# CHAPTER 1 – ADMINISTRATION

# 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 that 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/COMMERCIALLY 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 cased 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 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 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/ORA 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 1.2.2.2.2 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 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.

## 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.) 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, photo-graphic 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 athttps://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 Councel, 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.

## 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/HowtoMakeaFOIARequest/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/ershdb/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 Saftey 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 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.**

### 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 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”. 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 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/ORA/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/Ps 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 (OBSO-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 (OBSO-IO)

The Office of Business and Safety Operations-Immediate Office (OBSO-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 MANAGMENT (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/OfficeofFoods/CFSAN/default.htm

CBER - See https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/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/OfficeofFoods/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. 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. 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/emaillist.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.

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/HowtoMakeaFOIARequest/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, 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

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 |
|---|---|---|---|
| **BAGGAGE**<br>1. All fees pertaining to the first checked bag | xx | xx | |
| 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 FTR 301-70.300) | xx | xx | xx |
| 3. Excess Baggage Charges for government property | xx | xx | xx[1] |
| 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[2] |
| 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 |
| **FEES OR TIPS**<br>1. Tips – Allowable tips are 15 percent of the reimbursable fare. | xx | xx (over $75) | |
| 2. Parking Fees - charges for parking automobiles | xx | 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[3] |
| 4. Traveler Checks<br>Money Orders<br>Certified Checks<br>Transaction Fees for use of Automated Teller Machines (ATMs) – Government contractor issued charge card | xx<br>xx<br>xx<br>xx | xx<br>xx<br>xx<br>xx | |
| 5. Registration Fees – Attendance at local non-government sponsored meetings<br>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.<br>b. J.P. Morgan Convenience Checks<br>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<br>Please see your Administrative Officer for additional information and guidance when requesting payment of registration fees. | xx<br>xx<br>xx | xx<br>xx<br>xx | xx<br>xx<br>xx |
| 6. Exchange of Currency<br>a. Allowed | xx | xx | |

| | | | |
|---|---|---|---|
| i. Fees for cashing U.S. Government checks or drafts reimbursing traveler for travel expenses only incurred in foreign countries<br>ii. Commissions for conversion of currency in foreign countries<br>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.<br>b. Not allowed: exchange fees for cashing checks or drafts issued in payment of salary. | xx<br>xx | xx[4]<br>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 | |
| **HIRE OF ROOM**<br>1. Allowed when necessary to engage a room in a hotel or other place to transact official business | xx | xx | xx[6] |
| 2. Not allowed for personal use (cost included in subsistence allowance). | | | |
| **PERSONAL SERVICES**<br>1. Stenographic and typing services, guides, interpreters, drivers of vehicles, etc. | xx | xx | xx[5] |
| **POSTAGE**<br>Postage necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail. | xx | xx | xx[7] |
| **POST OFFICE BOX RENTAL**<br>Where necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail. | xx | xx | xx |
| **PUBLIC TRANSPORTATION WHILE IN TRAVEL STATUS**<br>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[8] |
| Public transportation fares between places where meals are taken, and places of business or places of lodging **are not** 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. | | | |
| **TAXICABS WHEN USED LOCALLY WHILE IN TRAVEL STATUS**<br>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[8] |
| 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[8] |
| Limousine service plus taxicab tip rates between airport and limousine pick-up or discharge point | xx | xx (over $75) | |
| **TELEPHONE CALLS / INTERNET CHARGES**<br>1. Official Business – Charges for local and long distance calls are allowed when made on official business | | xx[9, 10] | |
| 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) | |
| **RECORDS** Charges for copies of records furnished by State officials, such as Clerks of Courts, etc., when necessary for performance of official business | | xx | xx[5] |
| **SHIPMENTS (FREIGHT OR EXPRESS)** - see IOM 4.5.5 | | xx | xx[12] |
| **MISCELLANEOUS EXPENSES**<br>1. Cash used in lieu of transportation request for passenger transportation and accommodations.<br>2. Purchase of emergency supplies.<br>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<br>xx<br>xx | xx<br>xx<br>xx | xx[5] |
| **LAUNDRY EXPENSES**<br>1. Employees will be reimbursed for laundry, cleaning, and pressing expenses equal to the number of travel days multiplied by $5.<br>a. For CONUS travel, employees must be on travel for four or more nights.<br>b. Employees on OCONUS travel are not permitted to claim separate laundry expenses | | xx | |

FOOTNOTES:

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

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