	DAYS	MILES		
INVESTIGATORS TIME					
ANALYSTS TIME					
PER DIEM, PAID PER GOVERNMENT TRAVEL REGULATIONS					
AUTOMOBILE USE					
OTHER TRANSPORTATION EXPENSES <i>(itemize)</i>					
MISCELLANEOUS EXPENSES <i>(itemize)</i>					
<b>GRAND TOTAL</b>					
REMARKS					

6-4 Sample Collection in OASIS Screen Shot

OASIS Version 5.13.00 (PRDPP) - [Product Collection]

**Collections**

Entry/Doc/Line No: ABC-1234567-1 6 1 Lead Init: IOM Date Collected: 07-23-2014

Product Code: 28 B G H 08 Product Code Desc: Capsicums (Cayenne Chili, Hot Peppers), Gro

Imprtr/Crctd Desc: CHILI POWDER

Location of Goods: ABC Importers, 12345 Main Street NW, Kent, WA

Episode: Submitted To: PRL-NW Lab No: 711992

Quantity Collected: 3.5 Units: KG Calculated Cost: 11.80

Desc Text: Sample consists of 30 subs/100g each of chili powder collected at ran

Hand/ Ship: Transported from firm in a paper bag, stored in the locked sample prep

Remarks: Storage: ambient. Open and closed controls included. Analyze for Sa

**Collection Problem Area**

PAF	FACTS	PAF	PAC	Reference
MIC	MIC		03819C	Import Foods - General Program (Microbiology)

Buttons: OK, Cancel, Wk Details, Entry Smry, Update, Save Update, View Update, Print Notices

Desc Text:

OASIS Editor

Sample consists of 30 subs/100g each of chili powder collected at random from lot A124C1. Sample was collected aseptically from 30 bulk master cases and packed in sterile whirl-pak bags.

Hand/Ship:

OASIS Editor

Transported from firm in a paper bag, stored in the locked sample prep room until shipped via UPS to PRL-NW in a cardboard box.

Remarks:

OASIS Editor

Storage: ambient. Open and closed controls included. Analyze for Salmonella.

**6-5 FORM FDA 463a AFFIDAVIT**

<b>AFFIDAVIT</b>		SAMPLE NO.
STATE OF Texas	COUNTY OF Hunt	
<p>Before me, <u>Sydney H. Rogers</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>Felicia M. Rodriguez</u> in the county and state aforesaid, who, being duly sworn, deposes and says:</p> <p>I am the Import Manager for ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX, where I have worked for about 3 years, and as such have knowledge of products imported, held, processed and/or shipped by my firm.</p> <p>On 1/06/14, we received a shipment consisting of five 200 kg burlap bags of dried Ancho Peppers, manufactured by Del Campo, Extension Del Mina #4, Guadalajara, Mexico, covered by entry BAD-1234565-7.</p> <p>On 1/08/14, my firm repacked this shipment of peppers into 25 kg burlap bags for distribution to restaurants and other customers.</p> <p>On 1/13/14, Investigator Rogers visited my firm and showed me copies of documents including Customs form 3461 marked with the entry number of Entry BAD-1234565-7, Bill of Lading #2345RRR678, dated 1/03/14 and invoice 45678, dated 1/02/14. I am familiar with these documents and they cover the shipment of peppers my firm received.</p> <p>Part of the repackaged peppers from Entry BAD-123456-7 were sold and distributed by my firm on 1/08/14. Three 25 kg burlap bags were shipped to John's Pepper House, 3456 First Avenue, Dallas, Texas; and two 25 kg bags were shipped to Casa De Juanita, 5678 Mulberry Drive, Fort Worth, Texas. I have identified and provided copies of the shipping documents that cover this distribution to Investigator Rogers. These documents are invoice 999888, dated 1/08/14 and UPS B/L 787878000009, dated 1/10/04 which covers the shipment to John's Pepper House and invoice 757575, 1/08/14 and UPS B/L 2323232323, 1/10/14 which covers the shipment to Casa De Juanita. The rest of the repackaged peppers remain at my firm.</p> <p>I received the Customs and Border Protection release for this entry on 1/06/14 and I believed I could ship the product. I was informed by Investigator Rogers I was not supposed to ship the product until I received the FDA release. I will keep the remainder of the shipment intact.</p> <p style="text-align: center;"><i>I read this statement and agree it is true.</i></p>		
AFFIANT'S SIGNATURE AND TITLE		
<i>Felicia M. Rodriguez, Import Manager</i>		
FIRM'S NAME AND ADDRESS (Include ZIP Code)		
ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428		
Subscribed and sworn to before me at <u>ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428</u> ,		
(City and State)		
this <u>13th</u> day of <u>January</u> , 20 <u>14</u> .		
<i>Sydney H. Rogers</i> (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

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## SUBCHAPTER 7.1 - RECALLS

### 7.1.1 - DEFINITIONS

#### 7.1.1.1 - Recall

A recall is a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which it would initiate legal action (e.g., seizure). Market withdrawals and stock recoveries are not considered recalls. See the FDA's recall policy outlined in [21 CFR 7.1/7.59- Enforcement Policy - General Provisions, Recalls \(Including Product Corrections\) - Guidance on Policy, Procedures and Industry Responsibilities](#).

#### 7.1.1.2 - Recall Classification

Recall Classification is the numerical designation, i.e., I, II, or III, assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

##### 7.1.1.2.1 - CLASS I RECALL

Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

##### 7.1.1.2.2 - CLASS II RECALL

Class II Recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

##### 7.1.1.2.3 - CLASS III RECALL

Class III Recall is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

#### 7.1.1.3 - Recall Type

Recall type is a designation based on whether the recall is Voluntary, FDA Requested (at the request of the Commissioner or his/her designee), or ordered under [section 518\(e\) of the FD & C Act](#) [21 U.S.C 360h (e)].

#### 7.1.1.4 - Recall Strategy

Recall strategy is a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

### 7.1.1.5 - Depth of Recall

Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, i.e., wholesaler, retailer, user/consumer, which is known as the depth of recall.

### 7.1.1.6 - Recall Number

The recall number is assigned by the responsible Center, for each recalled product it classifies. This number comprises a letter designating the responsible Center (see Letter Codes below), a 3- or 4- digit sequential number indicating the number of recalls classified by that Center during the fiscal year, and a 4-digit number indicating the fiscal year the recall was classified. For example: F-100-2011 identifies the 100th recall classified by the Center for Food Safety and Applied Nutrition (CFSAN) in FY-2011. The following letters are used to identify the Centers.

#### Letter Center/Office

F	Foods and Cosmetics - (CFSAN)
D	Drugs - (CDER)
Z	Medical Devices & Radiological Health – (CDRH)
V	Veterinary Medicine and animal food/feed - (CVM)
B	Biologics - (CBER)
N	Medical Devices (Voluntary Safety Alerts and Notifications)
T	Tobacco Products – (CTP)

### 7.1.1.7 - Medical Device Notification Order

A medical device notification order is an order issued by FDA requiring notification under [section 518\(a\) of the FD&C Act](#) [21 U.S.C. 360h (a)]. The directive issues when FDA determines a device in commercial distribution, and intended for human use, presents an unreasonable risk of substantial harm to the public health. The notification is necessary to eliminate such risk when a more practicable means is not available under the provisions of the Act.

### 7.1.1.8 - Medical Device Notification

A medical device notification is a communication issued by the manufacturer, distributor, or other responsible person in compliance with a Notification Order. It notifies health professionals, and other appropriate persons, of an unreasonable risk of substantial harm to the public health presented by a device in commercial distribution.

NOTE: Medical Device Notifications are to be handled by the divisions as recalls. They will go through the stages of alert, recommendation, classification, field notification, firm notification letter, firm effectiveness checks and status reports, FDA audit checks and termination recommendations.

### 7.1.1.9 - Medical Device Safety Alert

A medical device safety alert is a notification to device users that, under certain circumstances, use of or exposure to the device may pose a risk of harm (the exposure mentioned in this definition excludes electronic product radiation exposure - see 21 CFR Subchapter J). CDRH will only consider a notification to be a safety alert if the device is not violative. The notification alerts users of the associated risk and steps to be taken to reduce or eliminate the risk.

### Safety alerts will be entered in RES and processed accordingly. 7.1.1.10 Sub-Recall

A sub-recall is an action taken by a recalling firm's account to notify own-accounts/consignees of the recall where no changes were made to the recalled product.

If the recalling firm's account changes the recalled product ( e.g. used the product as a component of a new product, re-labeled the product to obscure the original product name and/or lot code, repackaged the product, etc.) the account will have created a new product which could warrant a new recall instead of a sub-recall.

### 7.1.1.11 Consignee

A consignee is anyone who received, purchased, or used the product being recalled.

### 7.1.1.12 Account

The account is the location where the audit check is being done.

### 7.1.1.13 Division Recall Coordinator

Each Division has at least one Division Recall Coordinator who enters and monitors recalls. A list of Division Recall Coordinators and their contact information is at <https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

### 7.1.1.14 Market Withdrawal

A market withdrawal is a firm's removal or correction of a distributed product for a minor violation that would not be subject to legal action by the FDA or that involves no violation (e.g. normal stock rotation practices, routine equipment adjustments, repairs, theft, etc.).

### 7.1.1.15 – Notification, Non-distribution, and Recall of Controlled Substances for Human or Animal Use Order

A controlled substance notification order is an order issued by FDA requiring non-distribution and the mandatory recall of controlled substances under section 569D of the Act [21 U.S.C. 360bbb-8d], as amended by

section 3012 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act ([SUPPORT ACT](#)). Refer to Chapter 7 of the [REGULATORY PROCEDURES MANUAL](#), 7-5-3 FDA Mandated Controlled and Ordered Recalls and Attachment K.

**SUBCHAPTER 7.2 - RECALL NOTIFICATION / INSPECTION**

**7.2.1 - RECALL SCENARIOS ENCOUNTERED DURING INSPECTIONS**

The Division Recall Coordinator (DRC) or designee sends a recall alert within one working day of receiving necessary information to the appropriate Center Recall Unit (CRU) and OSPOP/DE/ROB (Office of Strategic Planning and Operational Policy Division of Enforcement Recall Operations Branch) through the Recall Enterprise System (RES) with basic information regarding the recall. See RPM Chapter 7-10, Attachment A for a list of information for the recall alert.

A recommendation for recall classification is submitted through RES by the DRC or designee within five working days after the recalling firm has provided the information (10 days if the recall has already been completed). See RPM Chapter 7-10, Attachment B for a list of information for the recall recommendation.

Due to the potential public health impact of recalls, when you find a recall during your inspection it is imperative to submit any information obtained to your DRC as soon as possible. The Division should not wait for writing, typing and submission of the EIR or memorandum when sharing recall documents with the DRC or submitting the recall alert or recommendation.

If the firm has decided to initiate a recall during an inspection or investigation, you should prioritize the removal of potentially hazardous product. Coordinate with your DRC and SCSO to ensure the following tasks are completed:

1. Provide firm management with your DRC's contact information and request that management obtain their FDA Division's review of recall correspondence and any press releases before they are issued to prevent misunderstandings between the firm, its customers, and the FDA. An updated list of contact information for FDA's DRCs can be found at <https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators>;
2. At the firm's request, provide guidance in preparing recall communications and obtain complete copies including the text of phone conversations to submit to your DRC. See Chapter 7 of the RPM and IOM

Exhibit 7-1 for an example of recall communications;

3. Obtain a complete distribution list of all shipments of the lot(s) involved, including foreign distribution;
4. Obtain copies of all labels and labeling associated with the recalled product(s) and any documentation of what led to the recall;
5. Advise the firm on how the returned products should be handled. Sometimes FDA will witness or otherwise verify the reconditioning or destruction of the products returned under the recall;
6. Obtain an Official Sample of the recalled product when necessary (See IOM 7.2.7);
7. Obtain as much information in the RPM Chapter 7, Attachment B as time allows; and
8. Take any other steps necessary in your judgment, or that your Division requires.

**7.2.1.1 – Firm Has Used Recalled Product to Manufacture New Product**

If you are conducting an inspection or investigation at a firm who has received recalled product and used it in the production of a new product, or has relabeled recalled product, it may warrant the initiation of a new recall. Collect documentation on how the recalled product was manipulated, including finished product labels, to provide to your DRC immediately. If there is question about the potential hazard or violation of the new product, discuss the situation with your DRC and SCSO prior to discussing the initiation of a new recall with the firm.

**7.2.1.1.1 – Potential New Food Recalls**

For potential new food recalls, the following are some areas to be covered:

1. Incoming ingredient quality control procedures;
2. Quality control over ingredients at the time of use, and the products in which the ingredients are used;
3. A detailed description of the methods used in preparation and packaging of the processed product;
4. How the finished product is stored and shipped;
5. Labeling of product, and any cooking instructions for consumer or purchaser;
6. Quality control testing of the finished product. Detail any test(s) performed by firm; and
7. For products produced in USDA plants, determine if the USDA was notified of the suspect incoming ingredient? Did USDA determine what testing was done by the firm?

**7.2.1.2 – Learning of Completed Recalls During Your Inspection**

If you are conducting an inspection and learn that a recall has occurred, obtain the following from the firm to provide to your DRC:

1. Complete copies of recall communications including the text of phone conversations;

2. Complete distribution list of all shipments of the recalled lot(s), including foreign distribution;
3. Specimens or copies of all labels and labeling associated with the recalled product(s); and
4. Take any other steps necessary in your judgment, or that your division requires.

This information should be shared immediately. Do not wait until the submission of the EIR to notify the DRC that a recall has taken place.

## 7.2.2 – ROOT CAUSE INSPECTIONS

If FDA learns of a potentially violative product that may cause or has caused a class I or significant class II recall, an inspection may be assigned to determine the root cause(s) of the problem(s). Deficiencies in the firm's corrective and preventive action should be documented as violations subject to possible regulatory action.

An important objective of the inspection is to identify the root cause for the recall and assure the firm has implemented effective corrective actions to eliminate its recurrence. In some cases, firm management will have conducted its own analysis and reached conclusions about the problem and its root cause. It is important to verify that the firm's conclusions and judgments, about the root cause of the problem that led to the recall, are discriminating enough to identify the true cause(s) and steps taken are sufficient in depth and scope. Without identifying the true root cause, it will be difficult for the firm to implement an effective corrective action.

Determine if the firm conducted a failure analysis using quality tools such as cause-and-effect diagrams (i.e. fishbone diagram or Ishikawa diagram), fault tree analysis (FTA), or failure mode and effects analysis (FMEA). Determine if the following variables were considered; 1) the length of time since the product had been manufactured and sold; 2) complaints or returns for the same or similar problems; 3) reworking of the product prior to release or distribution that may have been due to the same or similar problems; and 4) process or personnel changes which occurred about the time the problem appeared.

In addition to verifying the identification of the root cause:

1. Issue a Notice of Inspection (FDA 482);
2. Discuss the suspected problem with management and review the firm's complaint file;
3. Investigate all areas, control points and/or circumstances which may have a bearing on the product's deficiency;
4. Fully develop individual responsibility for the problem;
5. Review batch records, processing logs and/or other types of records for violative lots and associated lots;
6. Review and obtain copies of the firm's quality control/analytical data; and

7. Determine any actions the firm has taken, is taking, or has planned to take to prevent similar occurrences. If corrective action is not underway, determine the firm's timetable for achieving correction.

### 7.2.2.1 - State Monitored Recalls

The FDA is not ordinarily involved in classifying and auditing Interstate Milk Shippers (IMS) and Interstate Shellfish Shippers (ISS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the State(s). However, the FDA Division office in which the recalling firm is located must be assured that all States involved in an IMS or ISS plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, the States issue warnings to protect the public health.

In the event that the FDA determines that the States are unable to effect the recall actions necessary, it will classify, publish, and audit the recall; it will issue a public warning when indicated.

### 7.2.3 - MEDICAL DEVICE RECALLS

Medical device recalls may result from manufacturing defects, labeling deficiencies, failure to meet premarketing requirements [PMA, 510(k)], packaging defects or other nonconformance problems. How firms identify the causes of medical device recalls and corrective action activities is essential to the analysis of medical device failures and the determination of the effectiveness of the medical device GMP program. It is also useful in evaluating the medical device program, and for directing attention to problem areas during inspections. [21 CFR Part 806.1](#) requires device manufacturers and importers to report certain actions concerning device corrections and removals. They must also maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA. (See [21 CFR Part 806.20](#)). Failure to report as required by [21 CFR 806.10](#) is a violation and should be listed on the FDA-483, "Inspectional Observations." "Center concurrence is required prior to issuing warning letters for suspected violations of the user reporting regulations; to include Corrections or Removals regulations"

Each device manufacturer or importer must submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer, if one was initiated:

1. To reduce a risk to health posed by the device; or
2. To remedy a violation of the Act caused by the device which may present a risk to health, unless the information has been provided according to [21 CFR 806.10](#) (f), or the correction or removal action is exempt from the reporting requirements under [21 CFR 806.10\(b\)](#).

Collection of complaint, PMA and 510(k) related information is necessary to determine compliance with the GMP requirements. During recall follow-up inspections, answers should be obtained to the questions below, in addition to routine recall information. For firms where it has been established a manufacturing defect led to the recall, conduct a complete GMP evaluation of the manufacturing operations. Report such inspections into FACTS as "qualifying" GMP inspections.

### 7.2.3.1 - Problem Identification

1. How did the firm identify the nonconformance which led to the recall (e.g., complaint, in-house data, etc.)?
2. If the recall was due to a device defect, did the firm conduct a documented failure analysis of the device, using such techniques as fault tree or failure mode analyses? If so, report whether these results were provided for review.
  - a. Did the firm determine the failure mechanism (e.g., shorted component, incomplete weld, etc.)?
  - b. If not, how did firm determine the cause of the nonconformance?
  - c. If not, what rationale does the firm have for not conducting a failure analysis?
3. Did the firm determine at what phase of the device life cycle the nonconformance occurred (i.e., design, manufacturing, storage, use, etc.) and the actual cause of the nonconformance (i.e., software design error, process out of specifications, employee error, user misuse, etc.)? What evidence does the firm have to support the determination?
4. Did the firm determine if the nonconformance resulted in an injury or death?
5. If a component, at least partly, caused the defect, determine if the same component was used in other devices manufactured by the firm. If so, has the firm conducted an analysis to assure the defect in the component will not have a deleterious effect on the operation of the other device(s)?
6. If a component was responsible for the device defect, what other device manufacturers use the same component (and especially the same lot number of the component)? Has the manufacturer of the recalled device notified the component manufacturer? Has the component manufacturer contacted its other customers about the problem?
7. Why was the component defective? Did the manufacturer of the component change the specifications without notifying the finished device manufacturer? Did the component fail to meet its release specifications?  
NOTE: A visit to the component manufacturer may be needed to adequately answer questions 5, 6 and 7. Before doing so, confirm with CDRH and your supervisor that the matter is egregious enough to warrant this "next step."
8. Did the finished device manufacturer have an incoming component/raw material sampling and testing procedure? If not, why not?

9. If the manufacturer recalled the device because the labeling was inaccurate, or the wrong labeling was applied to the device (label mix-up), determine the following:
  - a. What quality system procedures should have been established to prevent the problem?
  - b. If the label or instructions for use were inaccurate, was the inaccuracy introduced in the design stage, or was it due to a printing problem?
10. If the device has been on the market for a year or more, and the manufacturer claims the problem is the result of design:
  - a. Determine why the problem was not detected earlier. How many reports concerning the problem did the firm receive before deciding a recall was necessary? Does the firm have a procedure established for determining if a recall is necessary, and if so, did it follow the procedure? Obtain a copy of the procedure.
  - b. If the firm doesn't provide rational answers to the above questions, determine if they explored other possible causes for the problem.
  - c. Was the design feature that caused the problem included in the design of the device that was the subject of a premarket submission?
  - d. If the design feature that caused the problem is part of the original design, did the manufacturer recall all products manufactured since the device was introduced to the market? If not, why not?
  - e. If the problem was introduced via a design change, did the manufacturer follow established design change or change control procedures? If yes, are the procedures adequate? Was the nature of the problem such that it should have been anticipated, and the design verification/ validation study fashioned to detect the problem?
  - f. Has the manufacturer recalled all products distributed since the design change was introduced? If not, why not?

### 7.2.3.2 - Corrective Action

1. Describe the corrective action taken to correct the immediate problem, e.g., redesign, modify SOP, process validation, etc.
2. Did the firm qualify/validate the corrective action?
3. Did the firm establish responsibility to assure that the corrective action would be implemented and satisfactorily completed?
4. What action did the firm take to prevent recurrence of the nonconformance, e.g., training, increased process monitoring, etc.?
5. Was the nonconformance information provided to those responsible for the areas in which the nonconformance occurred?
6. Did the firm determine if the nonconformance extended to other devices?
7. Did the firm determine if changes were needed in procedures and, if so, did it validate and implement the changes?
8. Has the manufacturer taken appropriate corrective action?

### 7.2.3.3 - Complaint and Medical Device Reporting (MDR) Reporting

Determine if adequate complaint investigations were performed as required by [21 CFR 820.198](#) (b). Also, determine if the investigation verified the complaint was a failure of the device to meet any or all of its specifications.

For complaints related to the recall, the firm should have made a determination whether the events are MDR reportable. Any event associated with a death or serious injury must be reported under MDR. Malfunctions likely to cause or contribute to a death or a serious injury are also reportable under MDR. Document the firm's explanations for the events they believe are nonreportable. Failure to submit required MDR reports are violations, and should be listed on the FDA-483 at the completion of the inspection.

Provide adequate documentation with the EIR to cross-reference complaints with associated MDRs.

Device Information - Obtain the 510(k) or PMA number for each device under recall. If there is no 510(k) or PMA, determine if the device is a pre-enactment device (i.e., in commercial distribution prior to May 26, 1976). If multiple devices are being recalled, obtain this information for each device model or catalog number under recall.

## 7.2.4 - DRUG RECALLS

### 7.2.4.1 - Recalls of Human Drug Products

If the recalled product is covered by a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), determine if the defective product involves the type of problems shown under [CFR 314.81](#) (b)(1)(i) and (ii). Also note whether or not the firm reported the problem to the FDA Division office that is responsible for the firm within 3 working days of its receipt of the information, as required by that section.

### 7.2.4.2 - Recalls of Veterinary Drug Products

Veterinary Drug Products recalls are classified by, and health hazard evaluations are obtained through, CVM's Division of Compliance. To inquire about specific veterinary drug product recalls or to obtain information on how to proceed, email CVM Recalls at [CVMRecalls@fda.hhs.gov](mailto:CVMRecalls@fda.hhs.gov).

### 7.2.5 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE BASED PRODUCTS (HCT/PS) FOR IMPLANTATION, TRANSPLANTATION, INFUSION, OR TRANSFER

The FDA may consider an order of retention, recall, destruction, or cessation of manufacturing when any of the conditions specified in [21 CFR 1271.440](#) (a)(1) to (3) exist. The conditions include an agency finding that:

1. The HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or

2. An establishment is in violation of the regulations in this part and, therefore does not provide adequate protections against the risks of communicable disease transmission.

In addition to the conditions noted above, the agency may issue an order of cessation of manufacturing until compliance with the regulations has been achieved, as stated in [21 CFR 1271.440](#) (a)(3), when the FDA determines there are reasonable grounds to believe there is a danger to health. An order to cease manufacturing would be issued where violations create an urgent situation involving a communicable disease, because an establishment is in violation of the regulations in Part 1271 and, therefore, does not provide adequate protections against the risks of communicable disease transmission. An order to cease manufacturing is a remedial action taken to put important protections in place to prevent communicable disease transmission.

NOTE: FDA will not issue an order for the destruction of reproductive HCT/PS, nor will FDA carry out such destruction itself ([21 CFR 1271.440](#) (f)).

## 7.2.6 – TOBACCO PRODUCT RECALLS

When you become aware of, or obtain information about, a possible tobacco product recall, contact the Center for Tobacco, Office of Compliance and Enforcement, Division of Enforcement and Manufacturing. See CTP's intranet site for contact information.

<http://inside.fda.gov:9003/CTP/ucm249908.htm>

## 7.2.7 - SAMPLE COLLECTION

Collection of samples for regulatory consideration is at the discretion of Division management. Consult your supervisor and/or compliance branch for guidance. If a sample is indicated, only collect documentary samples for electronic products or medical devices, unless otherwise instructed.

If, after consulting with the Centers and Division Management it is determined that an official sample should be collected, ship an appropriate sample as directed by the Center and your Division. Keep the Center informed on the status of the shipment.

## SUBCHAPTER 7.3 - MONITORING RECALLS

### 7.3.1 - INSPECTIONS TO MONITOR RECALL PROGRESS

It may be necessary to inspect the firm between the recall initiation and the termination of a recall for several reasons including: to monitor the recall's progress, verify product disposition, or conduct a reconciliation of the distribution records for the recall. An inspection may also be assigned by your division if the Division Recall Coordinator requires assistance collecting necessary information from a firm,

and the recall is potentially class I or significant class II. These visits are limited inspections on an as-needed basis. Issue an FDA-482 Notice of Inspection and collect needed information. During these inspections, remind recalling firms to submit periodic status reports to FDA. See [21 CFR 7.53](#).

### 7.3.2 - FDA RECALL AUDIT CHECKS

NOTE: Do not conduct recall audit checks at DOD and VA facilities, as the FDA has a Memorandum of Understanding with them, and they have their own procedures for recalls.

#### 7.3.2.1 - Definition

A recall audit check is a personal visit, telephone call, letter, or a combination thereof, to an account of a recalling firm, or a user or consumer in the chain of distribution. It is conducted to verify consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

#### 7.3.2.2 - Level of Audit Checks

Conduct the number of audit checks requested in your assignment. If you are unable to do so, contact your supervisor for further instruction.

#### 7.3.2.3 - Conducting a Recall Audit Check

The purpose of a recall audit check is to confirm the account received the recall notification from the notifying firm and followed all instructions included in the notification. The notifying firm may be the recalling firm, or a downstream account that received the recalled product and is conducting a sub-recall (such as a distributor). Notifications sometimes come in through other means, for example an automated notification system sent to hospitals. These other means are not considered to be an official notification of the recall, as the recalling firm, or a downstream account, did not directly contact the consignee.

Prior to conducting a recall audit check, review the recall audit check assignment given to you. Your assignment will contain the necessary details of the recall, recall strategy, and a list of accounts to be audited (Please Note: The assignment may list specific accounts to be audited or may provide a list of accounts to choose from). Conduct the audit check by the due date provided in the assignment. Pay particular attention to the type of product recalled, the labeling of the product, and the recall notification attached to the assignment which the recalling firm sent to their accounts. Take note of the depth of the recall listed in the assignment (i.e. wholesale, retail, consumer level). Your responsibility is to verify the account received the same recall information, they followed the instructions in the recall notification, and that the recall has been carried out to the appropriate depth listed in the assignment. The assignment will include how checks will be conducted, i.e., visit, phone calls, email, etc. as well as detailed instructions specific to the recall. Do not conduct recall audit checks by visit at consumer

homes unless specifically directed in your assignment. If the assignment is for email audit checks, please use the email audit check template provided in the assignment.

During your review of the assignment, try to gain an understanding of the list of accounts, and whether those listed actually received or may have received the recalled lot. This information affects the endorsement for the audit check. If the list is specific to the recalled product lot, the account should have received it. If the list is not so specific, or the account you are auditing does not know or remember if they received the recalled lot, the account should still follow the instructions in the recall notification and initiate a sub-recall of the product, if needed. This information affects the endorsement of the recall (see section 7.3.2.6 Endorsing the Recall Audit Check). It is appropriate to challenge the account if the distribution list is included with the assignment includes them as a consignee for the specific recalled lot, and they say they never received the product.

When initiating a recall audit check, attempt to make contact with an individual at the account who has knowledge of the receipt of recall notifications and the disposition of recalled products. In hospitals, this responsibility may be held within the Risk Management or Safety departments. PLEASE NOTE: In the case of an audit check at the consumer level, attempt to verify you are speaking with the individual who was indicated as having received the product before disclosing the name of the recalled product and verifying they received notification of the recall.

If the account did not have any knowledge of the recall prior to your recall audit check, inform them of the recall, provide them with a copy of the press release (if available) and recall notification letter, encourage them to follow the recall instructions, and document that you did so. DO NOT give the account a copy of your recall assignment.

If your audit check discloses the account did not follow the recall instructions (for example, recalled product being held for sale, or a requested sub-recall has not been initiated), encourage the account to follow the recalling firm's instructions. If the account chooses not to follow the recall instructions, document the title/responsibility of the individual at the account who chose not to follow the recall instructions and reason.

When you conduct an audit check by visit, it is important to examine the storage sites where the recalled product is stored and check the shelf stock to ensure all recalled product has been identified, removed from areas of use, and properly quarantined or destroyed/corrected. This is especially important in Class I recalls.

For some recalls, the strategy may be a correction instead of a removal. Recall audit check assignments for field corrections may instruct you to verify that either the field correction has been completed, or to assess whether the recalling firm issued the initial instructions to discontinue and/or modify the use of the product, and the account followed those instructions. Detail the status of the

correction in the remarks section of your form FDA 3177.

If you encounter a refusal to permit entry or provide information during a recall audit check, document the name and title of the individual who refused, and the reason why they refused the audit check. Contact your supervisor for additional instruction.

FDA has a contract with a third party to conduct recall audit checks on behalf of the FDA. Any questions you or the firm may have regarding the third party contract should be directed to OSPOP/DE/ROB at [orarecalloe@fda.hhs.gov](mailto:orarecalloe@fda.hhs.gov). There are also other entities conducting audits (e.g. state investigators conducting audits as part of their state duties or on behalf of the FDA, private firms who conduct audits on the behalf of a recalling firm)

If during your audit check you find that the consignee used the FDA regulated product to manufacture USDA-regulated product, distributed product to a USDA facility, or the product was used in or procured for one of the USDA nutrition programs (i.e. National School Lunch Program), complete the recall audit check. Provide the information to your Division Recall Coordinator, who will forward it to OSPOP/DE/ROB, who will share it with the USDA. If during your audit check you find that the consignee is a DoD supplier and/or used the FDA regulated product to manufacture DoD products, complete the recall audit check. Provide the information to the FDA Liaison to DoD as per IOM section 3.2.3 – DEPARTMENT OF DEFENSE (DoD), 3.2.3.6.1 – DoD/FDA Liaisons; the FDA Liaison will forward it to the DoD Liaison and appropriate ORA/OSPOP/DE/ROB contact.

During your audit check, verify that the consignee has conducted a sub-recall to the level specified in the assignment. If the consignee is unsure if he or she handled the recalled product, then collect the distribution list. Inform the consignee that a sub-recall may be necessary. If an account has not conducted a sub-recall, follow the procedures outlined in "Exhibit 7-3, #7."

Conduct sub-recall audit checks to the level specified in the assignment. Sub-recall audit checks may be made by telephone for accounts in another division, in lieu of creating a separate recall audit check assignment for that division to conduct the sub-recall audit checks.

### 7.3.2.4 - Audit Check Reporting

The results of your audit check should be reported on a form FDA 3177, "Recall Audit Check Report" form. See IOM Exhibit 7-3. It is preferred that Divisions complete the form FDA 3177 electronically. Divisions have the option of completing the form FDA 3177 electronically or as a hard copy. Directions for completing the form FDA 3177 can be found in Exhibit 7-3. Conducting the Recall Audit Check. The form FDA 3177 will be routed through your supervisor to the recall coordinator at the division monitoring the recall, who will store the official signed form in the recall file.

Identified exhibits should be submitted with your FDA 3177. Identify each page or file with the following information:

- RES Event number (as listed in your assignment)

- Direct account name or sub-account name, whichever is applicable
- Investigator's initials and date of the audit check
- Exhibit and page numbers

FACTS allows you to enter the amount of time spent conducting your audit check. When you complete a recall audit check, you should report your time using the "Miscellaneous Operations Accomplishment Hours" screen using the code OP 17.

Submit one OP 17 per RES event. In the Assignees Accomplishment Hours block of the Miscellaneous Operations screen, enter the FEI of the recalling firm and for the "#Ops" enter the number of separate audit checks conducted.

### 7.3.2.5 - Ineffective Recalls

An audit check is considered ineffective if one of the following conditions were found:

- A. The account did not receive formal notification from the notifying firm. Note: in instances where the account was not formally notified but still took action based on information learned about the recall from a source other than the notifying firm, the audit check is still ineffective.
- B. The account did not follow the instructions provided by the notifying firm. If the account is not sure if they received the recalled lot(s), they should still follow the instructions in the notification.
- C. The account distributed the recalled product, but did not conduct a sub-recall, if applicable.
- D. The account received the type of product under recall, cannot determine whether they received the specific recalled lots, and did not conduct a sub recall. The account should still conduct a sub recall if there is any possibility that they received the recalled lot(s).

### 7.3.2.6 Endorsing the Recall Audit Check

Recall audit checks should be endorsed by the Supervisory Investigator based on the information collected during the audit check.

The audit check should be endorsed based on conditions found when the audit check was conducted and not based on the account's actions to correct ineffectiveness. Choose the endorsement that is best described by one of the scenarios below.

An audit check should be endorsed "Effective" if the account was notified of the recall by the appropriate notifying firm and followed, or is in the process of following, the instructions in the recall notification. Please note: If you selected "No" for question 5a or 6a on the 3177, you cannot endorse the 3177 as "Effective". If both 5a and 6a on the 3177 are "Yes", the 3177 should be endorsed as "Effective"



The following are examples of ineffective recall audit checks:

A. "Ineffective – Recalling Firm"

- The account did not receive formal notification from the notifying firm. Note: in instances where the account was not formally notified but still took action based on information learned about the recall from a source other than the notifying firm, the audit check is still ineffective.

B. "Ineffective – Consignee"

- The account did not follow the instructions provided by the notifying firm. If the account is not sure if they received the recalled lot(s), they should still follow the instructions in the notification.
- The account distributed the recalled product, but did not conduct a sub-recall, if applicable.
- The account received the type of product under recall, cannot determine whether they received the specific recalled lots, and did not conduct a sub recall. The account should still conduct a sub recall if there is any possibility that they received the recalled lot(s)..

Your Division's Recall Coordinator can assist you if you need help evaluating if an account must conduct a sub-recall. In some instances, (e.g. field corrections) the effectiveness of the recall audit check may be determined by the assignment and discussion with the recall coordinator.

If the account assigned for a recall audit check is out of business, endorse the audit check as "Out of Business".

Endorse as "Other" on very rare occasions, such as if the account cannot remember whether or not they received the recall notification and does not carry the recalled product.

### 7.3.3 - RECALL TERMINATED/RECALL COMPLETED

#### 7.3.3.1 - Definitions

**Recall Terminated** - A recall will be terminated when the FDA determines that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Division office to the recalling firm.

**Recall Completed** - For monitoring purposes, the FDA classifies a recall action "Completed" when all outstanding product, which could reasonably be expected is recovered, impounded, or corrected.

### 7.3.3.2 - Closeout Inspection

Some recalls may require a limited inspection at the recalling firm as a final monitoring step to verify the recall has been completed. A memorandum or limited EIR should be prepared. See [RPM Chapter 7, Attachments B1](#), "Recommendation for Recall Classification and Termination" and [Attachment C](#), "Recall Termination or Recommendation for Termination" for the format. Portions of this format (i.e., Section II and certain items in Section III) will be completed by your supervisor, Recall Coordinator, or compliance officer, depending upon your Division's policy.

During the closeout inspection, you should witness destruction or reconditioning of the recalled product when possible, when unable to do so, obtain written documentation from the firm and/or any state or local government agencies that may have witnessed or otherwise verified product disposition. The disposal of large amounts of contaminated or hazardous items may require the firm to file an Environmental Impact Statement (EIS), or pre-disposal processing to render the goods harmless. Do not agree to witness destruction without resolution of these issues. Obtain a "Letter of Voluntary Destruction" from the firm whenever you witness this operation. See IOM 2.6.4.1.

## SUBCHAPTER 7.4 - SPECIAL RECALL SITUATIONS

### 7.4.1 - General

There are several special recall situations which may require you to deviate from the normal recall procedures. Seek your supervisor's or R&E Coordinator's guidance on these. Examples include:

1. Products in the possession of U.S. Defense Installations;
2. NDA and ANDA withdrawals;
3. National Academy of Science (NAS)/Nuclear Regulatory Commission (NRC) (DESI) recalls of drugs judged ineffective; and
4. Recalls involving jurisdiction of more than one Federal Agency (e.g., FDA/EPA, FDA/Consumer Product Safety Commission (CPSC), etc.).

**7-1 RECALL COMMUNICATIONS EXAMPLE**

## MODEL DRUG RECALL LETTER

John Doe Laboratories  
Somewhere, U.S.A. 12345

Control Division  
Date \_\_\_\_\_

**(red print) --URGENT: DRUG RECALL -- Nonsterile injectable**

Re: List 1234, Cyanocobalamin Injection Lot No. 4321

Recent tests showed that the above lot number of this product is not sterile and therefore, represents a potential public health hazard. Consequently, we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you have any of Lot 4321 on hand. If so, discontinue dispensing the lot and promptly return via parcel post, to our New York City Plant; ATTENTION RETURNED GOODS.

NOTE: If a sub-recall is indicated in a particular situation, the following paragraph should be added:)

“If you have distributed any of lot 4321, please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return these stocks as indicated above.”

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration. The FDA has classified this recall as class \_\_\_\_\_ (if classified).

We appreciate your assistance.

John Doe  
President

**PLEASE FILL OUT AND RETURN**

We do not have any stock of List 1234, Cyanocobalamin

Injection Lot No. 4321 on hand

We have requested our accounts to return their stocks of this merchandise to us.

We are returning \_\_\_\_\_ bottles of List 1234, Lot No. 4321

Name \_\_\_\_\_

Address \_\_\_\_\_

First Class  
Permit No. 2

**BUSINESS REPLY MAIL**  
No Postage Stamp Necessary if mailed in U.S.A.

Postage will be paid by:

JOHN DOE LABORATORIES  
Somewhere, U.S.A. 12345-0909

Henry Doe

<p><b>JOHN DOE LABORATORIES</b></p>	<p><i>FIRST CLASS MAIL</i></p>
<p>A. B. C. Pharmacy Anywhere U. S. A.</p>	
<p>(red print) <b>URGENT DRUG RECALL</b></p>	

7-2 FORM FDA 3177 RECALL AUDIT CHECK REPORT

<b>1. RECALL INFORMATION</b>			
a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
<b>2. PROGRAM DATA (FDA Users Only)</b>		<b>3. AUDIT ACCOUNTS</b>	
a. MONITORING DIVISION		a. DIRECT	
b. FEI NUMBER OF RECALLING FIRM		b. SUB-ACCOUNT (SECONDARY) (Leave blank if none.)	
c. PAC CODE		PHONE NO.:	PHONE NO.:
		c. SUB-ACCOUNT (TERTIARY) (Leave blank if none.)	
		PHONE NO.:	
<b>4. CONSIGNEE DATA</b>		<b>5. NOTIFICATION DATA</b>	
Contacted by: <input type="checkbox"/> Phone <input type="checkbox"/> Visit <input type="checkbox"/> Other		b. RECALL NOTIFICATION RECEIVED FROM	
a. NAME OF PERSON CONTACTED & TITLE		<input type="checkbox"/> Recalling Firm <input type="checkbox"/> Other (Specify below) <input type="checkbox"/> Direct Account <input type="checkbox"/> Sub-Account	
b. TYPE CONSIGNEE		c. DATE NOTIFICATION RECEIVED (mm/dd/yyyy)	
<input type="checkbox"/> Distributor <input type="checkbox"/> Consumer <input type="checkbox"/> Pharmacy <input type="checkbox"/> Retailer <input type="checkbox"/> Physician <input type="checkbox"/> Restaurant <input type="checkbox"/> Processor <input type="checkbox"/> Hospital <input type="checkbox"/> School <input type="checkbox"/> Other: _____		d. TYPE OF NOTICE RECEIVED (e.g., letter, phone)	
c. DOES (DID) THE CONSIGNEE RECEIVE RECALLED PRODUCT?			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
<b>6. ACTION AND STATUS DATA</b>		<b>7. SUB-RECALL NEEDED?</b> Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.)	
a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? (If "No", discuss in "Remarks" action taken as a result of audit check.)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION		<input type="checkbox"/> Returned <input type="checkbox"/> None on Hand <input type="checkbox"/> Corrected <input type="checkbox"/> Was Still Held for Sale/Use* <input type="checkbox"/> Destroyed <input type="checkbox"/> Held for Return/Correction* * - Ensure Proper Quarantine/Action	
		c. CURRENT STATUS OF RECALLED ITEMS	
		d. DATE AND METHOD OF DISPOSITION	
		8. AMOUNT OF RECALLED PRODUCT NOW ON HAND	
<b>9. INJURIES/COMPLAINTS</b>		<b>10. REMARKS (Include action taken if product was still available for sale or use.)</b>	
a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?			
<input type="checkbox"/> Injury <input type="checkbox"/> Complaint <input type="checkbox"/> Illness <input type="checkbox"/> None If answer is other than "None", collect relevant information, document findings, and route per division procedures.			
<b>CHECK</b>		<b>FDA ENDORSEMENT</b>	
Signature		Signature	
Printed Name and Title		Printed Name and Title	
Date of Audit Check (mm/dd/yyyy)	FDA Division	Date of Endorsement (mm/dd/yyyy)	
		<input type="checkbox"/> Effective <input type="checkbox"/> Out of Business <input type="checkbox"/> Ineffective (Indicate level) <input type="checkbox"/> Notifying Firm <input type="checkbox"/> Consignee <input type="checkbox"/> Other (Specify): _____	

## 7-3 Instructions for Completing the FDA 3177 Recall Audit Check Report

### Completing the FDA 3177 Recall Audit Check Report Form

Note: Obtain as much information as possible in order to successfully complete the FDA 3177 Recall Audit Check Report Form as follows:

#### 1. RECALL INFORMATION

- a. RES NUMBER – Enter the Recall Enterprise System (RES) number as listed in your assignment.
- b. RECALLING FIRM – Provide the name and address of the firm listed in your assignment as the recalling firm.
- c. RECALLED CODE(S) – Provide the lot, batch, or serial number indicated as the recalled product in your assignment. If there are more numbers than can fit in the space, state that there are numerous lots under recall and refer to the assignment.
- d. PRODUCT(S) – Provide the name of the recalled product as indicated in your assignment. If numerous products are involved, use a generic term (such as ice cream, dried fruit, etc.).

#### 2. PROGRAM DATA – Complete as per division policy.

- a. MONITORING DIVISION – Enter the monitoring division as listed in your assignment. The monitoring division is often the division where the recalling firm is located, and is responsible for evaluating the effectiveness of the entire recall.
- b. FEI NUMBER OF RECALLING FIRM – FEI number of the recalling firm as listed in your assignment.
- c. PAC CODE – PAC code given in your assignment.
- d. HOURS – has been removed from the 3177, but operational hours should still be entered into FACTS as instructed in IOM section 7.3.2.4.

#### 3. AUDIT ACCOUNTS

- a. DIRECT – The name, address, and telephone number of the account that was listed in your assignment as receiving the product directly from the recalling establishment. This may or may not be the same account at which you are conducting your audit check.
- b. SUB-ACCOUNT (SECONDARY) – If the Direct account indicates the recalled product(s) were further distributed, complete this section for each sub-account audited as well as the DIRECT account section with the name, address, and telephone number of the applicable establishments.
- c. SUB-ACCOUNT (TERTIARY) – If the Secondary account indicates the recalled product(s) were further distributed, complete this section for each sub-account audited, the SUB-ACCOUNT (SECONDARY) section, and the DIRECT account section with the name, address, and telephone number of the applicable accounts.

#### 4. CONSIGNEE DATA

Contacted by: The method used to conduct the audit check (check the appropriate box).

a. NAME OF PERSON CONTACTED & TITLE – The name and title of the person at the account being audited who provided the most information during the audit check.

b. TYPE CONSIGNEE – The type of establishment at which you are conducting your audit check (check the appropriate box – if none, check “Other” and describe the type of establishment).

c. DOES/DIDTHE CONSIGNEE RECEIVE THE RECALLED PRODUCT? – If the account at which you are conducting the audit check never received the recalled product, indicate “No”. If the account received or may have received the recalled product, indicate “Yes”. This includes if the company is unsure they received the recalled lot.

#### 5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? – Indicate if the account received formal notification of the recall (check the appropriate box). Formal notification may be received from the recalling firm, direct account or the secondary/tertiary firm. If notification is received informally e.g. press release, subscription service, or social media, indicate “No” and explain in Remarks how the account received notification. If there is some reason why you cannot determine if a notification was received (for example, it may have been discarded) indicate “Cannot be determined” and explain in Remarks.

b. RECALL NOTIFICATION RECEIVED FROM – The firm that formally notified the account at which you are conducting your audit check (check the appropriate box).

c. DATE NOTIFICATION RECEIVED – Date the account received the formal notification.

d. TYPE OF NOTICE RECEIVED – How the formal notification was received (letter, phone, e-mail, automated messaging system, etc.).

#### 6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? – If the account followed or is following all of the recall instructions prior to your audit check, indicate “Yes”. If the account did not follow or has not begun to follow the recall instructions prior to your audit check, indicate “No”. Explain what was/was not done in Remarks, and if the account took action as a result of your audit check.

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION – The amount of recalled product the account had at the time they received formal notification from the notifying firm.

c. CURRENT STATUS OF RECALLED ITEMS – Indicate the status of the recalled items at the account at the time of your audit check (check the appropriate box). If the recalled product is still being held for sale/use, or was being held for return/correction, ensure that the account properly quarantined the product (if applicable) and followed the recall instructions. In the case of a medical device recall with instructions that permit the device to remain in use awaiting correction or servicing of the device, mark “was still held for sale/use”. Include details of the product status in the Remarks

d. DATE AND METHOD OF DISPOSITION – Indicate the date and method the recalled product was destroyed/returned/corrected.

7. SUB-RECALL NEEDED? – If during the course of an audit check, you find the recalled product has been further distributed, and your audit check for the recall has not reached the depth indicated in your assignment, a sub-recall may be needed. For example, if your assignment indicates the recall depth is at the retail level, and you are auditing a wholesaler, the wholesaler should conduct a sub-recall to reach the retail level.

In the case of a sub-recall, collect distribution of the recalled product, the sub-recall notification, and any other pertinent information to attach to your form FDA 3177. Carry out the recall audit check to the depth indicated in the assignment. Determine if the consignee followed the instructions and conducted a sub-recall. If they did not, then inquire with the consignee about their willingness to continue the recall to the depth specified in the recall strategy and gather as much distribution information as possible. Indicate “Yes” in this section and add as much detail as possible in Remarks.

In some cases, if the consignee has re-labeled, repackaged, or remanufactured the recalled product, a new recall may be needed instead of a sub-recall. However, a new recall may not be needed, if the consignee has manipulated the recalled product in a way that corrects the initial reason for the recall (e.g. if the consignee re-labels the product so the labeling issue is no longer a concern, or if the consignee heat treats the product adequately to eliminate the hazard causing the original recall).

If you determine a new recall is needed, or are unsure, collect all relevant information, including labeling to be evaluated with the assistance of your division’s Recall Coordinator (refer to section 7.3.2.4 for labeling instructions of attachments).

Indicate “No” in this section if the product has not been further distributed and your evaluation finds that a sub-recall is not necessary.

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND – The amount of recalled product still at the account during your audit check.

#### 9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS? – Ask the consignee if they have firsthand knowledge of any injuries, illness, or complaints pertaining to the recalled product. Collect relevant information and route per division procedures.

10. REMARKS – Use this section to provide details that could not be addressed in the previous sections, or to give additional information. If you need additional space for remarks or other information, attach a written document to the 3177 and reference the attachment in the remarks section.

CHECK – Place a handwritten or electronic signature, followed by your name and title printed or typed, the date your audit check completed, and your division.

ENDORSEMENT – Follow section 7.3.2.6 Endorsing the Audit Check. Please note: If you selected “No” for question 5a or 6a on the 3177, you cannot endorse the 3177 as “Effective”.

If changes need to be made after the document has been signed, the signer needs to clear the electronic signatures by right clicking on the signature and pressing “clear signature”. Then the form can be modified and re-signed.



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## 8.1 - Investigations and Inspections

### 8.1.1 – Background – What is an investigation?

An *investigation* is an information-gathering activity conducted for several reasons and this definition applies across ORA programs. The purpose of an investigation is to determine and document facts concerning an issue to inform the agency in making sound decisions. Used informally, *investigation* can apply to a very general activity. It may refer to a response to a more formal request for specific information. Information obtained during an investigation may lead to other operations such as sample collections or inspections.

This chapter contains specific information on many types of investigations, and each section provides guidance on how to conduct those investigations, special reporting requirements, and where additional assistance can be obtained. Recall work, a special type of investigation, is covered in Chapter 7. Reporting an investigation is covered in Section 8.1.9 of this chapter.

### 8.1.2 - Investigations, Inspections, and Form 482? – When do you issue an FDA 482?

Investigations generally do not require an FDA 482, but there will be times when you need to issue an FDA 482, such as when you are at a manufacturing site or doing work like an *inspection* (e.g., collecting records at a manufacturer or shipper to document *interstate commerce*). Consult with your supervisor to determine the proper course of action for these situations. Investigations may be performed at a location not subject to FDA inspection.

### 8.1.3 - External Requests for Investigative Information – What if someone f

Investigations will naturally lead to interest from outside groups. Consumers, industry, press, and other external stakeholders may want information about your investigations. Do not reveal any information about an investigation to anyone outside of the agency without express permission. Direct any requests for information to the FDA's [How to Make a FOIA Request](https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request) webpage (<https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request>). Refer all media inquiries to the ORA Press Office at [ORAPress@fda.hhs.gov](mailto:ORAPress@fda.hhs.gov) (see IOM 1.6.1).

### 8.1.4 - Office of Criminal Investigations – Who is OCI?

#### 8.1.4.1 - OCI Responsibilities

ORA's Office of Criminal Investigations (OCI) has the primary responsibility for all criminal investigations conducted by the FDA, including suspected tampering incidents and suspected counterfeit products. Similarly, OCI has primary responsibility — and is the primary point of contact for — all law enforcement and intelligence matters.

#### 8.1.4.2 - Reports of Criminal Activity

All reports of suspected or confirmed criminal activity, including suspected tampering or counterfeiting incidents, must be reported to the appropriate OCI field office or resident office without delay. Additionally, all threats or perceived threats against FDA-regulated products are to be

referred immediately to the local OCI field office or to OCI headquarters. In those instances where OCI does not, or cannot initiate a criminal investigation in a timely manner, the division offices will consult with OCI to determine the proper follow-up.

### **8.1.4.3 - Liaison with Law Enforcement / Intelligence Community**

OCI is the FDA's liaison with the law enforcement community for criminal investigations and related matters. In addition, OCI serves as the primary point of contact between the FDA and the intelligence community on all matters of mutual interest. OCI participates in numerous law enforcement and intelligence task forces both nationally and internationally including as a full-time representative at Interpol.

All contacts regarding requests or questions received from federal, state, or local law enforcement agencies or intelligence agencies are to be referred without delay to the local OCI field office. Similarly, law enforcement contacts to FDA headquarters or centers should be referred to OCI headquarters.

When FDA personnel receive information or requests from law enforcement or other agencies, they should obtain the caller's name, organization, and the details of the request. The caller should then be referred to the appropriate OCI component. After referring the caller to OCI, contact the affected OCI unit to provide the caller's information. This will prepare OCI of the expected contact. FDA personnel should not respond to inquiries concerning criminal investigations, including questions seeking confirmation of whether FDA is or is not conducting a criminal investigation.

## **8.1.5 - Types of Investigations – What situations lead to investigations?**

You may conduct a variety of investigations in your career. Some types of investigations include, but are not limited to complaint investigations, disaster investigations, health fraud investigations, and product tampering investigations. When conducting any investigation, keep an open mind. Each investigation will be unique.

### **8.1.5.1 - Defective Products**

A defective product is one that fails to do what it is expected to do. For example, a diabetes medication that fails to adequately control blood sugar levels that is prescribed for that reason. A defective product will typically result in a recall where the product may be destroyed or reconditioned.

Investigations into defective products could be initiated as a result of consumer or industry complaints that may indicate the need for follow up with the consumer or industry representative, which would be conducted as an investigation. Investigations are initiated in order to determine facts surrounding a claim related to the status or disposition of a subject FDA-regulated product. Subsequent findings would determine necessary follow-up and/or FDA action (e.g., inspection, sampling, product recall).

### 8.1.5.2 - Injury, Illness, Death

Immediate follow up action should be made when there is indication of a serious injury or adverse reaction, including illness and death. Follow up may vary depending on the situation. You may be asked to conduct investigations at complainants' residences or at firms to investigate any potential causes for the adverse reaction. Inspections at firms may also be warranted. These investigations could be assigned by Office of Emergency Operations (OEO), the Coordinated Outbreak Response and Evaluation (CORE) Network, or other agency components.

You may need to collect medical records or in some cases autopsy reports during these investigations. (See *Section 8.1.6.2* of this Chapter for guidance on obtaining medical records.)

When discussing complaints with a firm representative, do not provide any identifying information of the complainant, for example, name, phone number, or city or state of residence. Reports of adverse reactions may be received from consumers or health care professionals through voluntary reporting such as MedWatch. Reports may be received from state or federal partners. These reports should be treated as confidential.

*NOTE: Follow any program specific guidance related to investigation preparation, collection of these records, etc.*

### 8.1.5.3 - Criminal Investigations

During your work, you may encounter situations that involve criminal or fraudulent activity as defined under Title 18 USC and Title 21 USC. Criminal activity noted by FDA consumer safety officers (CSO) is typically cases of individuals and/or firms making false statements or providing false documents during the course of an inspection or other official activity. There are other violations of Title 18 and criminal violations of Title 21 USC that you may encounter.

Fraud is a separate criminal act from false statements and involves a false representation of a matter of fact whether by words or by conduct, including concealment of information, intended to deceive another for advantage.

In all cases of criminal activity including fraud, OCI is the primary investigative office for FDA. Gather as much initial information as possible and notify your supervisor. You may be asked to assist OCI in its investigation. If so, follow their directions and do not discuss the investigation with anyone outside of the investigation.

### 8.1.5.4 - Surveillance

During your inspectional, investigational, and other activities, be alert to anything which may be new or unusual or interesting from FDA's viewpoint such as:

- New firms.
- New products.
- New production and distribution practices.
- New equipment and industrial processes.
- Seasonal practices.

- Industry trends.
- Recent or on-going construction and plans for future expansion.
- Proposed products.
- New ideas the firm is contemplating.
- New products in the development stage.
- Activities about a firm's competitor.
- Plans for consolidation, mergers, diversification, etc.

If this information relates to a firm you are not currently inspecting, report the information using a Memo of Investigation and route through your supervisor appropriately. If the information relates to a firm being inspected report in the Establishment Inspection Report (EIR). (See *Section 8.1.9* for details on reporting your investigation.)

### 8.1.5.5 - Washouts

A “washout” is defined as an operation where you are unable to complete an assigned inspection. When you encounter a washout, you should determine the reason you are unable to conduct the inspection. For example, a firm that operates seasonally may be available for inspection later in the year. If a firm has moved, attempt to find the forwarding address of the firm. If the firm remains in the local area, do not treat it as a washout but conduct the inspection at the new location. Each washout should be investigated so that you are able to explain why you could not conduct the inspection. (See *Section 8.1.9* for details on reporting your investigation.)

### 8.1.5.6 - For Cause/Fact-Finding/Information Gathering

A for cause, fact-finding, or information gathering investigation is generally received by the division from an outside source like a center, ORA headquarters, or another division. It will generally be a request to obtain specific information from a firm or other source. One example could be obtaining interstate documentation from a shipper of a product to support a regulatory action, such as a seizure in another division.

### 8.1.5.7 - Complaints

A complaint is a notification that a product may be adulterated or misbranded. A complaint may be related to the following areas:

- Economic problems/misbranding (i.e., labeling).
  - Short weight.
  - Deceptive or misleading packaging and labeling.
  - Fraudulent products.
- Filth, decomposition, foreign objects, microbial or chemical contamination
  - Animal/plant/insect material.
  - Off appearance, off odor, or off taste.
  - Glass, metal, plastic or other foreign objects.
  - Bacteria, yeasts, molds, or fungi.
  - Pesticides, industrial, or other chemicals.
- Defective products

- Sub potency or super potency.
- Particulate matter.
- Failure to operate as intended.
- Adverse reactions
  - Allergic reactions.
  - Expected reactions.
  - Birth defects and problem pregnancies.
  - Death.
- Tampering

Complaints are received from various sources, including consumers, other government agencies, Congress on behalf of their constituents, trade associations, etc. [SOP-000544 – Consumer Complaint Procedure](#) describes the receipt and processing of consumer complaints in detail.

The FDA Office of Emergency Management/Office of Emergency Operations (OEM/OEO), 1 (866) 300-4374 and [Emergency.Operations@fda.hhs.gov](mailto:Emergency.Operations@fda.hhs.gov), must be notified immediately of all significant injury, illness, and suspected tampering complaints. OEM/OEO must also be notified of all complaints regarding infant formula/baby food. Advise OEM/OEO of the status of all such follow-up investigations.

As unique situations arise, OEM may provide guidance concerning the type of follow-up to be made.

*Note: Link to SOP-000544 is only available to ORA users on the FDA intranet. The link is: [http://qmis.fda.gov/mc/Main/MASTERControl/vault/view\\_pdf.cfm?ui=062321012030&infocardID=7QYTPC6FZFEZBO7GPP](http://qmis.fda.gov/mc/Main/MASTERControl/vault/view_pdf.cfm?ui=062321012030&infocardID=7QYTPC6FZFEZBO7GPP). Users who need a copy of the SOP outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the SOP.*

#### **8.1.5.7.1 - Types of Complaints**

##### **8.1.5.7.1.1 - Injury/Illness Complaints**

A complaint indicating a serious injury, illness, hospitalization, or death requires immediate reaction. It will most likely require immediate investigation.

There are additional considerations with injury/illness complaints. The prior medical history of the complainant may provide indications regarding allergies, drug side effects or drug-food/drug-drug interactions which may be responsible for the illness or injury. Medical verification should be sought in these situations.

##### **8.1.5.7.1.2 - Non-Injury/Illness Complaints**

Generally, these do not require immediate follow-up at the consumer level. Follow-up may include examining the parent lot, referral to another FDA division, state, or local agency, or deferral until the next regularly scheduled inspection. Examples include mold in beverages, obvious filth or insects in canned goods, etc. It may be possible that adequate investigation would be contacting the dealer, advising them of the nature of the complaint and requesting notification of any action taken. Non-injury/illness complaints do not need to be reported to the OEM/OEO unless product tampering is suspected, or the product is a baby food or infant formula.



### *8.1.5.7.2 - Sources of Complaints – Who provides us with complaints?*

#### **8.1.5.7.2.1 - Consumer**

Consumers contacting field offices with complaints of injury or illness should receive a prompt, courteous response and assurance that their complaints will receive appropriate consideration. (See *SOP-000544 – Consumer Complaint Procedure*.) As the procedure describes, if the complainant cannot reach the complaint line, be sure to obtain all pertinent information (see *SOP-00054* step 6.1.1 C). You cannot rely on consumers responding to follow-up calls or providing additional information later.

#### **8.1.5.7.2.2 - Industry**

An industry official who contacts the field offices with complaints should receive a prompt and courteous response and consideration. Industry complaints should be treated in the same manner as consumer complaints.

#### **8.1.5.7.2.3 - Confidential Informant**

A confidential informant is typically an employee at a firm providing information they believe is a violation of FDA regulations. It is important to avoid the disclosure of a confidential informant to a firm. The investigator conducting the investigation or inspection should not disclose the complainant's information or report the information in the EIR. The complaint itself should be treated in the same manner as consumer complaints.

To maintain confidentiality, a memorandum regarding confidential information should be submitted as a separate operation, linked to the original report or submitted as an attachment to the EIR. There may be times when the report may be discussed in the EIR but, it will not disclose the source of the information. Discuss with your supervisor before including information about a confidential source complaint in the EIR.

#### **8.1.5.7.2.4 - Whistleblower**

A whistleblower is a person, usually an employee or ex-employee, who discloses information or activity within a private, public, or government organization that is deemed illegal, illicit, unsafe, or a waste, fraud, or abuse of taxpayer funds. The complaint itself should be treated in the same manner as consumer complaints. It is important in these types of complaints that the identity of the whistleblower is not disclosed. The investigator should follow the same protocol as dictated in the Confidential Informant section above by not disclosing the complainant's information or reporting the information in the EIR or any format where the information could possibly be released under the Freedom of Information Act.

### 8.1.5.8 - Disaster/Emergency Response – How do we protect the consumer during a disaster or emergency?

The objective of FDA investigations in the aftermath of disasters is to determine whether or not foods, drugs including biologics, cosmetics, and devices affected by the catastrophe are safe for human and animal use; and if not, to effectively have them removed from commerce.

In disaster operations, FDA may assist state, local, and other federal agencies in removing contaminated or unfit merchandise from the market.

State and local officials usually assume direct responsibility for facilities and products under their jurisdiction, as their laws and regulations can be immediately invoked; however, FDA assistance is sometimes requested. Based on the size and scale of the disaster, FDA may receive an official request for assistance through FEMA, FDA/state Rapid Response Teams, or ad hoc through traditional state contacts.

If contacted by emergency response personnel for follow-up assignments, please work with your supervisor to engage district Emergency Response Coordinator (ERC) for further coordination.

#### *8.1.5.8.1 - Preparedness*

Disaster preparedness is the first step to ensure personal safety and response efficiency. Measures taken to prepare for and reduce the effects of disasters both personally and professionally are crucial before an incident occurs.

It is recommended as a preparedness measure that you familiarize yourself with your local Continuity of Operations Plan (COOP). COOP is the initiative that ensures that federal government departments and agencies can continue operation of their essential functions under a broad range of circumstances including all-hazard emergencies, natural, man-made, and technological threats, and national security emergencies. Today's threat environment makes COOP planning even more critical. Your local COOP will alert you to likely disasters for your geographic area.

Preparedness Resources:

[FDA's Emergency Operations Plan](http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/EmergencyResponse/ucm381277.htm)

(<http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/EmergencyResponse/ucm381277.htm>)

[FEMA Preparedness](http://www.Ready.gov) ([www.Ready.gov](http://www.Ready.gov))

#### *8.1.5.8.2 - Safety*

ORA considers the safety of staff to be of the utmost importance.

In a disaster or pending disaster the personal protection of yourself and your family is your primary concern. Provide for your own safety as you perform your assigned FDA duties in a disaster area. Inoculations and protective clothing should be considered.

See IOM 1.5.1 and 1.5.1.3.



Disasters produce dangerous situations (e.g., high water, escaping gases, fallen electrical lines, damaged buildings, falling rubble, etc.), so care and extra safety precautions must be observed.

A Personal Safety Plan may be developed when dealing with disaster situations.

Be aware of hazards you may encounter while traveling in an affected zone such as power outages, damaged or impassable roads, and a lack of available supplies in the area. Personal Protective Equipment (PPE) should be considered where appropriate. For example, appropriately fit-tested respirators such as N95 masks should be worn where there is a risk of inhaling pathogens. Each situation requires a careful evaluation and determination of effective PPE. Your supporting industrial hygienist should be consulted for guidance.

Safety Resources:

- [DFI Field Alert #16](http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldivestigations/ucm010162.doc)  
(<http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldivestigations/ucm010162.doc>)
- [ORA Safety Contacts](http://inside.fda.gov:9003/ORA/Offices/OORS/Safety/default.htm)  
(<http://inside.fda.gov:9003/ORA/Offices/OORS/Safety/default.htm>)
- [ORA Radiation and Laser Safety Resources](http://inside.fda.gov:9003/ora/offices/oors/safety/ucm655438.htm)  
(<http://inside.fda.gov:9003/ora/offices/oors/safety/ucm655438.htm>)

*8.1.5.8.3 - Response*

CAUTION: Although procedures in this subchapter do not cover disasters resulting from a radiological event (presence or release of radioactive materials), it is possible you may discover products suspected of contamination by radioactive materials in the disaster area. If you suspect the presence of radioactive materials, take no action on the materials yourself, but have the area cordoned off at once. Notify the command official (official in charge) and immediately contact your IMT or supervisor, as applicable, to alert the radiological health representative and the state radiation control agency. Follow their instructions.



**8.1.5.8.3.1 - Use of Incident Command System (ICS)**

During some disasters, FDA may implement an Incident Command System (ICS) for response. ICS is a standardized approach to managing incidents at the on-scene level. It is the combination of procedures, personnel, facilities, equipment, and communications operating within a common organizational structure. ICS is scalable and flexible and can be used for small, as well as large and complex, incidents and planned events.

As a CSO, you will typically be assigned under the Operations Section of the Incident Management Team (IMT). All operations you conduct, and your reporting structure will be provided by the IMT and shared via an Incident Action Plan (IAP). An IAP contains the incident objectives, the overall strategy for managing an incident, personal safety guidance, a comprehensive listing of the tactics, resources, and support needed to accomplish the objectives. (Note: Some CSOs with ICS position specific training may serve in a leadership role on the IMT.)

While serving on an IMT, your reporting will be to your team leader and not to your supervisor. The IMT will provide specific guidance for reporting. Your activities will be reported through the IMT and not through normal channels. Reporting may vary depending on the incident and its objectives. You will not be following reporting guidance later in this chapter.

#### 8.1.5.8.3.2 - Management of Disasters without ICS

Specific investigation assignments should come from your supervisor and reporting will be through the normal means, unless directed otherwise.

Response Resources:

- Disaster Response Flow Diagram (DRFD) package (Exhibit 8-9)
- Incident Management Handbook (IMH)  
<http://inside.fda.gov:9003/downloads/policyprocedures/sopsbyprogram/emergencyresponse/ucm391230.pdf>
- Emergency Operations Plan (EOP)  
<http://inside.fda.gov:9003/downloads/PolicyProcedures/SOPsbyProgram/EmergencyResponse/UCM228297.pdf>
- Homeland Security Presidential Directive 5  
<https://www.dhs.gov/publication/homeland-security-presidential-directive-5>

#### 8.1.5.8.4 - Disaster Types

The types of natural and man-made disasters that affect FDA operations are:

##### 8.1.5.8.4.1 - Floods

All flood water, regardless of its source, must be considered a polluting medium because of overflowing sewers, outhouses, decomposing livestock, street run-off water, etc.

Depending on the extent of the flood, first determine the locations of the major stocks of regulated products. Food and drugs will normally receive first priority. As stocks of goods are located, rapidly survey the extent of damage, then concentrate on affected materials. Use your camera extensively. Examine the walls of buildings, storage areas, and the top and sides of stacked or tiered goods for flood water residue, debris, and a well-defined high-water mark. Finished products, ingredients, and containers stacked above this line are still of concern because other problems probably exist (e.g., vermin defilement, failure of refrigeration, thawing of frozen items, etc.).

Any suspect material should be embargoed by local officials or held pending final disposition. Management is usually cooperative and willing to do things it may not normally do to get back to normal operations as quickly as possible. Cooperate with management but avoid hasty decisions.

Many products are quickly rendered unsuitable for human consumption by flood water. Items such as bread, cakes, cookies, candies, bulk flour, sugar, bulk liquids, and similar items not in jars or hermetically sealed containers can often be immediately hauled to disposable areas and destroyed.

Determine areas which have lost power. In facilities such as frozen food firms, and frozen or refrigerated warehouses, check the sites for length of down-power and condition of the products. If power is restored in time to avoid thawing, or prevent spoilage of refrigerated items, and products were not inundated, or otherwise affected, there is no need for further examination.

Even though flood waters may not have inundated the firm, the situation may have caused sewer and waste lines to backflush into basements and immediately drain out again. Debris or sewage particles along walls and on low floor surfaces or presence of sewage odors are evidence of backflushing.

Grain, cottonseed, soybeans, dried bean products, peanuts, and similar products may become flood damaged in terminal elevators, on farms, and in flat storage facilities. In addition to flood water contamination, molding products may develop mycotoxin contamination. Examine susceptible products and facilities for damage, inundation, and mold.

Rodent activity may increase in flooded areas as the vermin seek food and shelter. Be alert to rodent defilement on products.

As lots of products are checked, embargoed, or released and the immediate situation returns to normal, firms will want to start operating. Prior to beginning operations, examine equipment and processing facilities for pollution and its aftermath. Plant operation must not be permitted unless proper cleanup and sanitizing is performed.

#### 8.1.5.8.4.2 - Earthquakes

Extreme care must be exercised when working in earthquake areas. Do not enter severely damaged buildings.



Most damage from an earthquake comes from the aftershocks, falling debris, and resulting fires and flooding. Items under FDA jurisdiction are most likely to suffer physical damage, spoilage from lack of refrigeration, and/or fire and flood damage.

#### 8.1.5.8.4.3 - Hurricanes and Tornadoes

Investigate following the guidance in *Flooding* Section above. In addition, examine products for evidence of physical damage caused by flying objects and crushing by debris. Physical damage to product containers may be extensive. Broken or leaking containers of materials such as chemicals, oils, fertilizers, etc., may have contaminated FDA-regulated products. See the *Chemical Spills, Hazardous Waste Sites, Wrecks* section below on chemical contamination from various sources.

#### 8.1.5.8.4.4 - Chemical Spills, Hazardous Waste Sites, Wrecks

Chemical spills occurring on land or water can pose a serious threat to the environment and contaminate FDA-regulated products both directly and indirectly. See IOM 3.2.11 for information.

In wrecks, the physical impact usually causes most damage. Toxic items in the same load may rupture and add to the contamination. In train wrecks, other railcars loaded with chemicals, oils, or other contaminating materials may rupture and contaminate food and drug products in otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Do not overlook the possibility that runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms under FDA jurisdiction.

Hazardous waste sites also pose a hazard to the immediate environment and other locations off-site, if runoff contaminates nearby surface waters or, if leachate, contaminates ground water supplies.

#### 8.1.5.8.4.5 - Fires, Explosions, Riots

FDA operations following these disasters are usually localized and do not normally involve many personnel or extended resources.

Examine products for exposure to excessive heat, physical damage from flying objects, falling debris, and lack of refrigeration in down-power areas. Examine for water damage from firefighting activities and handle these as a flooding situation. Be alert for possible pollution from using non-potable water in firefighting.

Firefighting often involves use of chemicals. Examine products for residues from possible toxic fire extinguishing materials and question fire authorities regarding this issue.

In addition, chemical contamination in fire disasters can also be present from other sources, including:

1. Stored chemicals rupturing from heat or from impact of falling debris.
2. Spraying or leaking chemicals (liquid, powder, dust, granules) as damaged containers are being removed or salvaged from the fire area.
3. Tracking of chemical material from contaminated areas to other areas by fire crews or others.
4. Burning or melting plastic containers, insulation, and other building materials.
5. Leaking fuels, storage batteries, anti-freeze, etc., from burning, damaged or overheated equipment.
6. Chemicals from melting or vaporizing electrical insulation and, in particular, cooling chemicals from leaking or exploding electrical transformers. Large commercial transformers are often directly involved in the fire area and may leak

or explode from the heat, spreading toxic liquid chemicals (some transformer oils contain concentrations of PCB) over a large area, even contaminating products in non-fire areas.

#### *8.1.5.8.5 - Bioterrorism*

The field was issued guidance from 2001 which includes the following:

*If a bioterrorism act is suspected, FDA staff should not collect or accept samples from any local, state, or law enforcement agency as such actions will be coordinated by OCI and the FBI, as appropriate. If an FDA-regulated product is suspected in a tampering, please call OEM/OEO immediately. In the FBI/OCI determines the product is not suspect, OEM/OEO will issue further guidance to the division office.*

Office of Emergency Operations / Office of Emergency Management (OEM/OEO) emergency operations 24-hour phone number is 1 (866) 300-4374. The e-mail is [emergency.operations@fda.hhs.gov](mailto:emergency.operations@fda.hhs.gov).

For additional information see [Guidance to the Field on Bioterrorism \(10/17/2001\)](http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldinvestigation/ucm023333.doc) (<http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldinvestigation/ucm023333.doc>). (Note: This link is only available on the FDA Intranet site and cannot be accessed by individuals outside the FDA network. Requests can be made through the FOI process described in Section 8.1.3)

#### *8.1.5.8.6 - Embargoes*

See [IOM 3.3.1](#) and [IOM 2.7.1](#).

FDA does not have embargo authority, but does have administrative detention authority as specified in:

- [The Federal Meat Inspection Act](https://www.fsis.usda.gov/policy/food-safety-acts/federal-meat-inspection-act) (<https://www.fsis.usda.gov/policy/food-safety-acts/federal-meat-inspection-act>)
- [The Poultry Products Inspection Act](https://www.fsis.usda.gov/policy/food-safety-acts/poultry-products-inspection-act) (<https://www.fsis.usda.gov/policy/food-safety-acts/poultry-products-inspection-act>)
- [The Egg Products Inspection Act](https://www.fsis.usda.gov/policy/food-safety-acts/egg-products-inspection-act) (<https://www.fsis.usda.gov/policy/food-safety-acts/egg-products-inspection-act>)
- Certain parts of the FD&C Act, namely [Section 304\(g\) \[21 U.S.C. 334\(g\)\]\(g\)](#) [21 U.S.C. 334(g)] for medical devices, drugs, and tobacco and [Section 304\(h\) \[21 U.S.C. 334\(h\)\]](#) for human and animal food

States and local jurisdictions have embargo authority over FDA-regulated products. Embargoes are an effective tool for keeping adulterated and misbranded products from the consumer market. State and local embargoes can be employed immediately requiring the merchandise be held, destroyed, or reconditioned without time consuming delays. Some state and local embargo powers are limited to the length of time the product can be embargoed and a minimal quantity or value. In these cases, the use of federal administrative detention, injunction, and seizure action should still be considered. Your division will determine if embargoes are warranted and work with state or local authorities to obtain them.

#### *8.1.5.8.7 - Field Operations*

On-site inspectional and investigational activities will normally be conducted with other FDA personnel and state or local counterparts.

An assessment must first be made of the disaster area to determine the extent of damage, and the amounts and kinds of merchandise involved. This may be done by contacting local Emergency Operation Centers on current conditions, and from firm and mapping details of the impacted area provided by the OEO Geographic Information System (GIS). If an IMT is activated the Planning Section and Safety Officer will perform this assessment.

Whether operating within an IMT or not, once personnel are mobilized and assignments are issued, operational procedures will be similar, regardless of the type of disaster. Normally, you will search, identify, and investigate foods, drugs, devices, and cosmetics for actual or possible contamination and taking the necessary steps to preclude their use until they are released, reconditioned, or destroyed.

CAUTION: Although procedures in this subchapter do not cover disasters resulting from a radiological event (presence or release of radioactive materials), it is possible you may discover products suspected of contamination by radioactive materials in the disaster area. If you suspect the presence of radioactive materials, take no action on the materials yourself, but have the area cordoned off at once. Notify the command official (official in charge) and immediately contact your IMT or supervisor, as applicable, to alert the radiological health representative and the state radiation control agency. Follow their instructions.



When in doubt as to the condition of any materials affected, request holds or embargoes pending final outcome of further examinations. See *Section 8.1.5.8.6*.

#### *8.1.5.8.8 - Field Examination and Samples*

Field examinations are an effective tool for determining adulteration or misbranding during disaster investigations. Judge the extent of field examination and sample collections necessary, based on the nature and magnitude of the disaster.

In major catastrophes, large numbers of samples may not be necessary because of obvious visible contamination and the emergency disposition powers invoked by state and local officials. In minor local disasters, such as fires, riots, train wrecks, truck accidents, or shipwrecks, lots may be held pending outcome of examinations and extensive sampling may be required.

Field examinations should focus on obvious adulteration, such as physical damage to products or containers, or damage to labeling.



Examine bulk containers and their contents, including underground storage tanks. Examine material in rail cars, truck trailers, and storage silos. Be especially alert for rail car and trailer movement. These may quickly disappear, as clean-up crews arrive.

#### *8.1.5.8.9 - Product Disposition*

Lots under embargo, or voluntarily held pending examination or analysis, must be secured until the examination or analysis is completed, and a release decision is made. If the material can be released, it is returned to the owner.

Depending on the circumstances and the magnitude of the disaster, segregation, destruction, or reconditioning of affected goods may be accomplished in the immediate area or the materials may be moved to distant locations for further manipulation.

FDA normally opposes movement of affected goods since control of the lots is difficult.

However, in cases of widespread disasters, reconditioning centers established in non-disaster areas may be the most efficient way to handle the problem.

##### **8.1.5.8.9.1 - Segregation**

The segregation process often creates a multitude of problems, especially when insurance claims agents and salvage firms become involved. You are not to segregate materials yourself. This is the responsibility of the owner or his agent. You should advise them what constitutes releasable conditions. After segregation, you may be instructed to advise them about product release based on your examination and/or laboratory results.

##### **8.1.5.8.9.2 - Destruction**

It is not your responsibility to say how condemned products are to be destroyed. This is a concern of the owner and the state or local health agencies that condemned the products. FDA may be asked to aid in or recommend destruction methods. The most common destruction method is crushing and dumping in a land fill in approved areas. See IOM 2.6.1. Destruction methods usually are worked out with state or local officials. The final decision in major operations may be required of the command officials or higher headquarters, especially if the environmental impact is significant.

Control products to be destroyed and protect them from pilfering at destruction sites.

##### **8.1.5.8.9.3 - Reconditioning**

Affected products may often be reconditioned depending on the condition of the product, its container, type of product, intended use, and extent and type of contamination.

Any reconditioning must be closely supervised, with proper safeguards for product accountability. Control must be maintained over the complete operation, with proper disposition of the rejected portion and the reconditioning of the acceptable portion performed to the satisfaction of all health officials.

Certain food products which cannot be salvaged for human or animal use might be of use in non-food or non-feed industries. However, these must be denatured to render them unfit for food or feed use. Firms must account for the amounts of product denatured, to whom it was sold, and the final use of the product. Examination of the product at its final destination and/or a spot check may be required to assure it is utilized in non-food or non-feed products. Reconditioning plans should be reviewed by the division's Compliance Branch in consultation with the appropriate center or by the IMT if ICS is being used for the incident.

It is your responsibility to assure the firm is following the reconditioning plan and that no product is diverted from the plan.

#### 8.1.5.8.9.4 - Relabeling

Relabeling may be the only reconditioning required if damage is solely to the label and all the following conditions are met:

- The new label contains all mandatory information, is not misleading in any way, and conforms with the FD&C Act in all other aspects.
- Label codes are carried over to the new label.
- The product is not contaminated; and
- The container has its original integrity.

### 8.1.5.9 - Counterfeiting and Tampering

#### *8.1.5.9.1 - Reporting Contacts*

All reports of counterfeiting, tampering, or tampering threats must be immediately reported to the Office of Criminal Investigations (OCI) headquarters office, Special Agent in Charge-Headquarters Operations (SAIC-HQS OPS) at 240-276-9500 and the Office of Emergency Management (OEM)/Office of Emergency Operations (OEO) at 1 (866) 300-4374 (24 hours).

If the complaint or report involves a United States Department of Agriculture (USDA) regulated product, the district office should report it directly to the USDA and notify OCI, SAIC-HQS OPS, and OEM/OEO immediately. Notification of OCI may be done online at OCI's [Report Suspect Criminal Activity website](https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm): (<https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>). OEM/OEO can be notified by e-mail at [emergency.operations@fda.hhs.gov](mailto:emergency.operations@fda.hhs.gov) and by phone 24 hours a day at 1 (866) 300-4374.

**Do not conduct any investigation into these reports unless you have been directed to do so by management following their meeting with OCI.**

#### *8.1.5.9.2 - OEM / OEO Responsibility*

OEO/OEM is the focal point for communications; especially in those counterfeiting/tampering cases where regional/national coverage is necessary. Alert OEM immediately to all suspected or confirmed counterfeiting/tampering incidents, whether or not there is an injury/illness involved, especially if media attention will be initiated by any source.

### *8.1.5.9.3 - Coordination with Other Government Agencies*

The Federal Bureau of Investigations (FBI) and the USDA share enforcement of the Federal Anti-Tampering Act (FATA) with FDA as described below:

1. **FBI Responsibility** - The FBI has concurrent jurisdiction under the FATA over products regulated by FDA. The FDA understands the FBI's primary interest in the FATA matters will be to investigate; particularly, those cases which involve a serious threat to human life or a death. SAIC-HQS OPS or the local OCI field office will coordinate all referrals to the FBI in accordance with agency policy.
2. **USDA Responsibility** - The USDA will investigate and interact with the FBI on counterfeiting/tampering of products regulated by USDA. If a counterfeiting/tampering complaint or report is made to an FDA district office and involves a USDA-regulated product, the district office should report it directly to the USDA and notify OCI, SAIC-HQS OPS, and OEM/OEO immediately. Notification of OCI may be done online at OCI's [Report Suspect Criminal Activity website](https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm): (<https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>).

Isolated incidents of counterfeiting/tampering not investigated by OCI and not meeting the criteria for FBI or USDA follow-up, may be referred to the appropriate state or local investigative agencies, as outlined in section 8.1.5.9.4. The appropriate center should be consulted in these cases. Assistance should be provided to cooperating officials as necessary or where requested.

### *8.1.5.9.4 - Authority & Responsibility*

FDA is authorized to investigate reported counterfeiting/tampering of FDA-regulated consumer products under the FATA, [Title 18, USC, Section 1365](#) and [Title 18, USC, Section 2320](#). See IOM Exhibit 8-1. In most cases, the authority for such investigations is also found in the FD&C Act.

OCI has the primary responsibility for all criminal investigations of counterfeiting/tampering/threat incidents of FDA regulated products. Given that responsibility, OCI field offices will coordinate responses to counterfeiting/tampering reports with the district offices they deem appropriate, to ensure initial investigative steps are taken in a timely and efficient manner.

In those incidents where OCI does not, or cannot, initiate a criminal investigation, they will inform the division of their decision and the division will determine the proper follow-up, which could include further investigation by the division or referral to local or state authorities. The division will keep OCI informed of their follow-up activities and any relevant changes in its status. Prior to initiation of any tampering investigation, you and your supervisor should evaluate the situation from a personal safety perspective. You and your division management may also need to determine if a situational plan is warranted. Refer to IOM 5.2.1.2 - Personal Safety, and IOM 5.2.1.4 Situational Plan, for more information.



#### *8.1.5.9.5 - Release of Information*

During any investigation related to counterfeiting or tampering, no information should be released without management approval. If there are inquiries about the investigation, contact your supervisor.

#### *8.1.5.9.6 - Investigation*

The purpose of these investigations is to determine if counterfeiting/tampering has occurred; the seriousness of the problem; the quantity of affected products on the market; the source of the counterfeiting/tampering; and quick removal from consumers or commerce of any contaminated product. OCI will seek to identify and initiate criminal prosecution of those persons responsible for criminal activity associated with counterfeiting/tampering/threat incidents.

FDA will investigate reports of counterfeiting/tampering associated with FDA-regulated products. Priority will be given to reports of death, illness, injury, or a potential health hazard. Adhere to existing procedures and instructions as outlined in the IOM and RPM when conducting counterfeiting/tampering investigations, inspections, sample collections, special investigations, and related activities including interviews, record examination, direct observation, affidavits, etc.

#### *8.1.5.9.7 - General Procedures*

Counterfeiting/Tampering incidents historically have occurred in unpredictable forms and products. Standard operating procedures (SOPS), in most cases, will suffice for these investigations. As events take place, specific instructions for some investigations may be provided by OCI headquarters and/or your division office. Expeditious resolution is important, especially when a health hazard may be involved.

Attempt to answer the following questions as rapidly as possible:

- Has counterfeiting/tampering occurred, or can the condition of the product be explained by other means?
- Is death, injury, or illness associated with the report and, if so, does it appear to be caused by the product counterfeiting/tampering?
- Does the incident appear to be isolated or wide-spread?
- Is it likely other, similarly affected FDA-regulated products remain in distribution, and if so, what is the extent and magnitude of distribution?
- If the incident involves more than a single container, could counterfeiting/tampering have occurred at the production facility or in the distribution chain rather than at retail?
- Can specific persons or points in the distribution chain be identified as possibly causing the problem?

Be sure to coordinate your efforts with OCI SAIC/IOD HQS OPS and OEM/OEO.

In many counterfeiting cases, ORA investigators and OCI agents conduct joint inspections/investigations at the distributors. It is the purpose of the ORA investigators to document receipt and distribution of counterfeit products and to discuss voluntary recall of

those products. OCI agents will at the same time conduct their investigation into the knowledge and source of the counterfeit products. It is not your purpose to accompany the OCI agent during his/her investigation.

### *8.1.5.9.8 - Sampling*

#### **8.1.5.9.8.1 - Tampering Cases**

Whenever a sample is collected for suspected tampering, you must collect an authentic sample of the same product. It should be from the same lot and code, if at all possible. The sample size for the authentic portion is at least six in-tact units. Follow normal sampling techniques; however, recognize that there may be forensic evidence available such as fingerprints and hair that can be lost if the sample is not handled properly.

The Forensic Chemistry Center should be contacted prior to sampling. They can give specific directions regarding sampling in each situation, especially related to the preservation of forensic evidence like fingerprints.

Samples should be packed to avoid movement of the product container within the bag. Individual dosage units from previously opened containers can be protected by removing them from their container utilizing spoons or forceps. Secure them in separate containers so they do not rub or smear possible evidence. Further guidance can be found in the FBI "HANDBOOK OF FORENSIC SERVICES" (<https://www.fbi.gov/file-repository/handbook-of-forensic-services-pdf.pdf/view>). As a precaution, rubber gloves may be worn inside of cotton gloves as protection against toxic or caustic substances.



Ship samples with extreme care to ensure their integrity. Thoroughly describe your sample and its characteristics on the collection report (C/R) to facilitate analysis. Include any descriptive terms used by individuals associated with the complaint. If special instructions to preserve fingerprints or for further handling are indicated, they should be noted on the C/R. If speed is imperative, consider hand delivery to the lab.

#### **8.1.5.9.8.2 - Counterfeiting Cases**

If sampling is indicated during an investigation of counterfeiting, follow the directions from OCI or the Forensic Chemistry Center regarding collection, packaging, and shipment of the sample. Authentic samples should only be collected when requested by OCI in consultation with FCC.

### *8.1.5.9.9 - Complainants*

Some complaints about "foreign objects" may be tampering complaints. The complainant may state they found something in a product. You should be aware that any complaint investigation of foreign objects may become a tampering investigation.

Consumers are likely unaware of the provisions of the Federal Anti-Tampering Act (FATA). A general discussion of the FATA, its provisions for investigation, filing of false reports, and

counterfeiting/tampering can be useful and informative to those individuals. Consumers are often unaware that merely filing a false report is a serious crime and once aware may rescind previous statements. In general, this would close an investigation, but you should discuss this with your supervisor.

Prior to concluding your interview of the complainant, obtain a signed affidavit attesting to the circumstances of the complaint, as directed by IOM 4.4.8. Include a statement in the affidavit similar to the following, "I have been informed of the provisions of the Federal Anti-Tampering Act and also that the providing of false information to the federal government is illegal." It is permissible to pre-type this statement at the bottom of an affidavit, FDA 463a, and photocopy it before use if you have a large number of counterfeiting/tampering complaints to investigate.

#### *8.1.5.9.10 - Continuance of Investigation*

Some investigations may continue after the interview and sample collection from the consumer. If you are directed to continue the investigation at the retail, distribution, or manufacturing sites, obtain specific guidance from your management or OCI before proceeding. You may be conducting an inspection at a firm simultaneously with an OCI investigation. You should not disclose to the firm officials anything about an OCI investigation.

#### *8.1.5.9.11 - Refusals*

All refusals encountered during counterfeiting/tampering investigations should be documented using existing procedures. Refusals of requests should be documented in detail. Assure the firm is aware of the non-routine nature of the request. If a search warrant or other court order is necessary, OCI will lead or direct this part of the investigation. Report all refusals to the local OCI field office.

## 8.1.6 - General Investigative Techniques – What do I do during an investigation?

### 8.1.6.1 - Interviews

An interview is a one-on-one structured conversation to obtain accurate, reliable information. To gain the most facts and information, be prepared and conduct the interview methodically with a set purpose.

#### *8.1.6.1.1 - Preparation*

Interviews may be conducted in various agreed upon meeting places. Choose a non-threatening place for the interview, such as a conference room or private office free from distractions or interruptions. Silence your phone to avoid incoming calls. If possible, conduct the interview away from the person's normal area of business. If interviewing a consumer at their home, try to interview them in an area of their home that has the least distractions. If possible, conduct the interview sitting directly across from the interviewee.

Begin by researching your topic. Set a specific purpose and objectives for what you want to learn during the interview.

### *8.1.6.1.2 - The Interview*

- Set the tone. In most cases, you may tell the interviewee what they can expect. Start out with generic or easy-to-answer questions to establish a baseline and to put the subject at ease.
- Avoid asking leading questions. Ask open-ended questions that encourage the interviewee to talk and provide a full answer rather than a “yes” or “no” (e.g., Tell me about..., How did you..., Why was this..., etc.) Avoid combining more than one idea into the same question. Frame the question to generate an answer one fact at a time. Avoid questions that are accusatory or that trigger a defensive response. ‘Yes’ and ‘no’ questions may be used at the end of the interview to affirm facts.
- Keep an open mind.
- Do not express your opinions, thoughts, and your own conclusions about the situation or what the interviewee says. You are trying to learn information and facts from the interviewee so avoid being too familiar with the topic in your responses. Set aside any potential biases while conducting the interview.
- Take detailed notes or have another CSO present to take notes. This is extremely helpful since you are focused on the objectivity of the interview. If taking notes makes the interviewee uncomfortable or hinders the interview, you may take notes immediately after the interview and identify the time between the interview and your notetaking and explain the circumstances for not taking contemporaneous notes during the interview. Only use quotes (“...”) if you are certain they are exact. It is a good practice to read a quote back to the interviewee to confirm its accuracy.
- Pay attention to the subject’s verbal and non-verbal communication.
- Ask for clarification and more detail if responses are not clear to you during the interview. Repeat answers back to the subject to ensure you heard the information correctly. Ask if documents exist and to support any part of the interviewee’s story. Collect any available relevant documents.
- Follow-up questions may help establish additional facts. If your questions are avoided or the answers seem evasive, try rephrasing the question and ask it again. You may also change topics and return to an issue later.
- Allow the interviewee enough time to answer your questions and avoid interrupting them. Sometimes silence can be a tool to prompt further explanation or reaction. Before concluding the interview, ask the subject if there is anything else they would like to provide or discuss. Ensure that the interviewee has your contact information in case they recall any more material information later.
- Interviews and discussions with complainants where tampering is suspected or alleged, should include a discussion of the Federal Anti-Tampering Act (Exhibit 8-14). This discussion needs to be documented in the investigation report/memo. See IOM 4.4.6.3

### *8.1.6.1.3 - Safety*

Developing a Situational Safety Plan may also be required. Refer to IOM 5.3.5.4.2 In preparation for any consumer complaint interviews, you should take your personal safety into consideration. Refer to IOM 5.2.1.2 for more information.



#### *8.1.6.1.4 - Basic Information to Obtain*

Obtain an accurate and complete description of the product, e.g., brand name, product name, flavor or variety, how packaged, storage conditions required (i.e., refrigerated or shelf stable) etc. Refer to *Consumer Complaint Procedure (SOP-000544)* Section 6.1.1 C.

It is important to accurately determine the sequence of events leading up to the complaint.

You cannot rely on consumers responding to follow-up calls or providing additional information later.

#### **8.1.6.2 - Medical Records**

In investigating complaints where the complainant was seen by a health professional, contact the health professional concerning the nature of the alleged illness/injury, and the relationship to the product. You may occasionally find the complainant has not mentioned the product to the health professional as a potential cause of the illness or injury. Use judgment as to the usefulness of collecting medical records. Examples of medical records to collect include: Admission History and Physical; Emergency Room/Clinic Record of the event if patient not admitted; Discharge Summary; Autopsy Report; and Death Certificate. See also IOM 5.3.8.6.

If collection of medical records is necessary, use the letter template found in Exhibit 8-2. It may be necessary to use multiple letters if medical records are at different locations. If you encounter resistance from the medical professionals in providing records, you may refer them to 45 CFR 164.512(b) which explains the exemptions allowing FDA access to the medical records.

FDA is exempt from the HIPAA Privacy Rule as a public health authority. If a situation arises in which information sharing is impeded by the belief that FDA lacks authority to receive this information, you may share the language below during disease outbreak investigations or consumer complaint follow-up. References are provided for further information.

*“The Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) permits disclosure of privacy information without a written patient authorization for specific public health purposes. Specifically, the Privacy Rule permits covered entities to disclose this type of information to ‘a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability, including...the conduct of...public health investigations’<sup>1</sup>. Per the Privacy Rule, ‘public health authority means an agency or authority of the United States...including the employees or agents of such public agency...that is responsible for public health matters as part of its official mandate’<sup>2</sup>. FDA, as a public health authority responsible for ensuring the public health and safety with regards to FDA-regulated products, meets this definition. Our authority to receive information related to FDA-regulated products comes from the Federal*

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<sup>1</sup> 45 CFR 164.512, from the Privacy Rule, available at <https://www.law.cornell.edu/cfr/text/45/164.512>

<sup>2</sup> 45 CFR 164.501, also from the Privacy Rule, available at <https://www.law.cornell.edu/cfr/text/45/164.501>



*Food, Drug and Cosmetic Act (FD&C Act), the Public Health Service Act, and regulations issued under those authorities.*

*“The Privacy Rule permits covered entities to disclose protected health information (including personal privacy information) directly to the FDA for certain public health activities and purposes, provided that the disclosure is limited to the minimum amount necessary. During FDA follow-up to reports of illnesses potentially associated with FDA-regulated products, access to personal privacy information including names and contact information is necessary in order to ensure timely follow-up and, potentially, removal of implicated products from commerce. FDA is also responsible for safeguarding personal privacy information released to us according to the Freedom of Information Act and the Privacy Act<sup>3</sup> and our information disclosure regulations<sup>4</sup>, and is obligated to comply with all applicable protections, procedures and legal requirements against the unauthorized disclosure of this information.*

*“Consequently, personal privacy information including case names and contact information should be shared by state and local health departments with FDA authorities during an investigation of potentially adulterated FDA-regulated products, including illness outbreaks potentially associated with FDA-regulated foods. Prompt information sharing speeds the agency’s investigation and can prevent additional illnesses and/or deaths due to an adulterated FDA-regulated product.”*

If the investigation is related to an outbreak/illness and the Office of Emergency Operations or Coordinated Outbreak Response and Evaluation is coordinating the incident and a medical officer has been assigned to the investigation it is preferred that the CSO, with supervisory concurrence communicates with the medical officer about the documents to collect prior to the collection. In the absence of a medical officer being assigned or available, the CSO in collaboration with the supervisor, should collect medical records most relevant to the incident. Once collected, the Office of Emergency Operations or CORE if involved, or the supervisor in consultation with their management should identify a medical officer to review the records.

The records containing personal identifiable information (PII) and medical information need to be protected. All medical information sent to the medical officer electronically needs to be encrypted. Hardcopy records shipped to the medical officer need to include shipment tracking information and request signature upon receipt. The medical records should be addressed to the attention of the specific medical officer who will be conducting the review.

Any hard copy medical records in the possession of the CSO after sending to the medical officer or returned by the medical officer, should be placed in a sealed envelope, identified to contain PII and medical information and filed with the investigation memo.

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<sup>3</sup> 5 USC 552, 5 USC 552a, from The Privacy Act of 1974 5 USC 552a (as amended), available at <https://www.law.cornell.edu/uscode/text/5/552> and <https://www.law.cornell.edu/uscode/text/5/552a>

<sup>4</sup> 21 CFR Parts 20 and 21, from FDA information disclosure regulations 21 CFR Parts 20 and 21, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=20>

When collecting medical records from a Department of Defense (DoD) medical facility, identify yourself to the commanding officer of the facility or representative and request authorization to examine and copy records. Please note that DoD Directive 6040.2, Release of Information from Medical Records authorizing release of medical information to government agencies, has been rescinded by DoD; if the representative of the facility requests a letter authorizing release, use the same letter as above.

If the hospital does not accept the FDA letter for Authorization for Medical Records Disclosure, obtain and complete the one the facility provides.

Collect all medical records pertinent to the investigation. See IOM 5.11.5.

References are available at: <https://www.law.cornell.edu/cfr/text/45/164.512> and <https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a3.htm>.

### 8.1.6.3 - Sample Collection

Chapter 4 covers general sample collection methods and authority. In general, collection of samples during an investigation will be directed by the assignment or in discussion with your supervisor. Opened containers of product are rarely sampled.

Prior to initiating sample collection, you may consider contacting the home division of the manufacturing plant. They may be aware of an existing issue related to the product and problem. Samples should be collected immediately, while they are available.

When a consumer portion is collected, intact containers of products of the same lot should be collected from the retail and wholesale levels if available. When collecting samples at retail or wholesale, ask if the firm is aware of any other complaints concerning the product. Refer to IOM 4.3.5.1 for additional information concerning collection of consumer portions. Maintain the confidentiality of the complainant. If the distributor inquires about holding or recalling the product, refer them to your supervisor.

### 8.1.6.4 - Internet Investigations

The internet can provide useful information when conducting many types of investigations, including obtaining basic background information. Often you can use your government issued computer or cell phone for basic firm information (e.g., hours of operation, key personnel, location, directions, etc.). In these cases, you are using the internet as a tool to assist as you determine where and how to collect information and conduct your investigation.

When conducting specific internet investigations and documenting evidence online, refer to [Introduction to Internet Investigations](http://inside.fda.gov:9003/ORA/Offices/OEIO/Enforcement/ucm560967.htm) (<http://inside.fda.gov:9003/ORA/Offices/OEIO/Enforcement/ucm560967.htm>).

*Note: This website is on the FDA Intranet and not accessible outside of the FDA Network.*

### 8.1.7 - Locations for Investigations – Where could you conduct an investigation?

Some examples of locations for investigations include:

- Retail establishments.
- A consumer's residence.
- Other government agencies.
- Location agreed upon with a complainant.
- Hospitals/physicians' offices.
- Online.

Depending on the circumstances involved, an investigation can be performed at almost any location.

### 8.1.8 - Internal and External Organizations Involved - Who else will I encounter during an investigation? Why are they involved?

The agency works cooperatively with many outside organizations, primarily other federal government agencies and state, local, tribal and territorial (SLTT) authorities. Internally, you may work with individuals from ORA headquarters, OCI, other programmatic divisions or center employees. Some of these organizations become involved due to contractual obligation, statutory obligation, request for expertise, or memorandum of understanding (MOU). Chapter 3 of the IOM provides information about major organizations that FDA interacts with, both federal and state.

#### 8.1.8.1 - Interagency Referral

One of FDA's functions is to assist SLTT and other federal agencies in conducting investigations, collecting samples, and conducting plant inspections. If you find information during the course of an investigation that may be relevant to another federal agency, a referral request can be made by filling out an online form <https://www.accessdata.fda.gov/scripts/IRF/>.

Primary regulatory authority may belong to FDA or another agency. It is important to be aware of which organization has primary regulatory authority during an investigation.

For Grade A Milk products, raw molluscan shellfish, and retail food operations, within ORA, the Office of State Cooperative Programs (OSCP) has lead responsibility. For these cooperative programs, the state has primary authority for investigations. FDA often accompanies and assists states during investigations through the Office of State Cooperative Programs. If your investigation involves Grade A Milk or Milk Products, raw molluscan shellfish, or retail food operations, contact the Office of State Cooperative Programs before investigating.

#### 8.1.8.2 - Intra-agency/Cross-Program

Outside of ORA, you may be involved other components of FDA. FDA staff work closely with one another to ensure the safety, efficacy, and security of FDA-regulated products. FDA functions are organized into the following:

- The Office of Foods and Veterinary Medicine (OFVM) provides oversight of FDA’s food and feed programs as well as leads the implementation of the FDA Food Safety Modernization Act of 2011 (FSMA). OFVM includes the Center for Veterinary Medicine (CVM) and the Center for Food Safety and Applied Nutrition (CFSAN) which includes the Coordinated Outbreak Response and Evaluation (CORE) Network.
- The Office of Medical Products and Tobacco (OMPT) provides high-level coordination and leadership across the centers for drugs, biologics, medical devices, and tobacco products. This office also oversees special medical programs.
- The Office of Global Operations (OGO) is focused on globalization and import safety of food and drug production and supply. OGO provides direction and support to ORA and the Office of International Programs (OIP).

## 8.1.9 - General Investigation Reporting - How do I report my investigation?

### How do I get credit for the time I spent on it?

Reporting an investigation is almost always done using a memorandum (see Exhibit 8-3) and captured as an operation in eNSpect (explained in more detail below). The format of the investigation memo is not as defined in sections as an establishment inspection report (EIR). As a general guideline you can first summarize why or give the reason for the investigation, what was covered, and briefly state the findings. After this, you can go into detail about how you conducted the investigation and what you found. Reporting the course of your investigation and your findings chronologically works in most situations. For long narratives, using headings will make it easier for the reader to follow your reporting. Some types of investigations have forms that need to be completed in addition to the narrative within the memo. For example, FDA Form 3623, the Farm Investigation Questionnaire (FIQ), must be completed for all farm investigations.

For import specific investigations see IOM 6.1.3.8.

### 8.1.9.1 - Entering investigation operations in eNSpect

eNSpect is used to capture information about the assignment, the establishment, and the investigation. Investigation operations are reported in eNSpect as either a Domestic Investigation (OP13) or Foreign Investigation (OP15). General information on how to complete these operations in eNSpect field client are provided below. (For complete instructions, refer to the [eNSpect Resources Site](#) for the current eNSpect User Guide and eNSpect training.) The “Investigation” tab in eNSpect includes the “Details,” “Time & Coverage,” and “Endorsement” pages.

The “Endorsement” page has three sections: Endorsement, Attachments, and Supervisor Feedback. Attachments, such as the investigation memo, are uploaded to support your findings under the “Attachments” section of the endorsement page. All three sub-sections must be completed, and each has a maximum of 4000 characters per text box. The narrative entered in these sub-sections will depend on several factors (e.g., program/division, type of investigation, assignment). If the character limit prevents you from describing all relevant facts, an investigation memo should be prepared and uploaded under the “Attachments” section. If the space is adequate to report your investigation, you may not need to prepare a memo. For example, reporting OEI improvement activities and firms determined to be out of business (OOB) are two situations where a memo

usually is not necessary. However, this can also depend on your program and/or division procedures. Programs of divisions may require a memo for all investigations. Consult with your supervisor if you are unsure whether a memo is required for the investigation.

Your supervisor or other designated individual will review and endorse the investigation report (OP13 or OP15) in eNSpect. An inspection (OP11 and OP12) can be converted to an investigation (OP15 and OP13, respectively) in eNSpect when you were unable to complete the inspection (often referred to as a “washout”). Obtain supervisory concurrence before converting an inspection to an investigation due to a washout. For example, your supervisor may want you to hold onto an inspection assignment and inspect a seasonal firm later in the year rather than converting the inspection to an investigation as a washout.

Reasons to convert an inspection to a washout include the following: Out of Business (OOB); Not Official Establishment Inventory (NOE); Inactive (INA); Seasonal (SEA); Operational but not an FDA obligation (OPR); Pre-Production (PRE-PROD), and Firm does not meet assignment criteria (OPR). The information reported in your investigation, especially the reason for the investigation, may be helpful to future investigators. If the investigation finds further action is recommended, do not convert the associated inspection assignment to a “washout” in eNSpect. Report the operation using an ad-hoc eNSpect investigation (OP13 or OP15). Do not return the associated inspection operation (OP12 or OP11) to FACTS for conversion to an investigation. An example of a further action would be a request for Import Alert because of an inspection refusal in a foreign country.

### 8.1.9.2 - Investigation memo: format, content, endorsement, and routing

Exhibit 8-15 demonstrates the general format of a memorandum of investigation (investigation memo), which includes the originating division/office; responsible firm; FDA Establishment Inventory (FEI); to/from; date; and subject. When writing an investigation memo, consider the following:

- Document all pertinent information (e.g., who, what, when, where, why). At a minimum, the investigation memo should contain the following information: the reason for the investigation; background and history, if any; findings; and recommendations.
- Provide details of how you conducted the investigation and describe pertinent data, references, attachments, etc.
- Headings may be used if it contributes to presenting your report in a clear, logical, and concise manner.
- Routing for the memorandum should be included. Consult with your supervisor if unsure of the correct routing information to include.

### 8.1.9.3 - Reporting complaints/follow-ups

Refer to *SOP-000544, Consumer Complaint Procedure*, in the Quality Management Information System (QMIS) for detailed instructions on the screening, evaluation, monitoring and investigation of consumer complaints of FDA-regulated products received by and/or submitted to ORA personnel.

If you conduct an inspection to follow-up on a complaint, any findings related to the complaint should be documented in the Establishment Inspection Report or in one of the following ways for an OP13/OP15, if not involving confidential informants, whistleblowers, etc.,

If you conduct an inspection as above, but it involves a confidential informant or whistleblower, follow directions for reporting provided in Consumer Complaint section related to Confidential Informant or Whistleblower.

Information contained in the investigation memo or sub-sections of the “Endorsement” section of eNSpect, should at a minimum include a general discussion of the complaints that were covered and the complaint number(s). The complaint numbers should be recorded in the endorsement of the OP13/OP15. In addition, consumer complaints are linked to these operations in eNSpect by entering the consumer complaint ID under the “Details” page in eNSpect.

The time spent on the consumer complaint follow-up should be reported in the eNSpect assignment (OP13 or OP15) under the appropriate complaint Program/Assignment Code (PAC) for any complaints covered during the investigation. Refer to the PAC Master List for the appropriate PAC.

If a sample is collected during a domestic consumer complaint follow-up investigation, the sample number is linked to the OP13 in eNSpect by entering the sample number under the “Details” page in eNSpect. In addition, an OP31 (Sample Collection) with a collection report containing all relevant information will be completed. If the primary response to the complaint is collection of a sample and no further investigation, no assignment (OP13 or Op12) is generally created for completion in eNSpect. In this case all relevant documents would be included with the OP31 collection report. If unsure of what operation to enter in eNSpect and/or FACTS, consult with your supervisor.

#### **8.1.9.4 - Reporting information obtained from a confidential informant**

During an investigation, inspection, or other operation, you may acquire information from a confidential informant. See IOM 5.2.9 for information on how to interview confidential informants and document information obtained from them. Information received from a confidential informant during an investigation should be captured in an investigation memo as an attachment to the OP13/OP15. See IOM 5.2.9.2 for suggestions on how to protect the identity of the confidential informant when writing your investigation memo. Information contained within an OP13/OP15 is outside the scope of FMD-145 (Release of the Establishment Inspection Report (EIR) and should be reviewed by FOIA personnel for appropriate action before release.

If during an inspection you interview a confidential informant or whistleblower, do not include any identifiable information in the EIR and prepare a separate memo of investigation to cover this part of the inspection. Enter as an OP 13 or OP 15. See 5.2.9.2.

#### **8.1.9.5 - Reporting investigations conducted during disaster response**

There is no prescribed format for narrative reporting of disaster operations. Consult with your supervisor as to your division's preference. If operations were conducted as an investigation, you will likely write an investigation memo to document the activities. The memo should briefly describe

the onset of the disaster, its magnitude, and your activities. Include cooperation with officials, planning operations, and the logical sequence of your activities.

Your memo must contain exhibits consisting of photographs, diagrams, records, references to samples, and any other items necessary for proper presentation of the operation. Refer to RPM Chapter 8 "Emergency Procedures," for guidance on reporting natural disasters and civil disorders. List amounts of materials or products destroyed and the method of destruction. Prepare charts and lists as necessary to provide documentation of all affected lots destroyed, reconditioned, or released. Include kinds and amounts of materials segregated, released, reconditioned, and destroyed and method of reconditioning and/or destruction.

In situations where an ICS structure has been implemented, operations are reported through the IMT and use of ICS forms, situation reports, after-action reports, or other documents as appropriate to the operation. The IMT will direct you on reporting your time spent working on the operation. If a sample of an FDA-regulated product is collected as part of the disaster response under ICS, an OP31 (Sample Collection) with a collection report containing all relevant information will usually be completed. In this case, your time spent conducting the sample collection would be reported in FACTS as part of the OP31 and using the PAC appropriate for the assignment.

## 8.2 - Human and Animal Food Investigations

### 8.2.1 - Coordination

The initial step in coordination of a human and animal food investigation is notification of the potential incident. Notification to FDA may be received from SLTT officials via the district ERC or divisional staff; consumer complaints or adverse event reporting portals; or from federal entities such as the Centers for Disease Control and Prevention (CDC) alerting the FDA of illness clusters. Regardless of the source, once a potential incident is identified, the district ERC (DERC) is the primary point of contact (POC) for coordination of the response at the field level. (See Communications SOP for ERCs)

If agency-level central coordination is needed, CORE or CVM will most often provide management of the incident based on whether human or animal foods are suspected. However, there are instances when food incidents may be coordinated by OEM or a CFSAN office based on the specific commodity and scope of incident. (See Exhibit 4 for the "Table Depicting Incident Coordination Body by Type of Incident.")

### 8.2.2 - Foodborne Illness Outbreak Investigations

#### 8.2.2.1 - Cooperation with Other Agencies

One of FDA's functions is to assist SLTT and other federal agencies in conducting investigations, collecting samples, and conducting firm inspections if warranted.

In addition to state and local health departments, the following federal agencies may also become involved in investigating foodborne disease outbreaks:

- Centers for Disease Control and Prevention (CDC)
- U.S. Department of Agriculture (USDA)
- Environmental Protection Agency (EPA)

CDC becomes involved in foodborne outbreaks when people in more than one state are sick with the same germ from contaminated food. Their role involves coordinating the epidemiologic investigation, including identifying illnesses. CDC works directly with CORE to provide epidemiological information to help identify a possible food vehicle and focus the scope of FDA's investigation. During an outbreak, CORE and CDC coordinate with internal and external partners (including international governments) to help determine the outbreak source and prevent future illness.

USDA is responsible for investigating outbreaks involving meat and poultry products under their jurisdiction. Whenever a complaint is received involving any meat-containing product, including such items as soups, combination infant foods, frozen dinners, etc., evaluate the need to contact USDA. Most products containing red meat or poultry are regulated by USDA. The exceptions include:

- products containing meat from game animals, such as venison, rabbits, etc.
- meat-flavored instant noodles
- "pork and beans" (which contains only a small amount of pork fat and is regulated by FDA)
- Closed face sandwiches



USDA-regulated products display on their labels a round "shield" with the USDA Establishment Number. Alternatively, the establishment number may be identified in the lot number. Red meat products under USDA jurisdiction will often contain the abbreviation "EST" followed by a one to four-digit number; poultry products under USDA jurisdiction will contain the letter "P" followed by a number.

IOM 3.2.1 and 3.2.4.3 provide information for reporting suspected outbreaks to USDA and CDC. In addition, FDA and CDC have an agreement that FDA will be immediately advised whenever CDC ships botulism antitoxin anywhere in the United States or its possessions.

Whenever a water source is suspected as a likely origin of the agent of an illness outbreak, the EPA should be notified. For example, when investigating a foodborne outbreak on a vessel passenger conveyance, you may find the water used in food preparation to be from a land-based source or from an on-board water treatment plant. Both of these sources would fall under EPA jurisdiction. See IOM 3.2.11.

When two or more people get the same illness from the same contaminated food or drink, the event is called a foodborne illness outbreak. For more information related to foodborne illnesses, please refer to <https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks-foodborne-illness>

### 8.2.2.2 - Outbreaks on Foreign Flag Vessels

If a suspect outbreak involving a foreign flag vessel or a U.S. flag vessel with an international itinerary comes to your attention, report it to your supervisor and the district ERC immediately. The district ERC will provide the information to OEM/OEO. The CDC assumes primary jurisdiction for foreign flag (non-U.S. registry) and U.S. flag vessels with international itineraries entering the U.S. and traveling in U.S. waters. See IOM 3.2.4.3.

### 8.2.2.3 - Outbreaks Involving Interstate Conveyances

Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are a shared responsibility of FDA, CDC, USDA, EPA, and potentially others. When a report of illness is received, notify the district ERC in your division/district. The ERC will contact the CORE Signals Team at [CORESignalsTeam@fda.hhs.gov](mailto:CORESignalsTeam@fda.hhs.gov). Please include the CFSAN Office of Food Safety Interstate Travel on any email correspondence (Glenda.Lewis@fda.hhs.gov). In addition, you are encouraged to share the report with state and local public health officials. The following activities are to be coordinated with local/state public health officials: Interviews with the ill passenger(s), family members (well and ill), caregivers, and/or health professional (as appropriate) should be sufficiently probative to hypothesize if the food, water, or an environmental transmission is related to the illness. Transmission of illnesses, particularly viral diseases, by ill employees and contaminated environmental surfaces can result in illness carryover between successive trips and should be considered. Factors such as symptoms, time of onset of symptoms, food history for the 72 hours prior to onset of the first symptom, any clinical laboratory results, and other potential exposures should be documented. The carrier should also be contacted to determine if other reports of illness have been received (passengers and employees). Obtain any illness logs from the carrier. The

information developed should be evaluated to determine if further follow-up is necessary. On those carriers where a reservation system is used, obtain the names and phone numbers of passengers, and a passenger manifest, if available. If a reservation system is used, then a passenger manifest should also be available. A manifest will provide passenger seating, which will help identify additional cases based on proximity or in the event of an etiological agent like Norovirus, the passengers who occupy the seat on the next flight could also be at risk of infection. It may be necessary for the state/local health authorities, CDC or FDA to contact other passengers to determine if they became ill.

If additional cases are uncovered during these contacts, immediately notify the appropriate ERC in your division who will then contact the CORE Signals Team at [CORESignalsTeam@fda.hhs.gov](mailto:CORESignalsTeam@fda.hhs.gov) and the state and local public health authorities in all of the affected states. FDA will work cooperatively with these authorities and request their assistance in conducting an epidemiological investigation and collecting patient specimens. Note: If at any time the local/state public health officials are unable to assist with an investigation, have the district ERC notify CORE Signals Team at [CORESignalsTeam@fda.hhs.gov](mailto:CORESignalsTeam@fda.hhs.gov) who will contact the CDC and request assistance with the epidemiological investigation.

#### 8.2.2.4 - Outbreak Management

CORE coordinates FDA's efforts to prevent, detect, investigate, respond to, evaluate and apply lessons learned from foodborne outbreaks and public health incidents. Along with ORA, CFSAN subject matter experts (SME), and others in FDA, CORE manages the strategy and implementation of outbreak response activities and evaluates environmental, epidemiologic, and laboratory data to inform assignments and direction of outbreak investigations related to foods, cosmetics, and dietary supplements. ORA's primary role in the outbreak investigation is to perform activities related to tracing food from source to destination; food and environmental sample collection and analysis; and facility investigations.

If you become aware of a foodborne outbreak, contact the appropriate district ERC immediately who will then contact the CORE Signals Team at [CORESignalsTeam@fda.hhs.gov](mailto:CORESignalsTeam@fda.hhs.gov).

#### 8.2.2.5 - Conducting Foodborne Illness Follow-up

A priority for all foodborne illness investigations is to establish the basis for implementing control measures to stop transmission and prevent additional illnesses.

CDC is the federal agency with primary responsibility for investigating large, multi-state foodborne illness outbreaks. FDA plays a role in outbreak response generally by collecting samples, obtaining traceback information, and conducting food establishment inspections. CDC guidance for investigating foodborne illness is available at [Investigating Outbreaks \(https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/index.html\)](https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/index.html). SLTT generally conducts small, local foodborne illness outbreaks using generally the same process. In FDA, CORE guides investigations into the cause of foodborne illness outbreaks after notification from CDC that an outbreak is ongoing.

A resource for conducting epidemiological investigations is the [Council to Improve Foodborne Outbreak Response](https://cifor.us/) (CIPHOR). Its website (<https://cifor.us/>) has many resources available to aid during an epidemiological investigation.

If you receive a report of a foodborne illness or an outbreak provide details to your district ERC and determine the extent of investigation you need to conduct. If you are required to respond to a foodborne illness outbreak use the following as guidance.

#### *8.2.2.5.1 - Preparation*

Divisions should maintain enough supplies of equipment used for sampling during a foodborne illness investigation. Assure all sterile supplies are within expiry. It is important that swabbing materials be monitored and utilized in a first in, first out manner to prevent the expiry of supplies.

#### *8.2.2.5.2 - Interviews*

Reports of foodborne illness can come from many sources, such as:

- Laboratories
- Hospital-based laboratories
- Clinical laboratories
- National or regional commercial referral laboratories
- Local or state health department laboratories
- CDC laboratories
- Health care institutions
- Hospitals (e.g., hospitalized patients reported by infection control practitioners)
- Emergency departments
- Long-term-care facilities or nursing homes
- Physicians
- Schools and childcare centers
- Food establishments (e.g., restaurants)
- State health departments

Regardless of the source of the report, the diagnosis must be verified by a thorough case history and, if possible, by examination of appropriate food samples and clinical specimens.

##### *8.2.2.5.2.1 - Conducting Interviews*

Normally, conducting foodborne illness interviews is not a role CSOs will perform since food history/symptoms are typically gathered by CDC and/or SLTT partners. Follow the guidelines upon contacting the affected person in the General Interview section (Section 8.1.6.1) of this chapter and the following:

- Identify yourself and explain the purpose of the visit or call.
- Ensure confidentiality.
- Conduct interviews in a private location.
- Be non-judgmental.
- Show empathy and attempt to build rapport with the interviewee.

- Exhibit genuine concern for persons affected and be sincere and respectful when requesting personal and confidential information.
- Set your level of communication based on the person being interviewed.
- Be tactful. People are sometimes sensitive to questions about age, gender, special dietary habits, ethnic group, excreta disposal, and housing conditions. Phrase questions thoughtfully.
- While keeping the interview as conversational and as natural as possible, communicate a sense of urgency and emphasize the positive contribution already made by the interviewee toward the control and prevention of foodborne illness.
- Use open-ended questions.
- Phrase your questions so the interviewee(s) will describe their illness and the foods and events which they feel are associated.
- Accurately record what interviewees say.
- Gently redirect, as needed.
- Probe if answers are vague, particularly about time of symptom onset.
- Asking references may help their memory, for example, “What did you do prior to eating lunch?”
- Work with epidemiology staff to provide language interpretation, if needed.
- Thank interviewee at closing and explain how the information will be used.

#### 8.2.2.5.2.2 - Information to Gather

Targeted, effective and pertinent information gathering is critical in a foodborne illness outbreak investigation. Per the CDC: Health officials use three types of data to generate hypotheses about the likely source of an outbreak: [epidemiologic, traceback, and food and environmental testing](#). Investigators begin by trying to pinpoint how the pathogen spread. They review details such as:

- The specific pathogen causing illness
- Where sick people live
- How old they are, their sex, and race/ethnicity
- Did they have contact with a sick person

When a contaminated food is suspected, investigators must consider many different foods that may be causing the illness. Interviews help to establish a list of foods people ate before getting sick and collect information on other exposures such as restaurants where the ill person ate and stores where they bought food. This list is used to help investigators determine what food or ingredients the sick individuals may have in common.

Consult with management, ERCs, CFSAN, SMEs, state liaisons, state partners, FDA, CORE, and others involved in the outbreak, as necessary, to determine what information is needed from the interviewee(s). Interview topics can include:

- Interviewee information
- Clinical information
- A standard list of food items

- Each meal a person ate before becoming ill and all meals and snacks eaten seventy-two hours before onset of illness. The food, even the meal, which precipitated the illness, might not be obvious and the type of illness will sometimes provide clues:
  - If the first and predominant symptoms are nausea and vomiting, concentrate questions on foods eaten recently.
  - If the first and predominant symptoms are diarrhea and abdominal cramps, foods eaten six to twenty hours before onset of illness are suspect.
  - If diarrhea, chills and fever predominate, foods eaten twelve to seventy-two hours before onset of illness are suspect.
  - More unusual illnesses often present different clinical patterns. For instance, some illnesses such as Typhoid Fever and Hepatitis A, have incubation periods greater than 72 hours.
- Food allergies, special diets, vitamins, and supplements
- Sources of food at home/outside of the home
- Animal contact and pets
- Specific food categories
- Food shopping habits
- Travel
- Restaurant dining
- Attendance at events where food was served

Although some may not have been ill, use this detailed interview approach with each individual identified in the initial complaint or alert, until there is sufficient information to determine the scope and source of the foodborne illness outbreak.

#### *8.2.2.5.3 - Medical Records*

Physicians' and hospitals' records can be useful in verifying reported signs, symptoms and other clinical data and can sometimes rule out the possibility of foodborne illness. See General Section on Medical Records (Section 8.1.6.2).

#### *8.2.2.5.4 - Sampling Procedures*

**CAUTION:** Never taste any of the food products. Handle all samples with caution to prevent accidental exposure to and/or ingestion of even minute amounts of the contaminated or suspect product.



##### **8.2.2.5.4.1 - Sample Collection**

During investigations of foodborne illnesses, cooperate with other public health officials in collecting samples of items that may be associated with the outbreak.

Use interview information and a menu or data from an attack-rate table to determine which of the foods from the implicated meal are most suspect and collect samples of the suspect foods. Check storage areas for items that may have been overlooked. Check garbage for discarded foods or containers. Suspect foods often are discarded by an operator if he thinks someone may have become ill as a result of eating in his establishment. Because one of the primary tasks of the investigator is to prevent further illness, take appropriate action to

prevent distribution or serving of any suspect food. If no foods remain from the suspect meal or lot, try to collect samples of items prepared in a similar manner, but subsequently to the suspect lot. Collect ingredients or raw items used in the suspect food. Determine supplier, distribution, and code information on ingredients and packaged foods to aid any investigation of the same lot in distribution channels.

Collect samples aseptically. If foods are to be examined for organophosphate pesticides or heavy metals, do not use plastic containers. Use glass jars with foil-lined lids because substances from the plastic can leach into the food and interfere with analysis.

The following are examples of articles normally collected:

- Remaining portions of all suspect foods.
- Parent stocks of suspect foods.
- Insecticides, rodenticides, or other poisons which may be involved.
- Suspect food containers such as cans, bottles, etc.
- Utensils or materials used in the preparation and storage of the suspect food.
- Table scrapings and food residues from equipment such as slicing machines, cutting boards, etc.

NOTE: Clinical specimens such as vomitus, stools, swabs of nasal and throat passages, or open sores or lesions of food workers are collected by local, state, or CDC health officials or private physicians. Do not collect these samples.

#### 8.2.2.5.4.2 - Sample Size

In general, follow the IOM SAMPLE SCHEDULE in Charts 1, 2, and 3 (IOM, Chapter 4). Where only small amounts of items remain, such as partial meals/leftovers, empty containers with adhering particles, etc., collect all or as much as possible by scraping from utensils, equipment, or containers. It may also be necessary to collect the empty containers.

#### 8.2.2.5.4.3 - Sample Handling

Record the temperature of the room, refrigerator, or warmer in which the food was stored, and the temperature of the food that remains after a sample is collected.

Inform the laboratory of the type and number of samples. Discuss methods to preserve and transport samples, time of arrival, and the person who will receive the shipment.

Follow guidance in Chapter 4 for collecting, handling, and shipping samples. See IOM 4.5.5.8.6.

If the suspect food is a commercial product, examine the original package or container for coding information to identify the place and time of processing. Your division may notify all agencies responsible for regulating the products alleged or suspected to have caused the illness. Collect additional packages bearing the same code number for analyses for microorganisms, toxins, seam defects, vacuum, leaks, or other conditions. Be as specific as possible in requesting the type of analysis.

### *8.2.2.5.5 - Establishment Investigation*

After a foodborne illness outbreak is reported and an investigation is initiated, the initial impact of the incident can create confusion at the facility and could result in conflicting information if too many entities become involved.

The responsibility for investigating foodborne illness outbreaks rests on a core team of people who each contribute different knowledge and skills. For FDA-initiated investigations/inspections, one FDA investigator should be designated as the inspection team leader. The team leader will set and enforce priorities, coordinate all activities associated with the investigation, serve as the point of contact about the investigation, communicate with other organizations involved in the investigation and communicate the recommended course of action determined by team to ORA management. A supervisor and/or ERC should be the coordinator for overall division activities and the division contact for headquarters personnel. All communications from FDA field or other offices to the firm's management should be channeled through the supervisor/ERC. The lead investigator should be responsible for all phases of the physical inspection of the facilities and briefing the supervisor about team progress. See IOM 5.1.2.5.2.

Upon arrival at the establishment where the suspect food was processed or prepared, identify yourself to the person in charge and state the purpose of your visit. Emphasize the purpose of the investigation is to determine what contributed to the outbreak, so preventive measures can be taken. Attempt to create a spirit of cooperation. Consider the position, feelings, and concerns of the manager and facility staff; defensive reactions are common.

Many factors could have contributed to contamination before foods came under the control of the manager. Assure him these possibilities will also be investigated. Inform the manager of the activities proposed.

Review of distribution records and examination of warehouse stock are two important aspects of a foodborne illness follow-up inspection. Field examination should include an inventory by code of all stock on hand. When conducting field examinations, follow instructions in IOM Sample Schedule Chart 2 (IOM, Chapter 4).

#### **8.2.2.5.5.1- Food Handlers Interviews**

If a food is already suspect, interview separately all persons who were directly involved in processing, preparing, or storing of the food and others who could have observed preparation and storage. Ask questions in a sequence that discloses the flow of food from the time it was received until it was served or distributed. Especially inquire about foods that were prepared several hours or days before being served with the suspect meal and about foods that have specific temperature requirements. Ask similar questions, suitably modified, of the managers or workers who were involved in producing, transporting, processing, preparing, or storing food at other levels of the food chain, as well as individuals who prepared the food at home.

Food workers who fear criticism or punitive action because of their possible role in the outbreak do not always accurately describe the food handling as it actually happened. Their descriptions should be plausible, account for possible sources of contamination, and

indicate possibilities of survival and potential for growth of pathogens. If the description does not contain all the information desired, rephrase the questions and continue the inquiry. Seek confirmation of one person's story by talking to others who have knowledge of the food operation, or by watching the food preparation or processing practices. Be alert for inconsistencies among the accounts, as told by different individuals.

#### *8.2.2.5.6 - Possible Contamination Source*

It is important to understand the pathogen and the factors that contribute to the contamination that resulted in the foodborne illness. Some pathogens, such as Norovirus, are associated with human fecal contamination, while other pathogens, may be more commonly associated with a particular food source (e.g., raw meat and E. coli O157:H7).

CDC has identified the most common causes of foodborne illness:

- Food from unsafe source.
- Poor personal hygiene.
- Improper food holding temperatures.
- Improper cooking temperatures
- Contaminated equipment or cross-contamination of raw with ready-to-eat foods

You may want to familiarize yourself with Factors that Contribute to Outbreaks of Foodborne Illness (<https://www.cdc.gov/nceh/ehs/news/factors-contribute-to-outbreaks.htm> ) before beginning a foodborne illness investigation.

Exhibit 8-5 ([https://cifor.us/uploads/resources/CIFOR-OUE-Agent-List\\_FINAL.pdf](https://cifor.us/uploads/resources/CIFOR-OUE-Agent-List_FINAL.pdf)) provides details about possible food associations with different illness symptoms, latency and factors that contribute to outbreaks. Although the table lists possible clinical specimens to collect, you should not collect clinical samples. A SLTT health department may be able to assist and collect those samples for analysis at a state laboratory.

#### *8.2.2.5.7 – Conducting Traceback Investigations*

Traceback investigations are important epidemiological tools that are used to determine the source of food implicated in foodborne outbreaks. Traceback investigations may prevent further sale and distribution of contaminated food. Commonly, SLTT agencies conduct the initial epidemiological investigation of foodborne outbreaks and identify suspect product(s) requiring tracebacks.

CORE issues traceback assignments to the appropriate division(s) and coordinate inter-division assignments for traceback investigations. The assignment will generally provide all the guidance needed to conduct the traceback investigation.

Other resources available include:

- the [FDA Guide to Traceback of Fresh Fruits and Vegetables Implicated in Foodborne Outbreaks](#), dated April, 2001
- the Office of Training Education and Development (OTED) training: *ER220: Traceback Investigations*.



## 8.2.2.6 - Reporting

### *8.2.2.6.1 - Reporting Epidemiological Investigations*

Follow the reporting guidance in this chapter to report epidemiological investigations. Promptly submit a complete narrative of the investigation, including references to exhibits, samples, medical records, and laboratory reports. There is no prescribed reporting format, but it should be in a logical order. With the inclusion of investigative memos in eNSpect EIR, eNSpect can be utilized to prepare these memos. See the eNSpect EIR Quick Reference Guide for detailed information. See also IOM 8.10.

Submit copies of any written reports and documents for all injury or illness complaints involving all CFSAN products (see section 8.2 and 8.4.5) using encrypted email, secure fax transmission, or mailing.

If using mail, use this address:

Food and Drug Administration  
CFSAN/OSAS  
CAERS Staff (HFS-700)  
5001 Campus Drive  
College Park, MD 20740  
Attn: CAERS Monitor

Illness/injury complaints involving special nutritional products (refer to IOM 8.2.3.2) must be accompanied by a completed FACTS Adverse Event Questionnaire when forwarded to CFSAN.

If additional follow-up on any complaint involving a CFSAN product is necessary, the Division of Field Program Planning and Evaluation (HFS-635) will issue an assignment.

### *8.2.2.6.2 - Reporting Food Adverse Events*

Prompt reporting is essential. You may save the lives of others with prompt reporting. If consumers contact you to report adverse events including injury, illness, or death related to a human or animal food, dietary supplement, or cosmetic, they should be directed to report through the following online reporting systems. If they do not want to report through those systems, you may report for them.

#### **8.2.2.6.2.1 - Food and Cosmetics**

Details on reporting adverse events related to human food can be found at the CFSAN Adverse Event Reporting System (CAERS) website (<https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers>).

#### **8.2.2.6.2.2 - Dietary Supplements**

Details on reporting adverse events related to dietary supplements can be found at the How to Report a Problem with Dietary Supplements website

(<https://www.fda.gov/food/dietary-supplements/how-report-problem-dietary-supplements>).

#### 8.2.2.6.2.3 - Cosmetics

Details on reporting adverse events can be found at the How to Report a Cosmetic Related Complaint website (<https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint>).

#### 8.2.2.6.2.4 - Veterinary Products

Details on reporting adverse events and complaints for animal food and animal medical products can be found at the CVM Report a Problem website (<https://www.fda.gov/animal-veterinary/safety-health/report-problem>).

#### 8.2.2.6.2.5 - Reports of Criminal Activity

If a consumer calls to report criminal activity, they should be directed to the Report Suspected Criminal Activity website (<https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>).

### 8.2.3 - Injury, Illness, Death

Injury and adverse reaction complaints should receive a prompt, courteous response, and assurance their complaints will receive appropriate consideration. An immediate follow-up should be made when there is an indication of a serious injury or adverse reaction.

When you are investigating injuries or adverse reactions, do not make comments or enter discussions with firms as to the involvement of particular products, unless specifically instructed to do so. Many adverse reactions come to FDA from consumers or health care professionals through the voluntary reporting branch of the MedWatch system. These reports are to be held confidential.

Whenever the press has been informed about a complaint, follow instructions found in Section 1.6.1. When the responsible firm invites the news media to observe the inspectional process, follow instructions found in Section 5.1.4.3.

NOTE: CFSAN Adverse Events Reporting System (CAERS) Staff, HFS-845, 240-402-2405, Fax: 301-436-2452, or email [CAERS@fda.hhs.gov](mailto:CAERS@fda.hhs.gov), can assist with questions pertaining to field follow-up related to foods, seafood, food additives, dietary supplements, infant formulas, and medical foods. CAERS personnel can assist in obtaining guidance from CFSAN's experts.

#### 8.2.3.1 - Procedures

When investigating all injuries and adverse reactions the consumer complaint coordinator will follow *SOP-00045 Consumer Complaint Procedure*.

Once it is determined by program management that follow-up is deemed necessary, an assignment will be created and assigned to a CSO, who will then fill out the Follow-up Consumer Compliant Report in FACTS.

The following should be addressed and confirmed during a follow up investigation with the complainant.

- Details on the product involved, including brand name, product labeling, and any codes including lot, expiry, and/or use by codes.
- The source of the product. Where did the consumer obtain it?
- Details of how the product was used, including frequency, in what amounts, any known previous adverse reactions or pre-existing allergies and whether anyone else used the product in the household.
- If appropriate, determine if label directions were followed.
- Copies of all labeling/inserts.
- Any research the complainant may have conducted or relied upon and collect copies or internet web addresses.
- Complete description of the incident (sequence of events) and the nature of the injury or adverse reaction, including date, time, location, and symptoms or description of injury.
  - Any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury or adverse reaction.
  - Photographs of the victim's injuries, if significant. See Section on Medical Records.
- List names of other persons involved, such as beauty salon operators, medical personnel, lawyers, insurance agents. Obtain their views on the injury or adverse reaction. The views of an attending physician are important because they may vary markedly from those of the patient.
- Determine if the consumer reported the adverse reaction to the manufacturer and the manufacturer's response.
- Any other consumer complaints, injuries or alleged adverse reactions reported to the manufacturer concerning the product.
- If necessary, obtain distribution information of the implicated lot(s) from the manufacturer.

### 8.2.3.2 - Specific Product Reporting (Food, Dietary Supplement, and Cosmetic – Injury or Reaction)

#### *8.2.3.2.1 - Dietary Supplements*

It is extremely important that FDA conducts appropriate investigations and follow-up on adverse events attributed to dietary supplement products. DSHEA removed dietary supplement and ingredients from food additive regulations and therefore it is the agency's burden to prove them unsafe. An important source of information concerning potentially unsafe dietary supplements and ingredients is consumer complaints.

Injuries or other adverse reactions may be associated with the use of products which:

- Vary from the declared potency or concentration.

- Contain deleterious substances accidentally included in manufacturing.
- Have changed composition or become contaminated after shipment.
- Are mislabeled as to identity warnings or instructions for use.
- Have not been used according to label instructions or the directions of the manufacturer or prescriber.
- Are dangerous when used according to directions.

When investigating adverse events attributed to dietary supplements, direct attention to, and document:

- Details on the product involved, including lot codes and expiration dates.
- Source of the supplement. Where did the consumer obtain it?
- Details on the consumer's use of the product including frequency, dose used, concomitant treatments, and whether administered by the user or someone else.
- Details on the directions of use provided with the product or otherwise (on the web or from a practitioner). Obtain copies of labeling and any additional information concerning use of the product by the consumer.
- Nature of the injury. Include any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury. Obtain photographs of the victim's injuries, if significant. See IOM 8.1.6.2 for the procedures used to obtain medical records.
- Names of other persons involved, such as medical personnel, lawyers, insurance agents, etc. Obtain their views on the injury. The views of the attending physician are important because they may vary markedly from those of the patient.
- Complete description of the incident (sequence of events) and the nature of the injury or adverse reaction, including date, time, location and symptoms or description of injury.
- Any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury or adverse reaction.

Photographs of the victim's injuries, if significant. See Section on Medical Records

#### *8.2.3.2.2 - Cosmetics*

For clarification of the distinction between cosmetics and drugs, refer to the document, "*Is it a cosmetic, a drug or both? (or is it soap?)*" located at <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap>

If you are unsure about a products status you may contact the Office of Cosmetics and Colors at (240) 402-1130.

#### **8.2.3.2.2.1 - Causes**

Injuries or adverse reactions may arise from cosmetics which:

- Are inherently dangerous or which may prove harmful or injurious to a consumer.
- Cause primary irritation of skin, eye, or mucous membranes (including the lungs and urinary tract) or which may be due to an individual sensitization reaction or allergic response, or due to ingestion.

- Have undergone formulation changes or been chemically or microbiologically contaminated while in the possession of the manufacturer, dealer, distributor, or end user.
- Are misbranded because they contain unlisted ingredients, lack instructions for safe use for certain high-risk products (e.g., depilatories, hair dyes), or lack any required warning statements.
- Have been misused.

#### *8.2.3.2.3 - Investigation Requirements for Serious Adverse Events of CFSAN Regulated Products*

If the suspect product is a cosmetic, interview the injured person and/or the reporter of the event and complete the FACTS Consumer Complaint Cosmetic Report. If the suspect product is not a cosmetic, interview the injured person and/or the reporter of the event and complete the FACTS Adverse Event Questionnaire.

If the suspect product is an infant formula or baby food, immediately inform OEM/OEO at 866-300-4374 or [Emergency.Operations@fda.hhs.gov](mailto:Emergency.Operations@fda.hhs.gov) and investigate on a high-priority basis due to the continued sensitivity to these incidents. This will include follow-up with the doctor or hospital, sample collection, and analysis of appropriate product. Refer complaints involving baby food regulated by USDA for appropriate follow-up. See IOM 8.1.8.1 and 3.2.1.2.

Obtain Medical Records as described in Section 8.1.6.2.

If the adverse event is a death, the following medical records should be considered for collection:

- Admission history and physical or emergency room/clinic record of the event if the patient was not admitted
- Discharge Summary
- Autopsy Report
- Death Certificate

If you believe a suspect product should be sampled, discuss with your supervisor.

For all events, a memo of investigation will be completed. Send a complete copy, including copies of all labels and labeling, Medical Records Letter [IOM Exhibit 8-4] and medical records collected to the CAERS Staff.

#### *8.2.3.2.4- Undeclared Allergen/Allergic Reactions*

Suspected undeclared allergen complaints should receive high priority. Undeclared allergens in food products often result in recalls.

The following should be addressed and confirmed during a follow-up investigation with the complainant:

- List all the complainant's food allergies.

- List all foods consumed within approximately an hour prior to reaction.
- Amount of suspect food consumed.
- Time of on-set.
- Specific symptoms experienced and the order they occurred.
- Medical or other treatment received.
- The ingredient statement from product packaging.
- Any label statement related to a “may contain” statement and record the statement.

Inspectional follow up at the manufacturing plant may be warranted to determine if suspect allergen is added to the product; or if the possibility of cross-contact exists.

### 8.2.3.3 - Veterinary Products-Complaints/Adverse Reactions

If you become aware of human illnesses associated with CVM-regulated products, contact the appropriate ERC in your division and/or regional office immediately who will then contact the CORE Signals Team at [CORESignalsTeam@fda.hhs.gov](mailto:CORESignalsTeam@fda.hhs.gov).

Investigations of complaints of animal food, both medicated and non-medicated, should be investigated like other complaints. Discuss any investigation with your supervisor. The CVM Office of Compliance can be consulted concerning appropriate follow-up and sample collection related to complaints.

### 8.2.3.4 - Sample Collection

When directed to collect a sample, collect the product which appears to have caused the injury and an official sample from both the same and other lot codes, if available. Check with your supervisor if you have any doubt as to the appropriateness of collecting a sample related to an investigation. See IOM 4.5.5.3 for routing of injury and complaint samples to the laboratory.

#### *8.2.3.4.1 - Cosmetic Samples*

Many cosmetic products such as permanent hair dyes, home permanents, deodorants, hair straighteners, etc. are known to cause adverse reactions. Samples of these products should not be collected except in cases of alleged severe or unusual injury (e.g., multiple complaints). In cases of obvious allergic type reactions, samples should not be collected. For example, most cosmetic products which get into the eye will cause temporary eye irritation and, in such cases, a sample generally should not be collected.

#### *8.2.3.4.2 - Microbiological Contamination*

Collect samples associated with consumer complaints in which microbiological contamination is suspected.

#### *8.2.3.4.3 - Allergen Samples*

Collect a sample if the allergen is visible (i.e., nuts,) is not declared on the label, and if deemed necessary by division management. In all other cases, collect a sample only after consultation with OEM/OEO (e.g., national consumer complaint coordinator) and CFSAN. See IOM Sample

Schedule Chart 13 for guidance on sample size. Note: the sample size may be modified depending on product availability.

### 8.2.4 - Special Events

Special Events (SEs) are organized, pre-planned mass gatherings of national or international importance that usually garner significant media coverage and are typically attended by dignitaries or public personalities. The venues for these events are frequently stadiums, arenas, convention centers, and hotels which contain retail food establishments that are under the jurisdiction of state and local agencies. SLTTs, United States Secret Service (USSS), or the event organizer may request FDA assistance. You may be requested to investigate food suppliers to the SE to verify compliance with regulations. This investigation, referred to as a Supply Chain Integrity Check (SCIC), may be performed onsite or through an online record review. The SCIC entails a review of a firm's inspectional and compliance history, including recalls, Reportable Food Registry (RFR) and whether the firm has been involved in a CORE investigation. (See IOM Chapter 3.2.5.2.9 for full details on SEs)

### 8.2.5 - Farm Investigations

A farm investigation of a raw agricultural commodity (RAC) may be conducted in response to traceback information obtained during a foodborne illness outbreak investigation that implicates one or more farms, ranches, packing houses, or other such operations as being involved in handling the outbreak suspect RAC. Generally, CORE would request a domestic farm investigation through the district ERC for the responsible ORA Human and Animal Food (HAF) program division office. HAF program division offices may also initiate or be assigned by CFSAN or ORA/OHAFO to perform a farm investigation as needed to protect public health. The goals of a farm investigation are to gather information, to identify potential environmental sources of the outbreak agent, to identify routes of contamination from potential outbreak agent sources to the implicated RAC, to observe and document potential contributing factors to the outbreak such as practices, procedures, or conditions that may facilitate proliferation, spread, growth, survival, or contamination by the outbreak agent, and to support regulatory action, if appropriate.

#### *8.2.5.1 - Approach*

A team approach is utilized for a farm investigation (see IOM 5.1.2.5 Team Investigations). A lead CSO should be identified from the Produce Safety Network (PSN) or the responsible HAF division office that has attended both the FD226 Produce Inspections for Regulators Course, and the FD326 Produce and Sprout Investigations for Regulators Course. A minimum of three team members should participate and ideally all members should have produce farm training and/or produce farm inspection experience. The appropriate state regulatory agency having jurisdiction over produce farms should be notified and invited to participate. Additional SMEs may be added to provide needed expertise such as wildlife, soils, agricultural water, or epidemiology. CORE, CFSAN Produce Safety Staff, and/or ORA HQ may assist with identifying appropriate SMEs and providing technical guidance during the investigation.

The implicated grower should be notified in advance of the investigation as he/she or a representative of the grower will need to be present to provide information to assist the investigation. Generally, an FDA 482 will be issued to the grower or packing house, if different. If the

investigation expands to fields not owned by the grower, a new 482 must be issued to those growers. Please see IOM 5.1.3.5 Team Investigations for additional information. CORE has implemented formalized outbreak incident operation processes. The CORE operation guides are available through the [inside.FDA.gov](https://www.fda.gov) website.

#### ***8.2.5.2 - Sampling***

A variety of environmental samples may be collected during a farm investigation, including environmental swabs and water from both the field and the packing house, and soil and wildlife scat samples from the growing environment. Do not collect human fecal matter unless specifically assigned or pre-approved to do so. In general, FDA laboratories are not prepared to receive human feces.

Instructions for collecting soil and water samples on farm investigations are found in IOM Ch. 4, in the Salmonella Sample Schedule Chart 1, and are also covered in FD326 (Produce and Sprout Investigations for Regulators Training Course). Additional sampling guidance can be found in ORA Field Bulletin #30; Food Program Area Instructions for Environmental Sampling, and ORA Outbreak Response Field Guide #1 covering E. coli, Listeria, and Salmonella inspections and investigations at sprout operations. Specific sample collection instructions or methods may also be included in the CORE farm investigation assignment.

All environmental samples are investigational. Use the product code builder to identify the proper code for the type of environmental sample collected, including swabs, soil, water, and animal scat. Do not use the product code of the implicated produce for environmental samples. Produce samples collected from the field or prior to packing (i.e., not finished product) are labeled as investigational. Product that has completed processing on the packing line are labeled official product samples.

#### ***8.2.5.3 - Form 3623 Farm Investigation Questionnaire***

FDA Form 3623, the Farm Investigation Questionnaire (FIQ), must be completed for all farm investigations, as covered in FD3263. Some portions may not be applicable, such as the use of biosolids. These questions may be marked as N/A. However, questions for practices that may be used but are not currently in use should be completed by use of interview techniques with the grower to the extent possible. The FIQ should be completed on-site to ensure all information is collected and submitted to CORE and/or the CFSAN Produce Safety Staff if requested and included in the Investigation Memo or EIR as an attachment. To avoid duplication, the FIQ may be used to provide information under the “Manufacturing Processes” section by either reference or cutting and pasting into that section. A short summary and flow diagram(s) describing the steps from planting through harvesting and/or packing should be included along with this.

#### ***8.2.5.4 - Reporting***

Domestic outbreak work assignments will be designated in FACTS as either an operation 12 inspection (OP12) or an operation 13 investigation (OP13). Foreign outbreak work assignments will be designated in FACTS as either an operation 11 inspection or an operation 15 investigation.



For FACTS operation 11 or 12 farm inspections see Chapter 5 for reporting; however, if an outbreak is ongoing and the information is needed immediately, it may be necessary to prepare a separate memo to submit to CORE prior to completing the EIR.

For FACTS operation 13 or 15 investigations, follow reporting guidance in this chapter.

### 8.2.6 - Infant Formula and Baby Food

There is a continued sensitivity to all reported incidents involving infant formula and baby food. All complaints involving either infant formula or baby food are to be thoroughly investigated on a high-priority basis. This includes with the consumer, inspection of the manufacturer, and with the doctor or hospital if appropriate. Samples should be collected as part of the follow-up. Complaints involving baby food regulated by USDA should be referred to USDA for appropriate follow-up. See IOM 3.2.1.2. There are two exceptions for collecting samples as part of the follow-up to infant formula/baby food complaints. Do not collect samples unless direct for:

- Complaints involving outdated product in the marketplace with no associated injury or illness only require investigation to ensure all outdated product has been removed from the identified retail and/or wholesale source.
- Complaints involving an illness associated with normal appearing product when the follow-up investigation discloses that the event does not appear to be product related or was an allergic response to a properly labeled product per a physician's diagnosis.

### 8.2.7 - Tampering Involving Alcoholic Beverages

All tampering complaints involving alcoholic beverages should be entered as a consumer complaint in FACTS. OEM/OEO and OCI should be notified immediately. OEM/OEO can be notified by e-mail at [emergency.operations@fda.hhs.gov](mailto:emergency.operations@fda.hhs.gov) and by phone 24 hours a day at 1 (866) 300-4374.

For all other complaints involving alcoholic beverages, please see IOM 3.2.8.1 for guidance.

## 8.3- Drug Investigations

### 8.3.1 - Investigations Coordination

The following procedures should be followed for investigating suspected adverse drug reactions, including drug-induced birth defects:

- If you are interviewing the consumer, conduct the normal complaint investigation and gather all pertinent information regarding the product, patient, adverse event, etc. If the consumer received medical treatment, obtain a medical records release (Exhibit 8-5). Reporting of drug adverse experiences is voluntary and you should encourage and assist complainants and health care providers to complete the MedWatch form (FDA 3500) (see Exhibit 8-10) and submit to MedWatch. Report your findings in the FACTS Consumer Complaint follow-up screens and in a memo of investigation.
- If you are investigating an adverse reaction at the manufacturer, conduct your investigation to determine whether the adverse event was caused by a drug quality defect. Determine if the manufacturer was aware of the complaint, has investigated, and per IOM 5.5.7 Adverse Event Reporting has submitted the reportable event to FDA. For additional information regarding DQRS (MedWatch Reports) and NDA FARS (New Drug Application Field Alert Report) see the applicable compliance program in the Compliance Program Guidance Manual (CPGM). Determine if the manufacturer is aware of any similar reported events. Collect current labeling of the product to determine whether this was an expected or unexpected adverse event. Your findings will be reported through the FACTS Consumer Complaint follow-up screens and a memo of investigation or EIR.
- You may also be directed to conduct investigations at other establishments, such as pharmacies, doctors' offices, or distributors. Conduct your normal complaint investigation determining each party's role and involvement. If individuals interviewed are not required to report adverse drug reactions, encourage and assist them to complete and submit the FDA 3500 form to MedWatch.

In all cases of suspect drug-induced adverse reactions, the center will review the information on the FDA 3500 form and will issue assignments to the field if additional information is needed.

### 8.3.2 - Illness/Injury

Drug injuries or reactions, either human or veterinary, result from the use of products which may:

- Vary markedly from declared potency.
- Contain deleterious substances.
- Be mislabeled as to identity, warnings, or instructions.
- Have been mistaken for other drugs despite proper labeling.
- Have changed composition or become contaminated after shipment.
- Be dangerous when used according to directions.
- Have not been used in accordance with label directions or directions from the prescriber.
- Have been improperly administered or administered without the necessary precautions.
- Have been contaminated with objectionable microorganisms, soaps, or cleaning solutions.
- Have been misidentified.
- Be labeled as sterile drugs but are found to be non-sterile.

- Have adverse effects that were not identified prior to marketing.

### 8.3.2.1 - Reporting

#### *8.3.2.1.1 - Reporting Forms – Drugs*

Submit drug complaints and injuries to:

MedWatch  
The FDA Medical Products Reporting Program (HFD-410)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857  
Fax Number: 301-827-7241

#### *8.3.2.1.2 - Reporting Forms – Veterinary Products*

Submit veterinary injuries or adverse reaction reports to:

Food and Drug Administration  
Center for Veterinary Medicine  
Division of Surveillance (HFV-210)  
7500 Standish Place  
Rockville, MD 20857

In addition, follow specific reporting instructions as indicated per an assignment

### 8.3.3 - Complaints

The FDA Office of Emergency Management/Office of Emergency Operations (OEM/OEO) HFA-615, 301-796-8240 must be notified immediately of all significant injury, illness, and suspected tampering complaints. This may be accomplished via the checkbox indicated in the FACTS Consumer Complaint.

- Injury/illness complaints
  - Any illness/injury related to infants should be considered significant. These complaints are to be thoroughly investigated on a high-priority basis.
- Complaints and adverse reactions associated with veterinary products including animal drugs, medicated feeds, and medical devices for animals are handled through the FDA CVM Division of Veterinary Product Safety (HFV - 240). Veterinarians, animal owners, and drug manufacturers may report problems to their local FDA district offices or directly to CVM. The division should advise the complainant to complete an FDA 1932a, "Veterinary Drug Adverse Experience, Lack of Effectiveness or Product Defect Report" for drug adverse events associated with unapproved animal and approved human drugs and veterinary devices. For approved animal drugs, the complainant should be instructed to call the manufacturer directly to report the event. Detailed instructions and options for different case scenarios are available at <https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/default.htm>.

For 3-day Field Alert Reports (FAR), drug sponsors now have the option to electronically submit 3-Day field alert reports (FARs) directly to CVM. CVM will receive the electronic 3-Day FAR from the sponsors and will automatically generate and email a .pdf of the FAR with associated attachments to the appropriate district office. Some sponsors may still send the 3-day FAR through the traditional route to

the district office. The district office should email the form and any other attachments to CVM. The drug manufacturer should notify and submit the FAR to their respective district office within three days. The district offices will ask for additional information if necessary and submit the 3-day FAR to the Division of Veterinary Product Safety.

Complaints and adverse reactions associated with animal feeds including pet food products are handled through the Division of Compliance (HFV-230) at CVM. Veterinarians, animal owners, and firms may report pet food problems to consumer complaint coordinators at their FDA district office or OEM/OEO; the district will complete a FACTS Consumer Complaint Report. Pet food reports may also be made directly to CVM using FDA's Safety Reporting Portal. Instructions for stakeholders to report problems associated with pet food products are available at

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/default.htm>. If you become aware of human illnesses associated with CVM-regulated products, contact the appropriate ERC in your division and/or regional office immediately who will then contact the CORE Signals Team at [CORESignalsTeam@fda.hhs.gov](mailto:CORESignalsTeam@fda.hhs.gov).

## 8.4 - Device Investigations

### 8.4.1 - Injury/Illness

The cause of medical device injuries may originate with the manufacturer, operator, user, or from other factors including, but not limited to, the transportation or installation of the device. Additionally, an illness may occur as a result of device specifications not being met, such as a device labeled as sterile not meeting sterility requirements.

Obtain the following information for medical devices:

1. A complete description of the incident (sequence of events) and the injury/illness, including:
  - a. Type, model, serial number and manufacturer of the device, and copies of any labeling for the specific device(s) involved including instructions for use or operations manual(s).
  - b. Details of the alleged incident, including: number of people involved; symptoms, onset time, duration, and outcome; date and time of occurrence; reports of other investigating agencies and their conclusions, (e.g., fire marshal or OSHA reports); similar incidents which may have resulted in injury/illness; and all operational SOPs, written or unwritten.
1. Copies of medical records and/or laboratory records. Use an FDA 461, Authorization for Medical Records Disclosure, IOM Exhibit 8-5, signed by the patient or other authorized person, when obtaining these records.
2. Official cause of death, death certificate, and/or autopsy report, if indicated.
3. Determine if the device malfunctioned, and the cause.
4. The condition of the device at the time of use. Review its maintenance history, including responsibility for maintenance (past and present), special service calls, repairs, whether component warning or safety systems were functional, maintenance records, changes or corrections accomplished just prior to or immediately after the incident, and who performed the activity. An interview with biomedical engineering department personnel may be indicated.
5. Who has access to the device? Determine if individuals using the device are familiar with its operation.
6. The results of any examination or inspection of the device by the hospital or other party to determine the cause of the incident.
7. Whether there are other devices of the same model number or lot number on the premises.

#### 8.4.1.1 - Types of device injuries or illnesses include:

##### *8.4.1.1.1 - Mechanical, Electrical, or Electromechanical Devices*

Injuries caused by mechanical, electrical, or electromechanical devices may result from devices that:

- Do not conform to specifications due to mistreatment (e.g., damage in transit), or failure to comply with good manufacturing practices.
- Malfunction because due to incorrect installation.
- Have not been used in accordance with labeled instructions.
- Have been used/installed with incompatible accessories or parts which are not compatible.

- Have been used under conditions which interfere with their ability to function (e.g., electromagnetic interference (EMI), fluid seepage into electrical circuits, etc.).
- Have been damaged during use, or random failures.
- Have been inadequately designed for intended use (e.g., unstable, poor structural integrity, sharp or pointed surfaces, electrical leakage, etc.).
- Do not contain adequate directions or warnings.
- Are intended to be sterile but are non-sterile.
- Failure or deterioration for any reason.

#### *8.4.1.1.2 - Devices for Implant*

Causes of injuries which may result from implanted devices include those listed in IOM 8.4.1.1.1. The term installation, as used above, does not include implantation. An injury or illness may also result because the materials used in the implant are not biocompatible, thereby causing an adverse tissue reaction and/or deterioration of the implant.

#### *8.4.1.1.3 - In-Vitro Diagnostic Devices*

Certain In Vitro Diagnostics (IVD) are instruments, such as gas chromatographs and automated blood analyzers, and much of the information under IOM 8.4.3.1 is applicable.

Injuries to patients from IVD products may, in many cases, be considered indirect, because they are due to complications resulting from misdiagnosis or delays in patient treatment due to incorrect test results. Examples of IVD failures include false positives, false negatives, and erratic results. Poor performance or failure may be due to poor manufacturing practices or user error.

Manufacturing problems include:

- Process errors and mix-ups (e.g., varying fill in kit components, improper ingredient addition, etc.).
- Labeling does not contain adequate directions or warnings or contains incorrect information.
- Labeling mix-ups.
- Contamination, making the product unusable or causing misdiagnosis.
- User error including failure to follow label directions for use, operator's manual, or other labeling requirements.
- Use of unclean, unmaintained, or improperly calibrated laboratory equipment.
- Improper storage or use of reagents.

## **8.4.2 - Confidential Informants**

FDA may receive external complaints that request their identity to be kept confidential or anonymous. In this case, the complainant's information should not be disclosed in the investigation memorandum or EIR. The complaint should be assessed to determine if it is a non-injury/illness complaint or an injury/illness complaint as this may impact the urgency of the response. An immediate follow-up may be warranted if there is illness, injury, or if directed by higher authority. All information should be obtained

in the least intrusive, yet constructive, manner that allows the investigator to collect the evidence required to evaluate the validity of the complaint to determine if additional action is warranted.

### 8.4.3 - Complaints

FDA may receive information from various sources, such as a consumer, whistleblower, employee, other governmental agency, Congress, or competitor alleging a potential violation of the FD&C Act that must be followed up to confirm the information provided by the complainant. For medical devices, a complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

As with all investigation types, report your findings in a memorandum and include all pertinent information and any attachments collected as evidence to support the complaint. Using eNSpect, create an operation 13, domestic investigation, or operation 15, foreign investigation, and complete all required fields. Upload all labeled attachments and submit for endorsement by your supervisor. Ensure the endorsement section includes verbiage to share the information with the divisional consumer complaint coordinator for appropriate follow-up in FACTS and completion of any other required documents for domestic complaints. If foreign, ensure the center is notified of the investigation and receives a copy of the investigation memorandum and any attachments.

## 8.5 - Biologics Investigations

### 8.5.1 - Illness/Injury

Reactions or symptoms of illness may occur in association with the administration of vaccines and other biological products. The Center for Biologics Evaluation and Research (CBER) is interested in all unexpected clinical responses to a biological product, as well as any expected responses of unusual frequency or severity. In some cases, a reaction or illness could occur because the product may:

- Vary from declared potency.
- Have been contaminated during manufacturing, shipment, or after shipment.
- Be mislabeled.
- Not have been given according to directions.
- Not have been stored under proper conditions.
- Have been provided to the wrong person.
- Contain substances innocuous to most people, but which the recipient is unable to tolerate (e.g., anti-Kidd, anti-Duffy), or contains substances not usually present in such a product which stimulate an adverse response in the recipient (e.g., HLA antibodies).

#### 8.5.1.1 - Reporting

##### *8.5.1.1.1 - Investigation/Reporting*

When a biologics reaction/injury complaint is received by a CSO or consumer complaint coordinator, they should forward the complaint to [ORABIOBiologicsInspectionsPOC@fda.hhs.gov](mailto:ORABIOBiologicsInspectionsPOC@fda.hhs.gov).

All complaints received by the ORA BIO Biologics Inspection POC will be reviewed and upon determination of initial follow-up status sent to the district consumer complaint coordinator to be recorded on the FACTS Consumer Complaint Report. When interviewing the complainant about a biologics complaint /injury, obtain:

- Complete description of the complaint/injury.
- Onset and duration of the reaction/injury.
- Name of product administered, include date and time of administration.
- Manufacturer and lot number of product(s), if available.

At this point, it is generally unnecessary to conduct interviews beyond the complainant, or obtain records, until a preliminary review has been conducted. It is important to rapidly communicate the basic information about the incident, implicated product, lot, license number, manufacturer, and presence of intact units to the ORA BIO Biologics POC email.

Confidential complaints received during an inspection should be captured in a memorandum as an attachment to the EIR. The confidential informant information should not be referenced in the EIR. Any findings related to complaints not involving confidential informants should be documented in the narrative to the EIR. The complaint number for all complaints should be written in the EIR coversheet in eNSpect. Complaint follow-up assignments will be issued in eNSpect as determined by OBPO.



If a complaint related to a vaccine product involves an adverse reaction of any kind, then a Form VAERS-1 (IOM Exhibit 8-6) should be completed online by complainant or their physician. If they cannot complete the form online, the VAERS Reporting Form can be mailed to them and they can send it to the address on the form. When you send a VAERS form to a complainant, note this fact in the Remarks Section of the FACTS Consumer Complaint Report.

The Vaccine Adverse Event Reporting System (VAERS) is administered under a joint FDA/CDC contract. For reporting adverse events which occur subsequent to vaccine administration, the system utilizes a fillable online form (Form FDA VAERS 2.0) or can be directly submitted at: <https://vaers.hhs.gov/reportevent.html> See IOM Exhibit 8-6.

#### *8.5.1.1.2 - Professional Reporting System for Vaccine Adverse Reactions*

The National Childhood Vaccine Injury Act of 1986, 42 USC 201, was passed to achieve optimal prevention of childhood infectious diseases through immunization. At the same time, it was intended to minimize the number and severity of adverse reactions to vaccines routinely administered to children. This law requires health care providers and vaccine manufacturers to report certain adverse events which occur following the administration of specific vaccines. The vaccines and reportable events are listed in the National Childhood Vaccine Injury Act Vaccine Injury Table. The Department of Health and Human Services (DHHS) has established a Vaccine Adverse Events Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine, in all age groups, including but not limited to those in the table.

If the complaint does not involve an adverse reaction, obtain the necessary information to allow the center to make an informed decision on follow-up at the manufacturer.

If the complaint is an adverse reaction to a biologics device, drug, or HCT/P product, an FDA 3500, MedWatch Form (See IOM Exhibit 8-7) must also be completed and forwarded to the complainant for completion by their physician. If the physician will not cooperate by completing the FDA-3500, request the complainant to do it. Assist the complainant in completing the FDA 3500, if necessary. Note in the "Remarks" section of the FACTS Consumer Complaints Report that the FDA 3500 was forwarded to the complainant. MedWatch forms can be found at <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>.

If the complaint does not involve an adverse reaction, obtain information necessary to permit OBPO make an informed decision on follow-up at the manufacturer. If a complainant desires further information, refer them to CBER, Office of Biostatistics and Epidemiology, Division of Epidemiology, at 301-827-3974.

If a CSO finds that there is a complaint of a fatality where blood or a blood component is implicated and that was not already reported to CBER, the CSO should notify their supervisor. The supervisor will then follow-up with OBPO management and CBER. Reporting a fatality is required of the collecting facility, in the event of a donor reaction, and by the facility which performed the compatibility tests, in the event of a transfusion reaction. An investigation of the

incident shall be conducted by either Healthcare Finance Administration (HCFA) Centers for Medicare and Medicaid Services (CMS) or FDA, based on the type of facility involved, for example, transfusion service, blood bank, plasma center or hospital. OBPO CSOs may be assigned to investigate a fatality through an assignment from CBER.

CSOs should follow OBPO's procedure as a guide for conducting the investigation. The CSO should also refer to the eNSpect assignment for additional information regarding the investigation. If the hospital, medical examiner, or other entity either refuses to provide or requires a written request in order to provide the CSO with medical history records, a death certificate, autopsy report, or other needed records, the CSO should complete and provide the firm with the Records Request Letter, that is referenced in OBPO's procedure.

### 8.5.2 - Surveillance

OBPO CSOs should review OSAR Firm 360 to determine if an existing complaint exists in preparation for conducting an inspection assignment. The CSO will review all firm information in OSAR Firm 360, including reviewing all complaints and address all complaints that do not have entries under follow-up disposition and follow-up disposition dates during the inspection assignment. CSO conducts the establishment inspection and investigates those issues identified in the complaint(s) and includes observations in the complaints and summary sections in the narrative of the EIR.

### 8.5.3 - Confidential Informants

In addition to this section, please refer to the general section on Confidential Informants (Section 8.1.7.2.3). Complaints can originate from public sources, including establishment employees at firm's we inspect, donors, donor family members, and industry. Confidential complaints can also come through CBER and through other agencies. If the complaint is from a confidential informant, the complaint is NOT documented in the EIR. Confidential Informant complaints are documented in an Investigation Memo and saved as an attachment to the EIR. Findings are considered in the initial classification of the inspection.

### 8.5.4 - Complaints

#### 8.5.4.1 - BIOLOGICAL PRODUCTS

OBPO CSOs should follow the OBPO procedure on oversight of consumer complaints. If any ORA office receives a complaint on a biological product, regardless of licensure status, the receiving office will notify OBPO at [ORABIOBiologicsInspection@fda.hhs.gov](mailto:ORABIOBiologicsInspection@fda.hhs.gov). OBPO will provide direction on how to proceed, and next steps, including instructions on any FACTS entries. For additional information or inquiries, send an email to the inspection POC address above or contact either of the OBPO division directors. OBPO staff receiving a complaint from external or internal sources should send the complaint to [ORABIOBiologicsInspection@fda.hhs.gov](mailto:ORABIOBiologicsInspection@fda.hhs.gov). Confidential complaints received during an inspection should be captured in a memorandum as an attachment to the EIR. The confidential informant information should not be referenced in the EIR.

Any findings related to complaints not involving confidential informants should be documented in the narrative to the EIR. The complaint number for all complaints should be written in the EIR

coversheet in eNSpect. Complaint follow-up assignments will be issued in eNSpect as determined by OBPO.

#### 8.5.4.2 -Biological Samples

Do not collect samples of a suspect product without first consulting with the supervisor. An evaluation of the preliminary information on the injury/reaction by CBER (for licensed products) and/or the home district division (for unlicensed products, plasma and blood products) may be necessary to determine if a sample should be collected.

#### 8.5.4.3 - BIOLOGICS INJURY/ADVERSE REACTION REPORTS

Submit biologics injury and adverse reaction narrative reports using encrypted email or mailing. If mailing, use this address:

Food and Drug Administration  
White Oak Bldg71  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

NOTE: In addition, check the “Notify EO/EOMPS?” box in FACTS for all injury and adverse reaction complaints. For serious injury/illness reports, please notify the OEM/OEO immediately at 1 (866) 300-4374 and [emergency.operations@fda.hhs.gov](mailto:emergency.operations@fda.hhs.gov).

## 8.6 - Bioresearch Monitoring Investigations

### 8.6.1 - Illness/Injury

#### 8.6.1.1 - Reporting

Submit drug complaints and injuries to:

MedWatch  
The FDA Medical Products Reporting Program (HFD-410)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857  
Fax Number: 1-800--322-0178

### 8.6.2 - Surveillance

For Cause assignments issued to OBIMO may require interviewing of subjects to verify their participation in the clinical trial. These activities would be conducted with supervisor approval. An OP13

(or OP15 for foreign) will be created in eNSpect, for the purpose of subject interviewing, with information correlating the OP12 (or OP11) For Cause assignment. An investigational memo will be uploaded as an “Attachment” as per Section 8.1.9 *General Investigation Reporting*. Additionally, the investigational memo will be included in the EIR as an “Attachment.”

### 8.6.3 - Complaints

Complaints are received via assignment memo from the respective center. The memo will have specifics about the complaint and any special instructions. Reporting of complaints are the same as an inspection via an EIR unless otherwise instructed (see section regarding For Cause/Fact Finding/Information Gathering above). See IOM 5.10.2 – BIMO Assignments as complaint information will be included in the overarching assignment memo.

## 8.7 - Tobacco Investigations

### 8.7.1 - Investigations Coordination

Tobacco Products Samples: When collecting tobacco product samples as a result of a product complaint or adverse report investigation, see IOM 4.5.5.3.8, for sample collection guidance and contact CTP's Office of Compliance and Enforcement. (extract from IOM 8.4.7.6)

### 8.7.2 - Complaints

Consumers who experience a [problem with a tobacco product](#), such as undesired health or quality problems, may report it online via the FDA Safety Reporting Portal (SRP) at [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov).

[Potential tobacco product violations](#) include (but are not limited to):

- Sales to minors.
- Flavored cigarette sales.
- Illegal marketing and advertising – The Tobacco Control Act gives the FDA the ability to regulate certain marketing and advertising activities by the tobacco industry, including describing tobacco products as “light,” “mild,” or “low” – or claiming a product is safer or less harmful without an FDA order.
- Distributing t-shirts or other promotional or novelty items with brand names of cigarette or smokeless tobacco products.
- Sponsoring events using the brand name of a tobacco product.
- Distribution of free samples of tobacco products except in limited circumstances.
- Placement of cigarette or smokeless tobacco product vending machines in prohibited areas (or providing access to self-service or direct access of tobacco products in prohibited areas).
- Sale of cigarettes in packages of less than 20.

If you see what you believe to be a violation of the Tobacco Control Act or other related regulations, you can:

- Submit [online](https://www.accessdata.fda.gov/scripts/ptvr/index.cfm) (<https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>)
- Call the Tobacco Call Center using CTP's toll-free number: 1.877.CTP.1373
- Send an email: [CTPCompliance@FDA.hhs.gov](mailto:CTPCompliance@FDA.hhs.gov)
- Print and mail:  
[Paper form](#) (Form FDA 3779, Potential Tobacco Product Violations Report) (<https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>) to:

### Potential Tobacco Products Violation Report

Food and Drug Administration  
Center for Tobacco Products  
Office of Compliance and Enforcement  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

## EXHIBITS

## 8-1 FEDERAL ANTI-TAMPERING ACT FULL LANGUAGE

**Federal Anti-Tampering Act****21 U.S.C. §1365. Tampering with consumer products**

(a) Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so, shall-

(1) in the case of an attempt, be fined under this title or imprisoned not more than ten years, or both;

(2) if death of an individual results, be fined under this title or imprisoned for any term of years or for life, or both;

(3) if serious bodily injury to any individual results, be fined under this title or imprisoned not more than twenty years, or both; and

(4) in any other case, be fined under this title or imprisoned not more than ten years, or both.

(b) Whoever, with intent to cause serious injury to the business of any person, taints any consumer product or renders materially false or misleading the labeling of, or container for, a consumer product, if such consumer product affects interstate or foreign commerce, shall be fined under this title or imprisoned not more than three years, or both.

(c)(1) Whoever knowingly communicates false information that a consumer product has been tainted, if such product or the results of such communication affect interstate or foreign commerce, and if such tainting, had it occurred, would create a risk of death or bodily injury to another person, shall be fined under this title or imprisoned not more than five years, or both.

(2) As used in paragraph (1) of this subsection, the term "communicates false information" means communicates information that is false and that the communicator knows is false, under circumstances in which the information may reasonably be expected to be believed.

(d) Whoever knowingly threatens, under circumstances in which the threat may reasonably be expected to be believed, that conduct that, if it occurred, would violate subsection (a) of this section will occur, shall be fined under this title or imprisoned not more than five years, or both.

(e) Whoever is a party to a conspiracy of two or more persons to commit an offense under subsection (a) of this section, if any of the parties intentionally engages in any conduct in furtherance of such offense, shall be fined under this title or imprisoned not more than ten years, or both.

(f)(1) Whoever, without the consent of the manufacturer, retailer, or distributor, intentionally tampers with a consumer product that is sold in interstate or foreign commerce by knowingly placing or inserting any writing in the consumer product, or in the container for the consumer

product, before the sale of the consumer product to any consumer shall be fined under this title, imprisoned not more than 1 year, or both.

(2) Notwithstanding the provisions of paragraph (1), if any person commits a violation of this subsection after a prior conviction under this section becomes final, such person shall be fined under this title, imprisoned for not more than 3 years, or both.

(3) In this subsection, the term "writing" means any form of representation or communication, including hand-bills, notices, or advertising, that contain letters, words, or pictorial representations.

(g) In addition to any other agency which has authority to investigate violations of this section, the Food and Drug Administration and the Department of Agriculture, respectively, have authority to investigate violations of this section involving a consumer product that is regulated by a provision of law such Administration or Department, as the case may be, administers.

(h) As used in this section-

(1) the term "consumer product" means-

(A) any "food", "drug", "device", or "cosmetic", as those terms are respectively defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(B) any article, product, or commodity which is customarily produced or distributed for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which is designed to be consumed or expended in the course of such consumption or use;

(2) the term "labeling" has the meaning given such term in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m));

(3) the term "serious bodily injury" means bodily injury which involves-

(A) a substantial risk of death;

(B) extreme physical pain;

(C) protracted and obvious disfigurement; or

(D) protracted loss or impairment of the function of a bodily member, organ, or mental faculty; and

(4) the term "bodily injury" means-

(A) a cut, abrasion, bruise, burn, or disfigurement;

(B) physical pain;

(C) illness;

(D) impairment of the function of a bodily member, organ, or mental faculty; or

(E) any other injury to the body, no matter how temporary.

## 8-2 LETTER TO HEALTHCARE PROVIDER FOR MEDICAL RECORDS

To access the word document, click [here](#). Note: Link to the Letter to Healthcare Provider for Medical Records is only available to ORA users on the FDA intranet. The link is

<http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=OMIJZHPT3ZE7FJRCSJ&static=false&mcuid=ANONYMOUS&mcsid=FPSFER5OBBABVCT55K>. Users who need a copy of the template outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the template.



Click or tap to enter a date.

[Insert name of hospital or state medical examiner & address]

Dear [Insert name of hospital or state medical examiner]:

The United States Food and Drug Administration (FDA) requests copies of available medical records for [insert patient specifics], including [medical history records, a death certificate, autopsy report and other reports] and any other related medical records. FDA is not required to request this information from you in writing but is doing so at your request.

In providing the requested information, please note that the Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) permits disclosure of privacy information without a written patient authorization for specific public health purposes. Specifically, the Privacy Rule permits covered entities to disclose this type of information to “a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability, including . . . the conduct of . . . public health investigations.” 45 C.F.R. § 164.512(b)(1)(i). Per the Privacy Rule, “public health authority means an agency or authority of the United States . . . including the employees or agents of such public agency . . . that is responsible for public health matters as part of its official mandate.” 45 C.F.R. § 164.501. FDA, as a public health agency, meets this definition. Our authority to receive information related to FDA-regulated products comes from the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, and regulations issued under those authorities.

The Privacy Rule permits covered entities to disclose protected health information (including personal privacy information) directly to FDA for certain public health activities, including activities related to preventing or controlling disease, injury, or disability and the conduct of public health surveillance, public health investigations, and public health interventions. As part of these public health activities, access to personal privacy information, including names and contact information, is necessary to ensure timely follow-up. FDA safeguards personal privacy information pursuant to the Freedom of Information Act and the Privacy Act, 5 U.S.C. §§ 552, 552a, and our information disclosure regulations, 21 C.F.R. Parts 20 and 21, and follows internal procedures to prevent its unauthorized disclosure.

Thank you for your assistance in this regard.

Sincerely,

|

U.S. Food and Drug Administration  
 XXX District  
 Street Address  
 City, State ZIP

[www.fda.gov](http://www.fda.gov)

### 8-3 INVESTIGATION MEMO

To access the word document, click [here](#). Note: Link to the Investigation Memo is only available to ORA users on the FDA intranet. The link is

<http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=C7ZQFEQOANEQ5JXMLX&static=false&mcuid=ANONYMOUS&mcsid=AQZ6DL5KXFHKBPWISH>. Users who need a copy of the SOP outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the SOP.



**Date:** (Enter Date)

**To:** Recipient

**From:** Title and Division

**Subject:** Special Investigation (May be changed appropriately to the assignment)

**Firm Information:** ABC Firm (May be N/A if no firm involved or you may list multiple firms)  
1<sup>st</sup> Avenue  
City, State, Zip Code

**FEI:** 12345678

**Text of Investigation (Do not use Bold Text in document)**

**NOTE: Be sure to update the footer with Division Address**

**Your Electronic Signature**  
**(Your Name, Title, Division)**



8-4 TABLE OF INCIDENT COORDINATION

<i>Incident Type</i>	<i>Coordinating Body</i>	<i>Points of Contact (POCs)</i>
Clusters and outbreaks of 2+ human illnesses	<b>CFSAN / CORE</b> (Coordinated Outbreak Response and Evaluation Network)	CORE Signals Team, <a href="mailto:CORESignalsTeam@fda.hhs.gov">CORESignalsTeam@fda.hhs.gov</a>
<b>Single human illness</b> (this includes single case retrospective incidents but also individual consumer complaints)	<b>CFSAN / OC</b> (Office of Compliance)	<a href="mailto:CFSANOCsrt@fda.hhs.gov">CFSANOCsrt@fda.hhs.gov</a>
Clusters and outbreaks of <b>human illness due to pet food/feed products</b>	<b>CVM</b> (Center for Veterinary Medicine)	<a href="mailto:David.Rotstein@fda.hhs.gov">David.Rotstein@fda.hhs.gov</a> , <a href="mailto:Mark.Glover@fda.hhs.gov">Mark.Glover@fda.hhs.gov</a>
<b>Allergen issues</b> (any and all)	<b>CFSAN / OC</b> (Office of Compliance)	<a href="mailto:Stefano.luccioli@fda.hhs.gov">Stefano.luccioli@fda.hhs.gov</a>
<b>Seafood toxin incidents*</b> (All toxins; All domestic and international waters)	<b>CFSAN / OFS / DSS</b> (Division of Shellfish Safety and DSST, Division of Seafood Science and Technology)	<a href="mailto:Ronald.Benner@fda.hhs.gov">Ronald.Benner@fda.hhs.gov</a> <a href="mailto:Jonathan.Deeds@fda.hhs.gov">Jonathan.Deeds@fda.hhs.gov</a> <a href="mailto:Karen.Swajian@fda.hhs.gov">Karen.Swajian@fda.hhs.gov</a>
<b>Molluscan shellfish outbreaks</b> (single and multiple human illnesses)	<b>CFSAN / OFS / DSS</b> (Division of Shellfish Safety and DSST, Division of Seafood Science and Technology)	<a href="mailto:Melissa.Farrell@fda.hhs.gov">Melissa.Farrell@fda.hhs.gov</a> (goes by Lizzie; OFS / DSS) <a href="mailto:Melissa.Abbott@fda.hhs.gov">Melissa.Abbott@fda.hhs.gov</a> (OFS / DSS) <a href="mailto:Jessica.Jones@fda.hhs.gov">Jessica.Jones@fda.hhs.gov</a> (OFS / DSST)
<b>Processed shellfish outbreaks</b> (e.g., non-molluscan shellfish (crustaceans such as lobster, crab, crab meat, crawfish, shrimp, and processed molluscan shellfish))	<b>CFSAN / CORE</b> (Coordinated Outbreak Response and Evaluation Network)	CORE Signals Team, <a href="mailto:CORESignalsTeam@fda.hhs.gov">CORESignalsTeam@fda.hhs.gov</a>
<b>Kratom-related / CBD / psychoactive substance incidents</b>	<b>OC / OO / OSEM / OEM / OEO</b> (Office of Emergency Operations)	FDA Emergency Operations list: <a href="mailto:emergency.operations@fda.hhs.gov">emergency.operations@fda.hhs.gov</a>
<b>Hepatitis A</b> positive samples (and subsequent coordination with CDC for PEP); no known associated HAV illnesses	<b>FDA Liaison to CDC</b>	FDA Liaison to CDC ( <a href="mailto:Susan.Lance@fda.hhs.gov">Susan.Lance@fda.hhs.gov</a> )

<p><b>Infant illnesses*</b> (<i>Salmonella</i>, <i>Cronobacter</i>, infant botulism with rule-out investigations for infant formula or related infant products such as gripe water or medicated foods)</p>	<p><b>CFSAN / OC</b> (Office of Compliance) - Powdered Infant Formula (PIF) <b>CFSAN / ONFL</b> (Office of Nutrition and Food Labeling) <b>NCCC</b> National Consumer Complaint Coordinator</p>	<p>OC contact for PIF is <a href="mailto:Marjorie.Davis@fda.hhs.gov">Marjorie.Davis@fda.hhs.gov</a> ONFL contact for infant formula are <a href="mailto:Andrea.Lotze@fda.hhs.gov">Andrea.Lotze@fda.hhs.gov</a> and <a href="mailto:Carrie.Assar.@fda.hhs.gov">Carrie.Assar.@fda.hhs.gov</a> NCCC in OEO is <a href="mailto:Joan.Trankle@fda.hhs.gov">Joan.Trankle@fda.hhs.gov</a></p>
<p><b>Disasters</b> (Natural and Manmade)</p>	<p><b>OC / OO / OSEM / OEM / OEO</b> (Office of Emergency Operations)</p>	<p>FDA Emergency Operations list: <a href="mailto:emergency.operations@fda.hhs.gov">emergency.operations@fda.hhs.gov</a></p>
<p><b>Food Defense incidents</b> (Intentional Contamination)</p>	<p><b>OC / OO / OSEM / OEM / OEO</b> (Office of Emergency Operations) <i>And</i> <b>CFSAN / OAO</b> (Office of Analytics and Outreach)</p>	<p>CFSAN/OAO/Food Defense and Emergency Coordination Staff contact is <a href="mailto:Leeanne.jackson@fda.hhs.gov">Leeanne.jackson@fda.hhs.gov</a></p>

### 8-5 CIFOR OUE Agent List

Agent Name	Median Incubation Period (Range) <sup>1</sup>	Primary Signs and Symptoms	Primary Specimen(s)	KEI <sup>§</sup> -Special group(s)	KEI-Geographic Considerations	KEI-Notable Exposures
<b>BACTERIAL</b>						
<i>Arcobacter butzleri</i>	32 hrs (6-83 hrs) <sup>2</sup>	D (persistent and watery), abdominal cramps, N, V	Stool in Cary-Blair, raw stool			
<i>Bacillus anthracis</i>	Usually ≤1 week (Up to 60 days)	Severe abdominal pain, N, V, fever, D (may be bloody), ascites, sepsis, meningitis	Blood, stool in Cary-Blair, raw stool		Recent travel to endemic areas, tropical or sub-temperate regions	Undercooked meat or hides of herbivores
<i>Bacillus cereus</i> , diarrheal toxin	10-16 hours (6-24 hours)	Abdominal cramps, D (watery), N	Stool in Cary-Blair, raw stool			Time and/or temperature-abused foods
<i>Bacillus cereus</i> , pre-formed toxin	30 min- 6 hours	Sudden onset of severe N, V, D	Stool in Cary Blair			Time and/or temperature-abused foods
<i>Brucella</i> spp.	3-4 weeks (1 week to several months)	Flu-like symptoms including fever, chills, sweating, HA, joint pain, weakness; may cause recurrent fevers and chronic joint pain/fatigue; <i>may cause diarrhea and bloody stools in acute phase</i>	Blood, serum	Animal handlers, especially farm workers and veterinarians		Ingestion of raw milk and dairy products
<i>Campylobacter</i> spp.	2-5 days (1-10 days)	D (may be bloody), abdominal cramps, Fever, possible N & V, Guillain-Barre Syndrome <sup>3</sup>	Stool in Cary Blair, raw stool			Undercooked or raw meat or poultry; raw milk/ milk-products
<i>Clostridium botulinum</i> , foodborne <sup>£</sup>	12-72 hours (6 hours-10 days)	V, D, blurred vision, diplopia, dysphagia, "bilateral" descending muscle weakness, cranial nerve palsies (e.g., blurred vision, diplopia, dysphagia)	Raw stool, vomitus or serum (specimens collected prior to anti-toxin administration)			Improperly processed and canned foods in airtight containers/packaging
<i>Clostridium botulinum</i> , infantile <sup>£</sup>	3- 30 days	Lethargy, weakness, poor feeding, constipation, hypotonia, poor head control, poor gag reflex and sucking reflex	Raw stool, serum	Infants		Honey; home canned vegetables, fruits; corn syrup
<i>Clostridium perfringens</i>	8-16 hours (6-24 hours)	D (watery), abdominal cramps, N; fever is rare	Stool in Cary-Blair, raw stool			Time and / or temperature abused foods
<i>Cronobacter sakazakii</i>	Less than 28 days	Bacteremia, meningitis, necrotizing enterocolitis	Blood, stool in Cary- Blair, raw stool	Premature infants		Infant formula
<i>Coxiella burnetii</i> (Acute Q fever)	2-3 weeks (3-39 days)	Fever, HA, fatigue, malaise, cough, anorexia, N, V, D, abdominal pain, pneumonia	Blood with EDTA/ serum, tissue	Pregnant women, immunosuppressed, and patients with a pre-existing heart valve defects		Consumption of raw cow or goat milk; contact with cows or goats
Enterohemorrhagic <i>E. coli</i> (EHEC) (including Shiga-toxin producing <i>E. coli</i> (STEC) and Verotoxin producing <i>E. coli</i> (VTEC))	3-4 days (1-10 days)	D (often bloody), abdominal cramps, V, hemolytic-uremic syndrome (HUS)	Stool in Cary-Blair, raw stool	Young children		Consumption of raw milk; contact with cattle/ruminants; undercooked ground beef; leafy greens
Enterotoxigenic <i>E. coli</i> (ETEC)	24-72 hours (10 hours- 6 days)	D (profuse watery), abdominal cramps, V	Stool in Cary-Blair, raw stool		Foreign travel especially to developing countries	Contaminated water and food sources

Enteroinvasive <i>E. coli</i> (EIEC)	As short as 10-18 hrs	D (watery), fever, abdominal cramps, dysentery (in rare cases)- scant stools w/ evidence of blood, mucous or leukocytes in stool	Stool in Cary-Blair, raw stool		Foreign travel especially to developing countries	
Enteropathogenic <i>E. coli</i> (EPEC)	As short as 9-12 hrs	D (watery with mucous), fever, V	Stool in Cary-Blair, raw stool	Children < 2 years of age		
Enteraggative <i>E. coli</i> (EAEC)	Estimated at 20-48 hrs	Chronic or acute D (watery), V	Stool in Cary-Blair, raw stool			
Diffuse-Adherence <i>E. coli</i> (DAEC)		D	Stool in Cary-Blair, raw stool	Young children		
<i>Leptospira interrogans</i>	5-14 days (2-30 days)	<b>Anicteric disease</b> (no liver involvement)- Abrupt onset of fever, HA, abdominal pain, N, V, severe myalgia, malaise, <b>conjunctival petechiae and/or hemorrhage</b> <b>Icteric disease</b> (liver involvement)- Jaundice, upper right quadrant pain, N, V, decreased urine output, edema, hemorrhage, vascular collapse, severe altered mental status (AMS)	Blood, CSF, Urine	Farmers, veterinarians, slaughterhouse and sewer workers		Water activities (swimming, kayaking)
<i>Listeria monocytogenes</i>	1 day- 3 weeks (3-70 days)	<b>Invasive disease-</b> Severe HA, N, V, stiff neck, confusion, and other neurological symptoms consistent with meningitis, sepsis, bacteremia, premature birth or stillbirth <b>Gastrointestinal disease-</b> Fever, D, myalgia	Blood, CSF, Stool in Cary-Blair	Pregnant women <sup>€</sup> , immunosuppressed <sup>¥</sup> , elderly <sup>¥</sup>		Raw milk/dairy; soft cheeses; deli or RTE meats, raw produce
<i>Mycobacterium bovis</i>	Undetermined	<b>Gastrointestinal disease-</b> Abdominal pain, D <b>Lung disease-</b> Fever, weight loss, night sweats, cough	Stool in Cary-Blair, sputum	Foreign born, immigrants, immunocompromised, dairy workers		Raw milk/milk products; contact with cattle, bison, elk and deer
<i>Salmonella spp.</i> (non-typhi)	12-36 hours (6- 72 hours)	D (can be bloody) fever, abdominal pain, N, V	Stool in Cary-Blair, raw stool			
<i>Salmonella Typhi/ Paratyphi</i>	<b>Typhi-</b> 7-14 days (3-60+ days) <b>Paratyphi-</b> 1-10 days	Fever, HA, malaise, chills, myalgia, weight loss, constipation or D, bacteremia, rash, cough	Stool in Cary-Blair, raw stool		Recent travel to endemic areas; Africa, Southeast Asia	Contaminated water and food sources
<i>Shigella spp.</i>	24-72 hours (1-7 days)	D (stools can have blood and mucus), abdominal cramps, fever, V, tenesmus	Stool in Cary-Blair, raw stool	Young children		Usually person to person, water or raw milk
<i>Staphylococcus aureus</i> (preformed toxin)	1-6 hrs (30 minutes-8hrs)	Severe N, V, abdominal cramps, prostration, D, drop in blood pressure	Stool in Cary-Blair, raw stool			Foods handled with bare hands especially those without further cooking or inadequate heating/refrigeration, time and /or temperature abused foods
<i>Streptococcus</i> , Group A	1-5 days	Sore throat (pharyngitis, tonsillitis), fever, malaise, rash, cellulitis	Throat swab			Milk/ raw milk, eggs, raw produce

<i>Vibrio parahaemolyticus</i>	12-24 hours (2-96 hours)	D (watery), N, V, abdominal cramps, HA, fever, chills; Wound infections are possible	Stool in Cary-Blair, blood, wound culture	Immunocompromised, pre-existing liver conditions	Coastal, brackish waters, estuaries	Raw or undercooked seafood (oysters, clams, squid, mackerel, tuna, sardines, crab, shrimp)
<i>Vibriovulnificus</i>	24-72 hours (1-7 days)	V, D, abdominal pain, wound infections, bacteremia, shock	Stool in Cary-Blair, blood, wound culture	Immunocompromised, pre-existing liver conditions	Coastal, brackish waters, estuaries	Raw or undercooked seafood (oysters, clams, squid, mackerel, tuna, sardines, crab, shrimp), contaminated water, open wounds.
<i>Vibrio cholerae</i> , toxigenic	24-72 hours (few hours to 5 days)	D (profuse watery), abdominal cramps, N, V, dehydration, shock	Stool in Cary-Blair, rectal swab	Immunocompromised, esp. pre-existing liver conditions	Coastal, brackish waters, estuaries esp. Pacific Northwest	Seafood, raw or under-cooked oysters, contaminated water Recent travel to endemic areas
<i>Yersinia enterocolitica</i>	3- 7 days (1-14 days)	Fever, abdominal pain, D, V	Stool in Cary-Blair, raw stool; blood	Children and elderly more susceptible		Undercooked pork products, raw milk
<i>Yersinia pseudotuberculosis</i>	3- 7 days (1-14 days)	Fever, abdominal pain, D, V, (can have scarlatiniform rash)	Stool in Cary-Blair, raw stool; blood	Males		
FUNGAL						
<i>Cryptococcus gattii</i>	2 to 14 months (C. gattii)	D, abdominal cramps	CSF, serum	Immunocompromised	Pacific Northwest, Australia, Africa	Inhalation
PARASITIC						
<i>Angiostrongylus cantonensis</i> or <i>A. costaricensis</i>	1-3 weeks (1 day- 6 weeks-cantonensis); weeks-1 year (costaricensis)	Severe HA, N, V, stiff neck, and other neurological symptoms consistent with meningitis ( <i>A. canontensis</i> ); Abdominal pain, fever, N, V ( <i>A. costaricensis</i> )	CSF, blood, serum		Texas, Pacific Basin, SE Asia ( <i>A. cantonensis</i> ); Latin America, Caribbean ( <i>A. costaricensis</i> )	Raw/undercooked snails, slugs; chopped vegetables contaminated with infected snails or slugs
<i>Cryptosporidium</i>	7 days (1-14 days)	D (severe watery; may be recurrent), abdominal cramps, N, fever	Stool (2-3 samples collected over several days)			Recreational water, drinking water, unpasteurized milk, contact with cattle, children in daycare settings (fecal-oral transmission)
<i>Cyclospora cayetanensis</i>	7 days (1-14 days)	D (watery), weight loss, anorexia, abdominal cramps, N, V and fatigue; fever rare	Stool, intestinal fluid, tissue biopsy		More common in tropical and subtropical countries, but occurs in other areas due to contaminated imported produce	Fresh fruit and vegetables (e.g. berries, basil, snow peas, lettuce), contaminated water
<i>Entamoeba histolytica</i>	1-4 weeks (from a few days to several months or years)	Fever, chills, lower abdominal pain, D, bloody D (amoebic dysentery), liver (or other organ) abscess	Stool (2-3 samples over several days), blood if disseminated	Invasive amoebiasis more common in young adults, liver abscess more common in males, dysentery rare before age 5	Tropical countries with poor sanitation (South and Central America, Africa, and Asia)	Human reservoir, fecally contaminated food or water; person-to-person less common

<i>Giardia lamblia</i>	1-3 weeks (3 days- 3 weeks)	D, abdominal cramps, greasy stools, gas	Stool (2-3 samples collected over several days)			Drinking water, recreational water, children in daycare settings (fecal-oral transmission); occasional food contamination
<i>Toxoplasma gondii</i>	7 days (4-23 days)	Cervical lymphadenopathy, flu-like illness; if immunocompromised, central nervous system (CNS) disease, myocarditis, or pneumonitis can occur	Serum			Raw beef
<i>Trichinella spiralis</i>	GI symptoms- 1-2 days; 5 days- 8 weeks for other symptoms	Muscle soreness accompanied by fever and edema of eyelids are characteristic; eosinophilia, N, V, chills, D, abdominal cramps, fatigue and weakness possible	Serum; biopsy of tissue			Consumption of raw or undercooked meat (particularly bear, pork, wild feline, fox, dog, wolf, moose, horse, seal or walrus)
VIRAL						
Adenovirus	1-10 days	D (prolonged), N, V, HA, fever, malaise, abdominal pain; Types 40 and 41 can cause GI outbreaks	Stool in Cary-Blair, raw stool, serum, nasopharyngeal swab,	Children		
Astrovirus	1-4 days	D (watery), N, V, fever, malaise, abdominal pain, HA, anorexia	Stool in Cary-Blair, raw stool, serum	Children and immunocompromised		Child care facilities, long-term care facilities
Hepatitis A	28 days (15-50 days)	Jaundice, dark urine, fatigue, anorexia, N, D, fever, HA, abdominal pain, weight loss	Stool in Cary-Blair, raw stool, Serum	Men who have sex with men, injection drug users, international adoptees	Foreign travel	Water contaminated with infectious human waste; raw, undercooked mollusks harvested from contaminated waters
Hepatitis E	26-42 days (15- 64 days)	Jaundice, dark urine, D, fever, abdominal pain, arthralgia, rash, hepatomegaly, altered consciousness	Stool in Cary-Blair, raw stool, Serum		Foreign travel, especially Asia, Middle East, Africa and Central America; exposure to pigs	Contaminated drinking water; oysters, mussels and other shellfish; pork, pig liver; and raw/rare deer and boar
Norovirus	12-48 hours (10- 50 hours)	N, V, D, abdominal cramps, fever (low grade), HA, myalgia, malaise	Stool in Cary-Blair, raw stool	Institutionalized populations		
Parvovirus (Human Bocavirus, HBoV 2-4)	Unknown- emerging pathogen	D, V, fever, abdominal pain, coryza, cough	Stool in Cary-Blair, raw stool, serum, CSF	Children		
Rotavirus	1-3 days	D (watery), V, fever (low grade), abdominal pain	Stool in Cary-Blair, raw stool	Children		
Saffold virus (SAFV)	Unknown-emerging pathogen	D, V, respiratory symptoms (children); if invasive, then meningitis, encephalitis, myelitis, myocarditis, enanthema, exanthema, septicemia	Stool in Cary-Blair, raw stool, nasopharyngeal swab, CSF	Children		
Sapovirus	12-48 hours	N, V, D, abdominal pain, fever, HA, myalgia	Stool in Cary-Blair, raw stool	Infants, young children and		

				institutionalized populations (esp. long-term care facilities)		
OTHER						
Brainerd D agent	Unknown	D (Profuse, watery, prolonged 2-36 months)	Stool in Cary-Blair, raw stool			
Toxins						
Azaspiracid Poisoning (AZP)	12-24 hours	N, V, D, abdominal cramps	Shellfish, toxin detection		Europe	Mussels, oysters
Carchatoxin	< 1-6 hours	N, V, D, and paresthesias	Food		Madagascar	Shark, particularly the liver
Ciguatera toxin	GI symptoms- 1-6 hours (few minutes- 48 hours) Neurologic symptoms- few minutes- 48 hours	N, V, D, abdominal cramps, sweating, HA, muscle aches, paresthesia of lips, tongue, face or extremities and temperature sensation reversal (hot/cold sensation flip)	Fish for purification/ extraction and mouse bioassay		Tropical areas	Predatory fish like barracuda, grouper, sea bass, snapper, mullet
Scombroid	Few minutes- 3 hours	Rash, D, flushing, sweating, HA, V, burning/tingling sensation in mouth, swelling in mouth, abdominal pain and metallic taste	Fish, histamine testing			Fish such as tuna and mackerel; (bacterial action in) Swiss cheese
Tetrodotoxin	< 30 minutes	Paresthesia of lips, tongue, face or extremities often following numbness; floating sensation, V, D, abdominal pain, ascending paralysis, respiratory failure	Puffer fish, toxin testing			Puffer fish consumption
Mushroom toxin (short-acting)	Few minutes- 2 hours	V, D, confusion, vision problems, salivation, diaphoresis, hallucinations	Mushrooms, toxin detection			Mushroom consumption
Mushroom toxin (long-acting)	4-24 hours	D, abdominal cramps, liver and kidney failure	Mushrooms, toxin detection			Mushroom consumption
Shellfish toxin (diarrheic)	30 minutes- 2 hours	N, V, D, abdominal pain, chills, HA, fever	Shellfish, toxin detection			Mussels, oysters, scallops from Gulf of Mexico, FL
Shellfish toxin (neurotoxic)	Few minutes- 3 hours	Tingling and numbness of lips, tongue and throat; muscle aches, dizziness and reversal of hot/cold sensation, D, V	Shellfish, toxin detection			Mussels, oysters, scallops from Gulf of Mexico, FL
Shellfish toxin (amnesic)	< 24 - 48 hours	V, D, abdominal pain and neurologic symptoms of confusion, memory loss, disorientation, seizure or coma	Shellfish, toxin detection			Mussels, oysters, scallops
Shellfish toxin (paralytic poisoning)	30 minutes- 3 hours (15 minutes- 10 hours)	N, V, D, paresthesia of mouth and lips, weakness, dysphasia, dysphoria, respiratory paralysis	Shellfish or water, toxin detection			Scallops, mussels, clams, cockles
Chemicals						

Antimony	<1 hour (5 mins- 8 hours)	V, D, abdominal pain, metallic taste	Food or beverage			Metallic container
Arsenic	Few hours	N, V, D, pins and needles sensation, colic	Urine analysis			
Cadmium	<1 hour (5 mins- 8 hours)	N, V, D, myalgia, increased salivation, abdominal pain; often a metallic taste	Food			Seafood, oysters, clams, lobsters, grains and peanuts
Chlorinated hydrocarbon insecticides (aldrin, chlordane, DDT, endrin, lindane, toxaphene)	30 minutes- 6 hours	N, V, paresthesia, dizziness, muscular weakness, anorexia, weight loss, confusion	Blood, urine, stools, gastric washings			Storing insecticides in same areas as foods; mistaking pesticides for powdered foods
Copper	<1 hour (5 mins- 8 hours)	N, V (blue or green), D; often a metallic taste	Food or beverage			Metallic containers
Mercury	<1 week	N, V, D, numbness, skin rash, eye irritation, weakness of legs, spastic paralysis, impaired vision, blindness, coma	Blood, hair			Fish; grains treated with mercury containing fungicides
Monosodium glutamate (MSG)	Few minutes to 1 hour	Tingling, flushing, dizziness, HA, N, burning sensation in back of neck, forearms; feeling of tightness in chest	N/A			Foods seasoned with MSG
Nicotinic acid/Niacin	Few minutes to 1 hour	Flushing, sensation of warmth, itching, abdominal pain, puffiness of face and knees	N/A			Meats or other foods with sodium nicotinate as color preservative; high doses of dietary supplements
Nitrite poisoning	1-2 hours	N, V, cyanosis/blue skin, HA, dizziness, weakness, fatigue, loss of consciousness, chocolate-brown colored blood	Blood, food			Cured meats and spinach
Organophosphates or carbamate pesticides (Diazinon, Malathion, Parathion, TEPP; Carbaryl, Sevin®, Lannate®, Aprocarb®)	Few minutes to few hours	N, V, abdominal pain, HA, nervousness, blurred vision, twitching, convulsions	Blood, food			Spraying foods just before harvesting; storing insecticides in same areas as foods; mistaking pesticides for powdered foods
Sodium fluoride	Few minutes to 2 hours	Irritation of skin, eyes, and respiratory tract, salty or soapy taste in mouth, numbness of mouth, V, D, dilated pupils, spasms, pallor, shock, collapse	Vomitus, gastric washes and food			Dry goods (powdered milk, flour, baking powder, cake mix), insecticides and rodenticides
Thallium	Few hours	V, D, hair loss, neurologic manifestations (paresthesia, respiratory depression, bronchospasms, cranial nerve palsies)	Urine, hair			Centers for Disease Control and Prevention. Thallium Poisoning from Eating Contaminated Cake-- Iraq, 2008. MMWR. September 19, 2008 / 57(37);1015-1018.
Tin	Few hours	N, V, D; often a metallic taste	Food			Metallic container



Triorthocresyl phosphate	10 days (5-21 days)	N, V, D, leg pain, ungainly high stepping gait, food and wrist drop	N/A			Using compound to extract foods or as cooking or salad oil
Zinc	Few hours	Stomach cramps, N, V, D, myalgias; often a metallic taste	Blood, stool, saliva, urine and food			Metallic container

Notes:

- <sup>1</sup> Unless otherwise noted, the median incubation period and range were obtained from the following three sources: Heymann, D.L. (Ed.)(2008). **Control of Communicable Diseases Manual** (19th ed.). Washington, DC: American Public Health Association; Centers for Disease Control and Prevention (CDC) (March 26, 2014) A-Z Index for Foodborne Illness. Retrieved from <http://www.cdc.gov/foodsafety/diseases/index.html>.
  - <sup>2</sup> Victoria Lappi, John R. Archer, Elizabeth Cebelinski, Fe Leano, John M. Besser, Rachel F. Klos, Carlota Medus, Kirk E. Smith, Collette Fitzgerald, and Jeffrey P. Davis. Foodborne Pathogens and Disease. March 2013, 10(3): 250-255. doi:10.1089/fpd.2012.1307.
  - <sup>3</sup> B.R. Jackson, J. Alomia Zegarra, H. Lopez-Gatell, J. Sejvar, F. Arzate, S. Waterman, A. Sanchez Nunez, B. Lopez, J. Weiss, R. Quintero Cruz, D. Y. Lopez Murrieta, R. Luna-Gierke, K. Heiman, A. R. Vieira, C. Fitzgerald, P. Kwan, M. Zarate-Bermudez, D. Talkington, V. R. Hill and B. Mahon (2014). Binational outbreak of Guillain–Barré syndrome associated with Campylobacter jejuni infection, Mexico and USA, 2011 . *Epidemiology and Infection*, 142, pp 1089-1099. doi:10.1017/S0950268813001908.
- §- Key epidemiological information
  - £- Clinical consultation and testing recommendations (including lab collection recommendations) can be obtained through consultation with CDC.
  - €- Pregnant women may be more likely to present with mild, flu-like symptoms.
  - ¥- Elderly or immunocompromised may be more likely to present with sepsis or meningitis.
  - N- nausea, D- diarrhea, V-vomiting, HA- headache

8-6 – VAERS Form

VAERS

**Vaccine Adverse Event Reporting System**  
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18** and **21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)

1. Patient name: (first) _____ (last) _____ Street address: _____ City: _____ State: _____ County: _____ ZIP code: _____ Phone: ( ) _____ Email: _____	9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination: _____
2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	10. Allergies to medications, food, or other products: _____
4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm _____ AM/PM	11. Other illnesses at the time of vaccination and up to one month prior: _____
5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm _____ AM/PM	12. Chronic or long-standing health conditions: _____
6. Age at vaccination: _____ Years _____ Months 7. Today's date: (mm/dd/yyyy) _____	
8. Pregnant at time of vaccination?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)	

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN
13. Form completed by: (name) _____ Relation to patient: <input type="checkbox"/> Healthcare professional/staff <input type="checkbox"/> Patient (yourself) <input type="checkbox"/> Parent/guardian/caregiver <input type="checkbox"/> Other: _____ Street address: _____ <input type="checkbox"/> Check if same as item 1 City: _____ State: _____ ZIP code: _____ Phone: ( ) _____ Email: _____	15. Facility/clinic name: _____ Fax: ( ) _____ Street address: _____ <input type="checkbox"/> Check if same as item 13 City: _____ State: _____ ZIP code: _____ Phone: ( ) _____
14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____	16. Type of facility: (Check one) <input type="checkbox"/> Doctor's office, urgent care, or hospital <input type="checkbox"/> Pharmacy or store <input type="checkbox"/> Workplace clinic <input type="checkbox"/> Public health clinic <input type="checkbox"/> Nursing home or senior living facility <input type="checkbox"/> School or student health clinic <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use Continuation Page if needed

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)  
 \_\_\_\_\_  
 Use Continuation Page if needed

19. Medical tests and laboratory results related to the adverse event(s): (include dates)  
 \_\_\_\_\_  
 Use Continuation Page if needed

20. Has the patient recovered from the adverse event(s)?  Yes  No  Unknown

21. Result or outcome of adverse event(s): (Check all that apply)  
 Doctor or other healthcare professional office/clinic visit  
 Emergency room/department or urgent care  
 Hospitalization: Number of days (if known) \_\_\_\_\_  
 Hospital name: \_\_\_\_\_  
 City: \_\_\_\_\_ State: \_\_\_\_\_  
 Prolongation of existing hospitalization (vaccine received during existing hospitalization)  
 Life threatening illness (immediate risk of death from the event)  
 Disability or permanent damage  
 Patient died – Date of death: (mm/dd/yyyy) \_\_\_\_\_  
 Congenital anomaly or birth defect  
 None of the above

ADDITIONAL INFORMATION

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
select			select	select	select	
select			select	select	select	

22. Any other vaccines received within one month prior to the date listed in item 4: Use Continuation Page if needed

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)  
 Yes \_\_\_\_\_  No  Unknown

24. Patient's race:  American Indian or Alaska Native  Asian  Black or African American  Native Hawaiian or Other Pacific Islander  
 White  Unknown  Other: \_\_\_\_\_

25. Patient's ethnicity:  Hispanic or Latino  Not Hispanic or Latino  Unknown

26. Immuniz. proj. report number: (Health Dept use only) \_\_\_\_\_

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination:  Active duty  Reserve  National Guard  Beneficiary  Other: \_\_\_\_\_

28. Vaccinated at Military/DoD site:  Yes  No

FORM FDA VAERS 2.0 (03/21)

SAVE

8-74

**VAERS**

**CONTINUATION PAGE** (Use only if you need more space from the front page)

17. Enter all vaccines given on the date listed in item 4 (continued):						Dose number in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site		
select			select	select		select
select			select	select		select
select			select	select		select
select			select	select		select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):						Dose number in series	Date Given
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site			
select			select	select		select	
select			select	select		select	
select			select	select		select	
select			select	select		select	
select			select	select		select	
select			select	select		select	

Use the space below to provide any additional information (indicate item number):



[RETURN TO PAGE 1](#)

## COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

### GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit [www.vaers.hhs.gov/uploadfile/](http://www.vaers.hhs.gov/uploadfile/).
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to [info@vaers.org](mailto:info@vaers.org).
- Fill out the VAERS form as completely as possible and use the **Continuation Page** if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at [www.vaers.hhs.gov/reportable.html](http://www.vaers.hhs.gov/reportable.html) for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

### SPECIFIC INSTRUCTIONS

**Items 2, 3, 4, 5, 6, 17, 18 and 21** are **ESSENTIAL** and should be completed.

- **Items 4 and 5:** Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6:** If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- **Item 8:** If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.
- **Item 10:** List any allergies the patient has to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 14:** List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- **Item 15:** Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- **Item 16:** Select the option that best describes the type of facility where the vaccine(s) was given.



- **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:
  - Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
  - By mouth/oral
  - Other (specify)
  - In nose/intranasal
  - Unknown

For body site, the options include:

  - Right arm
  - Right thigh
  - Nose
  - Other (specify)
  - Left arm
  - Left thigh
  - Mouth
  - Unknown
  - Arm (side unknown)
  - Thigh (side unknown)

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."
- **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** For health department use only.
- **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

**GENERAL INFORMATION**

- VAERS ([www.vaers.hhs.gov](http://www.vaers.hhs.gov)) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see [www.hrsa.gov/vaccinecompensation/index.html](http://www.hrsa.gov/vaccinecompensation/index.html)).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

8-7 **MedWatch Form**

Reset Form

U.S. Department of Health and Human Services  
Food and Drug Administration

**MEDWATCH**

FORM FDA 3500 (2/20)  
The FDA Safety Information and  
Adverse Event Reporting Program

For VOLUNTARY reporting of  
adverse events, product problems  
and product use/medication errors

Form Approved: OMB No. 0910-0291, Expires: 11-30-2021  
See PRA statement on reverse.

Page 1 of 2

**FDA USE ONLY**

Triage unit sequence #
FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2018.

**A. PATIENT INFORMATION**

1. Patient Identifier	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925)	3. Gender (check one) <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Intersex <input type="checkbox"/> Transgender <input type="checkbox"/> Prefer not to disclose	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg
5. Ethnicity (check one) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	6. Race (check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander		

In Confidence

**B. ADVERSE EVENT, PRODUCT PROBLEM**

1. Type of Report (check all that apply) <input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input type="checkbox"/> Product Use/ Medication Error <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine	
2. Outcome Attributed to Adverse Event (check all that apply) <input type="checkbox"/> Death Date of death (dd-mmm-yyyy): <input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Hospitalization (Initial or prolonged) <input type="checkbox"/> Congenital Anomaly/Birth Defects <input type="checkbox"/> Other Serious or Important Medical Events <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage	
3. Date of Event (dd-mmm-yyyy)	4. Date of this Report (dd-mmm-yyyy)
5. Describe Event, Problem or Product Use/Medication Error  <p style="text-align: right;">(Continue on page 2)</p>	
6. Relevant Tests/Laboratory Data	Date (dd-mmm-yyyy)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)  <p style="text-align: right;">(Continue on page 2)</p>	

**C. PRODUCT AVAILABILITY**

1. Product Available for Evaluation? (Do not send product to FDA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on (dd-mmm-yyyy)
2. Do you have a picture of the product? (check yes if you are including a picture) <input type="checkbox"/> Yes

**D. SUSPECT PRODUCTS**

1. Name, Strength, Manufacturer/Compounder (from product label). #1 <input type="checkbox"/> Yes Does this report involve cosmetic, dietary supplement or food/medical food? #2 <input type="checkbox"/> Yes	
#1 - Name and Strength	#1 - NDC # or Unique ID
#1 - Manufacturer/Compounder	#1 - Lot #
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot #

2. Dose or Amount	Frequency	Route
#1		
#2		
3. Treatment Dates/Therapy Dates (give best estimate of length of treatment (start/stop) or duration.)		4. Diagnosis for Use (Indication)
#1 Start		#1
#1 Stop		
Is therapy still on-going? <input type="checkbox"/> Yes <input type="checkbox"/> No		
#2 Start		#2
#2 Stop		
Is therapy still on-going? <input type="checkbox"/> Yes <input type="checkbox"/> No		
5. Product Type (check all that apply)		6. Expiration Date (dd-mmm-yyyy)
#1 <input type="checkbox"/> OTC <input type="checkbox"/> Compounded <input type="checkbox"/> Generic <input type="checkbox"/> Biosimilar		#1
#2 <input type="checkbox"/> OTC <input type="checkbox"/> Compounded <input type="checkbox"/> Generic <input type="checkbox"/> Biosimilar		#2
7. Event Abated After Use Stopped or Dose Reduced? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply #2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply		8. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply #2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name	
2a. Common Device Name	2b. Procode
3. Manufacturer Name, City and State	
4. Model #	Lot #
Catalog #	Expiration Date (dd-mmm-yyyy)
Serial #	Unique Identifier (UDI) #
5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Patient/Consumer <input type="checkbox"/> Other	
6a. If Implanted, Give Date (dd-mmm-yyyy)	6b. If Explanted, Give Date (dd-mmm-yyyy)
7a. Is this a single-use device that was reprocessed and reused on a patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	7b. If Yes to Item 7a, Enter Name and Address of Reprocessor
8. Was this device serviced by a third party servicer? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

1. Product names and therapy dates (Exclude treatment of event)  <p style="text-align: right;">(Continue on page 2)</p>
---

**G. REPORTER (See confidentiality section on back)**

1. Name and Address	
Last Name:	First Name:
Address:	
City:	State/Province/Region:
ZIP/Postal Code:	Country:
Phone #:	Email:
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation
4. Also Reported to: <input type="checkbox"/> Manufacturer/Compounder <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer	
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: <input type="checkbox"/>	

FORM FDA 3500 (2/20)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.  
\* Please see Instructions

[Reset Form](#)

U.S. Department of Health and Human Services  
Food and Drug Administration

# MEDWATCH

FORM FDA 3500 (2/20) (continued)  
The FDA Safety Information and  
Adverse Event Reporting Program

(CONTINUATION PAGE)  
For VOLUNTARY reporting of  
adverse events, product problems  
and product use/medication errors

Page 2 of 2

B.5. Describe Event or Problem (continued)

[Back to Item B.5](#)

B.6. Relevant Tests/Laboratory Data (continued)

Date (dd-mm-yyyy)

Relevant Tests/Laboratory Data

Date (dd-mm-yyyy)

_____	_____
_____	_____

Additional comments

[Back to Item B.6](#)

B.7. Other Relevant History (continued)

[Back to Item B.7](#)

F.1. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

[Back to Item F.1](#)

## ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: <https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500>

**Report adverse events, product problems or product use errors with:**

- Medications (drugs or biologics)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)
- Food (including beverages and ingredients added to foods)

**Report product problems – quality, performance or safety concerns such as:**

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

**Report SERIOUS adverse events. An event is serious when the patient outcome is:**

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

**Report even if:**

- You're not certain the product caused the event
- You don't have all the details
- Just fill in the sections that apply to your report

**How to report:**

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)

**How to submit report:**

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To fax report: 1-800-FDA(332)-0178
- To report online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves an adverse event with a vaccine, go to <http://vaers.hhs.gov> to report or call 1-800-822-7967.

**Confidentiality:**

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

Please DO NOT RETURN this form to the PRA Staff e-mail above.

**OMB statement:**

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration



8-8 Potential Tobacco Product Violations Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration <b>Potential Tobacco Product Violations Report</b>	Form Approved: OMB No.: 0910-0718 Expiration Date: 07/31/2020 (See page 3 for PRA Statement)
---	--

**Directions:**

Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.

**WHO** can report? - Any member of the public.

Tell us:

**WHEN** did you see the potential violation?

**WHERE** did the potential violation occur?

**WHAT** is the potential violation?

**WHY** report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

To submit your report, complete the form below:

Date and State Where Violation Occurred		
Date potential violation occurred (mm/dd/yyyy)	I do not recall the date this potential violation occurred <input type="checkbox"/>	State in which potential violation occurred <div style="text-align: right;">▼</div>
Description of Product		
Type <div style="text-align: right;">▼</div>	Tobacco Brand	
<b>Potential violation type (choose all that apply)</b>	<input type="checkbox"/> Sales to minors <input type="checkbox"/> Flavored cigarette sales <input type="checkbox"/> Advertising/promotion/marketing <input type="checkbox"/> Vending machine/direct access to cigarette or smokeless tobacco or covered tobacco products	<input type="checkbox"/> Free samples <input type="checkbox"/> Self-service display/direct access to cigarette or smokeless tobacco <input type="checkbox"/> Sale of cigarettes in packs of less than 20 <input type="checkbox"/> Unsure
<b>Type of potentially violative promotional materials (choose all that apply)</b>	<input type="checkbox"/> Newspaper <input type="checkbox"/> Magazine <input type="checkbox"/> Periodicals <input type="checkbox"/> Billboard <input type="checkbox"/> Direct mail <input type="checkbox"/> In-store advertisements	<input type="checkbox"/> Price signage <input type="checkbox"/> Posters <input type="checkbox"/> Coupons <input type="checkbox"/> Internet <input type="checkbox"/> Unsure
<b>Who potentially violated? (choose all that apply)</b>	<input type="checkbox"/> Retailer <input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer	<input type="checkbox"/> Distributor <input type="checkbox"/> Unsure

**Potential Tobacco Product Violations Report**

Description of potential violation

**Name and physical address of the potential violator, if known**

Retailer, manufacturer, importer, or distributor name

Street Address

Street Address Line 2

City

State/Province/Region

Postal/Zip Code

If report is about a website, insert website address:

*All reports will remain private to the extent allowed by law. For more information about FDA's internet policies, please visit: <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm>*

**May we contact you if we need additional information?**

No, I want my report to be anonymous. *(Please note that if you submit this form by email, FDA will receive your email address. However, if you choose "no" FDA will not contact you.)*

Yes, FDA may contact me. *(Please fill in contact information below.)*

Name

Affiliation *(such as company, school, or group)*

Street Address

Street Address Line 2

*(continued on next page)*

**Potential Tobacco Product Violations Report**

City	State/Province/Region
Postal/Zip Code	Phone Number

Email

Please email me to notify me that FDA got my complaint  No  Yes *In order to receive a response, please configure your email spam/junk filter to allow messages from [ctpcompliance@fda.hhs.gov](mailto:ctpcompliance@fda.hhs.gov). In most cases, this is solved by adding our email address to your address book.*

If you would rather submit your report to us in writing, along with any attachments, please do so at the the following address:

Food and Drug Administration  
 Center for Tobacco Products  
 Document Control Center  
 Building 71, Room G335  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

To reach us by telephone, please call 1-877-CTP-1373, and select option 3.  
 You may also email us at [ctpcompliance@fda.hhs.gov](mailto:ctpcompliance@fda.hhs.gov).

An email message automatically will be produced when you click the SUBMIT BY EMAIL button. In the resulting email message, please don't forget to click the "Send" button or its equivalent when you are ready to send the email.

**OMB Paperwork Reduction Act Statement**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden for this collection of information is estimated to average 0.25 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Operations  
 Paperwork Reduction Act (PRA) Staff  
[PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov)

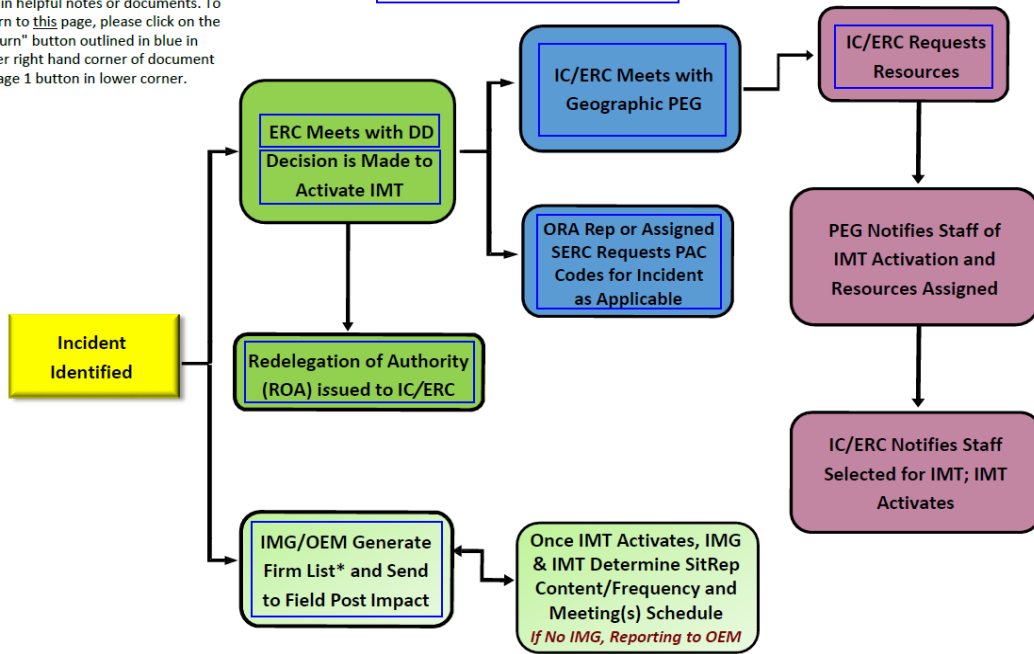
*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

8-9 – Disaster Response Flow Diagram

Please click on outlined words to obtain helpful notes or documents. To return to this page, please click on the "Return" button outlined in blue in upper right hand corner of document or page 1 button in lower corner.

**DISASTER RESPONSE FLOW DIAGRAM**

(Written Description on Pages 3-5)

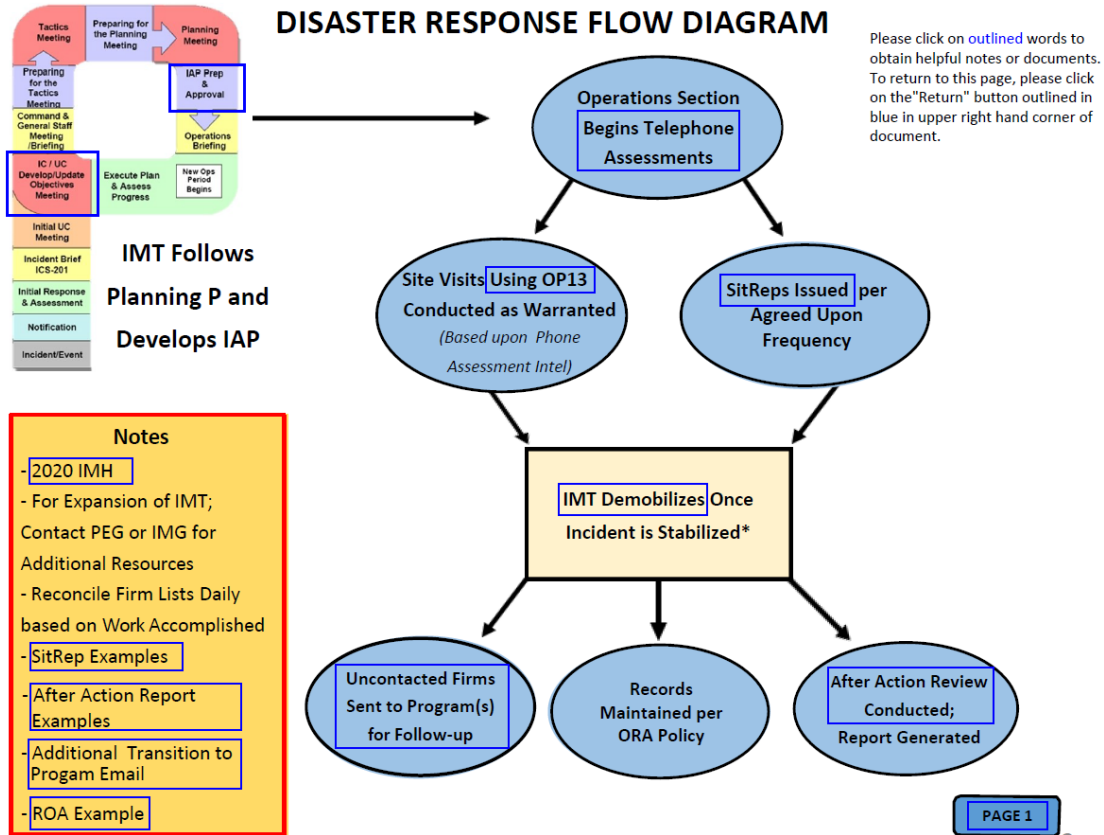


Please Click for Acronym Legend

\*Lists from States and other USG agencies (e.g. USDA, EPA) are received and reconciled to prevent duplication of effort.

NEXT

1



\* Demobilization announced in last SitRep

## Disaster Response Flow Diagram

(Steps are Not Always Sequential)

1. Incident identified.
2. Initial notifications provided to DD/PDD or PEG based on incident.
3. ERC Meets with DD and decision is made to activate IMT. Local PDD may be in this initial meeting. *(Note: When an IMT is not activated, the ERC coordinates the disaster response with the Program Divisions.)*
  - Click link in flow diagram for discussion points for the ERC and DD/PDD meeting and AHOD or refer to page 6
  - Click link in Notes for DD/PDD meeting for Emergency Response Resource and Funding Allocation Memo also referred to as All Hands on Deck (AHOD) memo
  - Click link in flow diagram to see IMT activation flow chart, and link in flow chart for example of PEG notification email
4. Redelelegation of Authority issued to ERC/IC as applicable.
  - Click link for Redelelegation of Authority (ROA) template. (Also see link of completed ROA example in Note Box on Page 2)
5. Initial communication between OEM or IMG (as applicable) and ERC/IC. *(Note: IMG is not activated for all storms; coordination is via OEM/OEO when there is no IMG.)*
  - ERC provides courtesy notification to OEM/IMG of IMT activation
  - OEM/IMG provides a map to ERC of projected area of impact prior to storm
  - OEM/IMG provides Center-vetted firm list for impacted area to PEG with copy to ERC post landfall
  - SitRep frequency and content are established with OEM/IMG. *(Note: When an IMT is not activated, ERC establishes with OEO Coordinator how updates will be provided.)*
6. DD/ERC meets with Geographic PEG to receive response priorities.
  - Click link in flow diagram for discussion points for PEG meeting or refer to page 7
  - Click link on PEG Meeting Notes page for "Current Year" Program Priorities for Disaster Response lists
7. Have ORA Rep or assigned SERC request PAC codes for incident if applicable. Otherwise, use General Disaster PAC Codes.
  - Click link in flow diagram for email with Natural Disaster and Emergencies PAC Codes
8. IC/ERC requests resources for IMT from PEG via Resource Request Form as warranted.
  - Click link in flow diagram for Resource Request form.

19. Telephone assessments and site visits are recorded as Op 13s in eNspect with the documents attached.
20. IMT records (IAP, Sitreps, emails, etc.) are stored in EON.
21. Hotwash is held prior to demobilization of IMT. A formal After Action Review is performed with IMT participants shortly after demobilization and an After Action Report generated.
  - Click link in flow diagram for Tips for Conducting an After Action Review (Also see link of After Action Report Examples in Note Box)

*(Note: Click on Acronym Link on Page 1 for list of Acronyms used in document or refer to Page 8)*

- Get IT assistance commitment
- Suggest initiation of **ALL HANDS ON DECK** as applicable
- Discuss number of resources and proposed length of activation
- Discuss Delegation of Authority
- Ensure PDD communicates resource commitment to supervisory level

Notes:

No completing of OEI forms. If a firm is OOB, an email or Disaster Telephone Assessment form will be sent to OEI coordinator.

Run ORADSS report prior to meeting for general picture of potential impact

## Acronym Legend

[RETURN](#)

- AAR = After Action Report or After Action Review
- AHOD = All Hands on Deck
- DD = District Director
- EPA = Environmental Protection Agency
- ERC = Emergency Response Coordinator
- FSC = Finance Section Chief
- HQ = Headquarters
- IAP = Incident Action Plan
- IC = Incident Commander
- ICP = Incident Command Post
- ICS = Incident Command System
- IMG = Incident Management Group
- IMH = Incident Management Handbook
- IMT = Incident Management Team
- LSC = Logistics Section Chief
- OEM = Office of Emergency Management
- OEO = Office of Emergency Operations
- Op13 = Operation 13
- ORA = Office of Regulatory Affairs
- ORS = Office of Regulatory Science
- OSCP = Office of State Cooperative Programs
- PAC = Program Assignment Codes
- PD = Program Director
- PDD = Program Division Director
- PEG = Program Executive Group
- ROA = Redelelegation of Authority
- SERC = Senior Emergency Response Coordinator
- SitRep = Situation Report
- UC = Unified Command
- USDA = United States Department of Agriculture
- USG = United States Government



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