

CHAPTER 3 - FEDERAL AND STATE COOPERATION

SUBCHAPTER 3.1 - COOPERATIVE EFFORTS.....	3-2	3.2.5.2.9 - STEPS FOR CONDUCTING A SPECIAL SECRET SERVICE INVESTIGATION.....	3-12
3.1.1 - POLICY.....	3-2	3.2.5.2.10 - SAMPLING.....	3-13
3.1.2 - LAWS, CODES, AGENCIES.....	3-2	3.2.5.2.11 - REPORTING.....	3-13
3.1.2.1 - Agreements and Memoranda of Understanding (MOU).....	3-2	3.2.6 - DEPARTMENT OF JUSTICE.....	3-14
3.1.3 - OTHER GOVERNMENT INSPECTION.....	3-3	3.2.6.1 - U.S. Attorney.....	3-14
3.1.3.1 - Federal.....	3-3	3.2.6.2 - Drug Enforcement Administration (DEA) (Formerly: Bureau of Narcotics).....	3-14
3.1.3.2 - Discussion with Federal Inspector.....	3-3	3.2.6.3 - Federal Bureau of Investigation (FBI).....	3-14
3.1.3.3 - State and Local.....	3-3	3.2.6.4 - U.S. Marshals Service.....	3-14
SUBCHAPTER 3.2 - FEDERAL AGENCY INTERACTION.....	3-3	3.2.7 - DEPARTMENT OF LABOR: OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA).....	3-14
3.2.1 - U. S. DEPARTMENT OF AGRICULTURE (USDA).....	3-3	3.2.8 - TREASURY DEPARTMENT.....	3-14
3.2.1.1 - Foods Rejected by USDA.....	3-3	3.2.8.1 - Alcohol and Tobacco Tax and Trade Bureau (TTB).....	3-14
3.2.1.2 - USDA Complaints.....	3-4	3.2.8.2 - Internal Revenue Service (IRS).....	3-15
3.2.1.3 - USDA Acts.....	3-4	3.2.9 - DEPARTMENT OF VETERANS AFFAIRS VETERANS ADMINISTRATION (VA).....	3-15
3.2.1.4 - FDA-USDA Agreements & MOUs.....	3-4	3.2.10 - CONSUMER PRODUCT SAFETY COMMISSION (CPSC).....	3-15
3.2.1.5 -.....	3-4	3.2.11 - ENVIRONMENTAL PROTECTION AGENCY (EPA).....	3-15
3.2.1.6 - Animal Plant Health Inspection Service/USDA (APHIS).....	3-6	3.2.11.1 - EPA MOUs.....	3-15
3.2.1.7 - Federal Grain Inspection Service/ USDA (FGIS).....	3-6	3.2.12 - AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR).....	3-16
3.2.1.8 - Food Safety and Inspection Service/USDA (FSIS).....	3-6	3.2.13 - FEDERAL TRADE COMMISSION (FTC).....	3-16
3.2.1.9 - Science and Education Administration/USDA (SEA).....	3-7	3.2.14 - U.S. NUCLEAR REGULATORY COMMISSION (NRC).....	3-16
3.2.2 - U.S. DEPARTMENT OF COMMERCE (DOC).....	3-7	3.2.15 - U.S. POSTAL SERVICE (USPS).....	3-17
3.2.2.1 - Commerce (DOC).....	3-7	3.2.15.1 - Change of Address Information.....	3-17
3.2.2.2 - National Oceanic and Atmospheric Administration (NOAA) - National Marine Fisheries Service (NMFS).....	3-7	3.2.15.2 - Postal Box Information.....	3-17
3.2.2.3 - U.S. Patent and Trademark Office (USP&TO) (DOC).....	3-7	3.2.15.3 - Authority.....	3-17
3.2.3 - DEPARTMENT OF DEFENSE (DOD).....	3-7	3.2.16 - FIRM LOCATIONS.....	3-17
3.2.3.1 - DOD MOUs.....	3-7	3.2.17 - FEDERAL FOOD SAFETY COALITION.....	3-18
3.2.3.2 - U.S. Army Corps of Engineers (DOD).....	3-7	SUBCHAPTER 3.3 - STATE OPERATIONAL AUTHORITY.....	3-18
3.2.3.3 - U.S. Army Medical Research and Development Command (DOD).....	3-8	3.3.1 - STATE OPERATIONAL AUTHORITY.....	3-18
3.2.3.4 - Defense Personnel Support Center (DPSC).....	3-8	3.3.1.1 - FDA Personnel with State Authority.....	3-18
3.2.3.5 - Department of Navy/Bureau of Medicine and Surgery.....	3-8	3.3.1.2 - Joint Inspections.....	3-19
3.2.3.6 - Defense Health Agency (DHA), Public Health Division, Veterinary Services Branch (DHA VS) (DoD).....	3-8	3.3.1.3 - FDA Commissioned State Personnel.....	3-19
3.2.3.6.1 - DoD/FDA Liaisons.....	3-8	3.3.2 - STATE MEMORANDA OF UNDERSTANDING.....	3-19
3.2.4 - DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS).....	3-8	3.3.3 - STATE AUTHORITIES AND PHONE CONTACT NUMBERS.....	3-19
3.2.4.1 - HHS MOUs.....	3-8	3.3.3.1 - Alabama (AL).....	3-19
3.2.4.2 - Administration for Children, Youth and Families (ACYF).....	3-8	3.3.3.2 - Alaska (AK).....	3-19
3.2.4.3 - Centers for Disease Control and Prevention (CDC).....	3-8	3.3.3.3 - Arizona (AZ).....	3-19
3.2.4.3.1 - INTERVIEWS.....	3-9	3.3.3.4 - Arkansas (AR).....	3-19
3.2.4.3.2 - INFORMATION EXCHANGE AND COORDINATION.....	3-9	3.3.3.5 - California (CA).....	3-19
3.2.4.3.3 - ROUTINE REQUESTS FOR INFORMATION.....	3-9	3.3.3.6 - Colorado (CO).....	3-19
3.2.4.3.4 - EMERGENCY REQUESTS FOR CONFIDENTIAL INFORMATION.....	3-10	3.3.3.7 - Connecticut (CT).....	3-20
3.2.4.3.5 - LIAISON OFFICERS.....	3-10	3.3.3.8 - Delaware (DE).....	3-20
3.2.4.4 - Centers for Medicare and Medicaid Services (CMS).....	3-10	3.3.3.9 - Florida (FL).....	3-20
3.2.4.5 - Health Services Administration (HSA).....	3-10	3.3.3.10 - Georgia (GA).....	3-20
3.2.4.6 - National Center for Health Statistics (NCHS).....	3-10	3.3.3.11 - Hawaii (HI).....	3-20
3.2.4.7 - National Institute of Drug Abuse (NIDA).....	3-10	3.3.3.12 - Idaho (ID).....	3-20
3.2.4.8 - National Institutes of Health (NIH).....	3-10	3.3.3.13 - Illinois (IL).....	3-20
3.2.5 - DEPARTMENT OF HOMELAND SECURITY.....	3-10	3.3.3.14 - Indiana (IN).....	3-20
3.2.5.1 - U.S. Customs and Border Protection.....	3-10	3.3.3.15 - Iowa (IA).....	3-20
3.2.5.2 - Secret Service.....	3-10	3.3.3.16 - Kansas (KS).....	3-20
3.2.5.2.1 - LIAISON.....	3-11	3.3.3.17 - Kentucky (KY).....	3-20
3.2.5.2.2 - DEFINITIONS.....	3-11	3.3.3.18 - Louisiana (LA).....	3-20
3.2.5.2.3 - PURPOSE.....	3-11	3.3.3.19 - Maine (ME).....	3-20
3.2.5.2.4 - CRITERIA FOR REQUESTING FDA ASSISTANCE.....	3-12	3.3.3.20 - Maryland (MD).....	3-20
3.2.5.2.5 - SCOPE OF INVESTIGATION.....	3-12	3.3.3.21 - Massachusetts (MA).....	3-20
3.2.5.2.6 - INTERAGENCY COOPERATION.....	3-12	3.3.3.22 - Michigan (MI).....	3-21
3.2.5.2.7 - DISTRICT CONTACT.....	3-12	3.3.3.23 - Minnesota (MN).....	3-21
3.2.5.2.8 - LEAD INVESTIGATOR QUALIFICATIONS.....	3-12	3.3.3.24 - Mississippi (MS).....	3-21
		3.3.3.25 - Missouri (MO).....	3-21
		3.3.3.26 - Montana (MT).....	3-21
		3.3.3.27 - Nebraska (NE).....	3-21
		3.3.3.28 - Nevada (NV).....	3-21

3.3.3.29 - New Hampshire (NH).....	3-21
3.3.3.30 - New Jersey (NJ)	3-21
3.3.3.31 - New Mexico (NM)	3-21
3.3.3.32 - New York (NY).....	3-21
3.3.3.33 - North Carolina (NC)	3-21
3.3.3.34 - North Dakota (ND)	3-21
3.3.3.35 - Ohio (OH)	3-22
3.3.3.36 - Oklahoma (OK)	3-22
3.3.3.37 - Oregon (OR)	3-22
3.3.3.38 - Pennsylvania (PA)	3-22
3.3.3.39 - Rhode Island (RI).....	3-22
3.3.3.40 - South Carolina (SC).....	3-22
3.3.3.41 - South Dakota (SD).....	3-22
3.3.3.42 - Tennessee (TN).....	3-22
3.3.3.43 - Texas (TX)	3-22
3.3.3.44 - Utah (UT)	3-22
3.3.3.45 - Vermont (VT)	3-22
3.3.3.46 - Virginia (VA).....	3-22
3.3.3.47 - Washington (WA).....	3-22
3.3.3.48 - West Virginia (WV).....	3-22
3.3.3.49 - Wisconsin (WI).....	3-22
3.3.3.50 - Wyoming.....	3-23
SUBCHAPTER 3.4 - INTERNATIONAL ARRANGEMENTS.....	3-23
3.4.1 - INTERNATIONAL ARRANGEMENTS.....	3-23
3.4.2 - MUTUAL RECOGNITION AGREEMENTS.....	3-23
3.4.2.1 - European Community	3-23
3.4.2.2 - Food Products	3-23
SUBCHAPTER 3.5 - NON-GOVERNMENT AGREEMENTS.....	3-23
3-1 FDA/USDA JURISDICTION.....	3-24
USDA JURISDICTION.....	3-24
HISTORY OF MENU ITEMS.....	3-26
HISTORY OF MENU ITEMS.....	3-27
ADDRESS INFORMATION REQUEST	3-28

SUBCHAPTER 3.1 - COOPERATIVE EFFORTS

3.1.1 - POLICY

The scope of consumer protection is extended by cooperative efforts of federal, state, and local agencies and international cooperation. Procedures to appropriately share responsibilities and cooperate with our consumer protection partners are essential.

Federal, state, and local cooperation shall be fostered whenever possible. The Agency issues the IOM as well as other FDA manuals to international regulators and conformity assessment bodies, and state and local inspectors. FDA fosters cooperation through correspondence, FDA testimony, press releases, reprints from the Federal Register, and distribution of all pertinent policy and regulations issued by FDA which have significance in other regulatory jurisdictions. The Agency may share FDA's non-public information as long as the sharing complies with the Agency's confidentiality laws and procedures.

Districts, headquarters' offices, and resident post personnel in particular, should maintain liaison with federal, state and local officials.

Follow District policy regarding contacts with appropriate federal, state, county and local officials to exchange information, coordinate operations, and arrange joint inspections. If an assignment calls for joint work with state or local inspectors, make every effort to accomplish this work. See IOM 3.3.1. When you travel internationally, follow policy established in the "GUIDE TO INTERNATIONAL INSPECTIONS AND TRAVEL."

3.1.2 - LAWS, CODES, AGENCIES

Many states have enacted the basic Uniform Food, Drug, and Cosmetic Bill, and others have adopted at least a part of the Uniform Bill. The provisions of these laws are very similar to the 1938 provisions of the Federal Food, Drug, and Cosmetic Act. A few states have enacted the Pesticide Food and Color Additives or Kefauver-Harris type amendments. See IOM 3.3.3.

Most states without the Uniform FD&C Act, have laws based on the 1906 Food and Drug Act. Most larger cities have their own ordinances and regulations. A portion of the food supply of the United States is consumed within the state in which it is produced, and is therefore, not directly under the jurisdiction of the Federal Food, Drug and Cosmetic Act as amended. Thus, the various state and local agencies are solely responsible for policing this supply.

The departments of the executive branch of the federal government operate under the laws and regulations which they are specifically responsible for enforcing. Since responsibilities may overlap and be duplicated, operating agreements and liaison between agencies is essential for smooth and efficient governmental operation. Section 702(c) of the FD&C Act [[21 U.S.C. 372\(c\)](#)] recognizes this by providing that the records of any department in the executive branch shall be open to inspection by authorized DHHS personnel.

District management is responsible for maintaining official liaison between FDA and other federal agencies. However, for day by day operations, personal contact between various operating federal investigators, inspectors, and agents is desirable and encouraged.

3.1.2.1 - Agreements and Memoranda of Understanding (MOU)

It is FDA's policy to enter into MOUs with other entities in situations in which there are a need to define lines of authority or responsibility, or to clarify cooperative procedures (see SMG 2820.1). FDA and various agencies often enter into formal or informal agreements, and/or understandings to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities. These agreements and understands specify areas of primary responsibility.

Prior to disclosing FDA's information, ensure that the

Agreement and MOU contain confidentiality provisions that comply with FDA's information disclosure laws and procedures (e.g., sharing with the public (FOI), federal government officials [21 CFR 20.85](#), state/local [21 CFR 20.88](#), foreign [21 CFR 20.89](#)). Contact DIDP's ORA OSPOP Testimony – Info Sharing Team ORainfoshare@fda.hhs.gov when encountering an MOU for the first time, drafting an MOU, or for clarification of disclosure

A complete listing (domestic, academia and non-profit) is publicly available on the [FDA MOUs page](#)

3.1.3 - OTHER GOVERNMENT INSPECTION

General procedures regarding cooperation with other federal, state, and local officials are furnished below.

During establishment inspections determine the specific type of inspection service and inspecting units, such as the name of the federal, state, county, or city health agency or department. Obtain the name and title of the inspectional official, and general method of operation. IOM 5.4.9.3 discusses coverage of grade A Dairy Plants.

3.1.3.1 - Federal

Compulsory Continuous Inspection - Do not inspect firms, or that portion of a plant, under compulsory, continuous inspection under United States Department of Agriculture's (USDA) Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act, except on specific instructions from your supervisor or assignment document.

Ingredients or manufacturing processes common to both USDA and FDA regulated products should be inspected by FDA. See IOM 3.2.1.3 for FDA/USDA Agreements in specific areas.

Provide routine FDA coverage of such firms as breweries and wineries, which may be intermittently inspected on a compulsory basis by the U.S. Treasury Department, U.S. Public Health Service, or other agencies.

Voluntary - All products inspected under the voluntary inspection service of the Agriculture Marketing Service (AMS), USDA, and the National Marine Fisheries Service (NMFS), US Department of Commerce, are subject to FDA jurisdiction and are usually given routine coverage; however, formal written Agreements or a MOU between FDA and other agencies are often executed and may govern the agreeing agencies' operations on these types of inspected plants.

3.1.3.2 - Discussion with Federal Inspector

If you are assigned to cover a federally inspected plant which is under either compulsory or voluntary inspection,

check to see if an Agreement or a MOU exists between FDA and the agency involved to determine the obligations of both agencies. When you arrive at the firm:

1. Identify yourself to the inspector(s) and invite him/her to accompany you on the inspection but do not insist on their participation.
2. At the conclusion of the inspection, offer to discuss your observations and provide the in-plant inspector with a copy of your Inspectional Observations (FDA 483).

3.1.3.3 - State and Local

State and local officials usually have extensive regulatory authority over firms in their area regardless of the interstate movement or origin of the food products involved. Joint FDA-State or local inspections are occasionally conducted. These are usually arranged by district administrative or supervisory personnel. See IOM 3.3.1.

SUBCHAPTER 3.2 - FEDERAL AGENCY INTERACTION

This subchapter deals with the interaction of the FDA with other federal agencies. This interaction will be discussed below. Each agency with which FDA has agreements or an MOU is listed separately. Information regarding MOUs and other interactions are discussed as appropriate. Information about the complete MOU or agreement can be found in the appropriate Cooperative Agreements Manual. Listings of all Liaison Officers are included below.

3.2.1 - U. S. DEPARTMENT OF AGRICULTURE (USDA)

See IOM 3.1.3 for procedures to be followed when making inspections of firms under USDA inspection or subject to inspection by USDA.

3.2.1.1 - Foods Rejected by USDA

All procurement and processing contracts administered by USDA for edible food products require compliance with FDA regulations. The USDA routinely reports to the FDA its findings on lots of flour, cereal, or other products which have been rejected for acceptance into USDA-sponsored programs, based on FDA guidelines. This notification of rejection is routinely furnished to the involved District office. When a District office receives such notification, it will determine appropriate follow-up by evaluating the reason for rejection, current priority assignments, and workload.

Samples should not be routinely collected from the USDA rejected material. If a follow-up inspection is made the District will then determine the need for samples or additional action.

3.2.1.2 - USDA Complaints

Whenever a complaint is received involving any meat-containing product, including such items as soups, combination infant foods, frozen dinners, etc., evaluate the need to contact USDA. Most products containing red meat or poultry are regulated by USDA. The exceptions include:

1. Products containing meat from game animals, such as venison, rabbits, etc.
2. Meat-flavored instant noodles
3. The product "pork and beans" which contain only a small amount of pork fat and for historic reasons is regulated by FDA.

Determine from the consumer whether there is a round "shield" on the label with the USDA establishment number. Alternatively, the establishment number may be identified in the lot number. Red meat products under USDA jurisdiction will often contain the abbreviation "EST" followed by a one to four-digit number; poultry products under USDA jurisdiction will contain the letter "P" followed by a number.

FDA reports suspected outbreaks to USDA and CDC. In addition, FDA and CDC have an agreement that FDA will be immediately advised whenever CDC ships botulism antitoxin anywhere in the United States or its possessions. See IOM 3.2.4.3 regarding interaction with CDC.

USDA and FDA have an agreement whereby FDA informs a designated USDA Compliance and Evaluation Area Office about any foodborne disease where a meat or poultry product is suspected. Conversely, USDA will alert the FDA District office on suspected products subject to FDA jurisdiction. In order for your District to alert USDA promptly, check with your supervisor immediately if meat or poultry products are involved in an outbreak you are investigating, or which comes to your attention.

3.2.1.3 - USDA Acts

The following USDA Acts under which FDA has been delegated detention authorities for products subject to USDA inspection are:

1. Federal Meat Inspection Act (FMIA) see IOM 2.7.1.2.2
2. Poultry Products Inspection Act PPIA see IOM 2.7.1.2.3
3. Egg Products Inspection Act (EPIA) see IOM 2.7.1.2.4

See IOM 2.7.1 for additional information. See IOM Exhibit 3-1 for a chart depicting jurisdictional lines for products regulated by FDA and USDA.

3.2.1.4 - FDA-USDA Agreements & MOUs

MOUs and Agreements with USDA and its various units will be listed and, in some cases, described below. This first subsection covers MOUs with the USDA, USDA/other agency, and FDA. The following subsections provide information about MOUs with other USDA units.

MOU with:

1. US Department of Commerce and USDA Concerning Inspection of Industrial Fishery Products Intended for Animal 315 Feed Use ([225-75-7001](#)).
2. USDA, NIH Regarding Importation of Biological Specimens under US/USSR Scientific Exchange Agreement ([225-74-1010](#)).
3. USDA and DHHS Regarding General War Food Inspection ([225-75-8004](#)).
4. USDA Concerning the trade facilitation of milk and milk products exported from the United States ([225-20-017](#)).

3.2.1.5 - Agricultural Marketing Service (AMS)/ USDA (MOUs)

MOU with:

1. AMS Concerning the Inspection and Grading of Food Products (225-72-2009).

This MOU has extensive separation of duties between AMS and FDA.

Both agencies agree to maintain a close working relationship, in the field as well as headquarters. Both agencies will work with industry toward greater efficiency connected with improvement of coding methods. Each agency will designate a central contact point to which communications dealing with this agreement or other issues may be referred to for attention.

The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).

The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).

2. AMS Regarding the Egg Products Inspection Act. FDA has exclusive jurisdiction over restaurants, institutions, food manufacturing plants, and other similar establishments, that break and serve eggs or use them in their products (225-75-4003).

AMS shall notify FDA whenever it has reason to believe that shell eggs or egg products have been shipped in commerce in violation of the act to a receiver for which FDA has exclusive jurisdiction, and notify FDA when applications are made to import shell eggs into the U.S. FDA will notify AMS so that they can check on the seller of any restricted eggs when it is determined that more restricted eggs than are allowed in U.S. Consumer Grade B. are encountered. FDA will also notify AMS of any unwholesome egg products it encounters, including imported shell eggs which contain restricted eggs not in accordance with USDA regulations and labeling requirements.

The FDA Liaison Officer is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).

The FDA Liaison Officer for imported shell eggs is the Branch Chief, Import Product Adulteration Branch, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-606 (1-888-723-3366).

The USDA Liaison Officer is the Deputy Administrator, Poultry Program, Agricultural Marketing Service (202-

- 720-4476).
3. AMS Concerning Imported Dates and Date Material (225-72-2001).
 FDA inspects samples and examines imported dates and date products intended for processing to determine whether they are in compliance with the statute.
 AMS, upon request, will provide FDA with a copy of each examination report which will contain information such as that in the FDA Technical Bulletin Number 5, Microanalytical Procedures Manual.
 The FDA Liaison Officer is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).
 The USDA Liaison Officer is the Chief, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service (202-720-4693).
 4. AMS Concerning Cooperative Efforts for Inspection, Sampling, and Examination of Imported Raisins (225-73-2007).
 AMS evaluates raisins for grade condition requirements and at the time and place of entry all lots of imported raisins. Upon completion of the examination, AMS promptly notifies the appropriate FDA District Office of any lots found not to meet minimum acceptance criteria because of insect infestation, filth, etc., and any questionable cases regarding the laboratory examination results. At the end of the season, the AMS provides FDA with a copy of each examination report.
 FDA accepts, unless it notifies USDA to the contrary, AMS findings on any lot of raisins sampled and inspected by them. FDA will detain any lots of raisins rejected by USDA because they contain insect infestation, etc. See the cooperative agreement manual for details of responsibilities.
 The FDA Liaison Officer is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).
 The USDA Liaison Officer is the Chief, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service (202-720-4693).
 5. AMS Regarding Aflatoxin Testing Program for In-Shell Brazil Nuts (225-96-2002).
 Importers of Brazil Nuts voluntarily offer for USDA inspections before introducing them into U.S. commerce. USDA is responsible for sampling and testing each lot for aflatoxin in accordance with procedures prescribed by FDA and for issuing an analysis certificate for each lot. The Agricultural Marketing Service (AMS) will forward a copy of each certificate to the appropriate FDA District office. FDA accepts the certificate and then allows entry of the lots into U.S. commerce provided the aflatoxin level does not exceed the current action level prescribed by FDA.
 The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).
 The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).
 6. AMS Concerning Aflatoxin in Peanuts (225-96-2001).

- AMS will use FDA administrative guidelines on objective samples to certify peanuts, recognizing that GMPs remove significant quantities of unfit peanuts and that levels of aflatoxin are reduced by heating. USDA will provide FDA with a copy of the analytical certificate and identification of the applicant on each lot found to exceed 25 ppb of aflatoxin and the analysis certificate on any lot on request. FDA will routinely confirm chemical assays in finished product at 20 ppb by bioassay procedures.
- FDA will not formally object to the offering of lots of peanuts to processors where certificates show levels of aflatoxin above 25 ppb but will examine finished products from such lots. Such lots of raw peanuts may be subject to appropriate action in cases where there is lack of assurance that the finished product will comply with current standards.
- The FDA Liaison Officer is the Director, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-600 (240-402-1364).
 The USDA Liaison Officer is the Chief of Technologies Services Branch, Science Division, AMS (202-690-4025).
7. AMS and FSIS and EPA re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8910).
 Parts of this MOU are discussed below. Information about the complete MOU can be found in the appropriate Cooperative Agreements Manual. The contact offices are as follows:
 The FDA Liaison Office is the Director, Division of Natural Products, Microanalytical Branch, Center for Food Safety and Applied Nutrition, HFS-315 (240-402-1990).
 The USDA Liaison Office is the Administrator, Food Safety and Inspection Service (202-720-7025).
 The EPA Liaison Office is the Office of Pesticide Programs, (703-305-7090), or Health Effects Division, (703-305-7351).
 8. AMS Concerning Salmonella Inspection and Sampling Coverage of Dry Milk Plants (225-75-4002).
 Parts of this MOU are discussed below. Information about the complete MOU can be found in the appropriate Cooperative Agreements Manual.
 USDA has two types of voluntary inspection programs: Plant Inspection Program for USDA Approved for Grading Services, and their Resident Inspection and Grading Program.
 Plant Inspection Program (PIP). Under the PIP, dry milk plants are surveyed for approval every three months. This includes a salmonella surveillance testing of the plant's product and environmental material. Product inspection and grading is provided on request and dry milk products produced under this program are eligible to bear the USDA shield.
 FDA will accept the AMS Salmonella Surveillance Program results on such plants and the finished dry milk products after shipment from those plants will not be sampled by FDA for Salmonella examinations. This does not preclude FDA sampling dry milk at manufacturing plants using dry milk as an ingredient as a follow-up to consumer complaints, or where the dry milk may have become contaminated or adulterated

after leaving the dry milk manufacturer's control. Neither will it preclude FDA inspections of any plant for problems other than Salmonella whether or not such plant produces dry milk products under USDA inspection, or the sampling of their products, including dry milk products, for problems other than Salmonella. The FDA Liaison Office is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).

The USDA Liaison Office is the Chief, Grading Branch, Dairy Division, Agricultural Marketing Service, (202-720-3171) or Chief, Standardization Branch, (202-720-7473).

3.2.1.6 - Animal Plant Health Inspection Service/USDA (APHIS)

MOU with APHIS Concerning Mutual Responsibilities for Regulating Biological Products (225-82-7000).

Referral and exchange information for purposes of investigation and appropriate legal action. To coordinate investigations and enforcement actions and to avoid duplication of effort, FDA and USDA agree to provide each other with any information which may be germane to either agency's enforcement functions. Information regarding pending investigations and enforcement actions shall be provided to the liaison officers noted below on a regular basis.

The FDA Liaison Office is the Director, Office of Surveillance and Compliance, Center for Veterinary Medicine, HFV-200, (240-453-6830).

The USDA Liaison Office is the Director, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, (301-734-8245).

APHIS and NIH Regarding the Care and Welfare of Laboratory Animals.

3.2.1.7 - Federal Grain Inspection Service/USDA (FGIS)

MOU with FGIS Concerning Inspection of Grain, Rice, Pulses, and Food Products (225-80-2000).

During an FDA inspection of any facility that processes, packs, or holds agricultural products, the investigator and or inspector will request that the FGIS inspector or licensee stationed at a facility accompany him/her during the inspection.

The inspector/investigator will request from FGIS any information concerning quality determinations of specific lots of products against which FDA has taken or may take action.

FDA will notify FGIS of any details concerning serious objectionable conditions found by FDA to exist in processing plants, packing plants, grain elevators, or any other facility where FGIS provides official services.

General matters involving this agreement may be referred to the agencies' liaison officers.

The FDA Liaison Office is the Director, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, HFS-300, (240-402-1488) or Director, Division of Programs and Enforcement Policy, Center for Food Safety and Applied Nutrition, HFS-305, (240-402-1988).

The USDA Liaison Office is the Director, Field Management Division, Federal Grain Inspection Service, Grain Inspection, Packers and Stockyards Administration (202-720-0228).

3.2.1.8 - Food Safety and Inspection Service/USDA (FSIS)

1. FSIS Pertaining to Class I and Class II Recalls of Food Products that Contain Poultry and/or Meat Products that have been Manufactured in a FSIS Inspected Establishment (225-75-4072);

FDA and FSIS agree that they will keep the customary records and make those related to the operation of this agreement available to the other agency. Both agencies will furnish reports of the progress of the work and such other reports as may be mutually agreed upon from time to time between cooperating parties.

The FDA Liaison Officer is the Director, Office of Emergency Operations, HFA-615, (866-300-3474). The USDA Liaison Officer is the Director, Emergency Planning Office, Food Safety and Inspection Service (301-504-2121)

2. FSIS Concerning Inspection of Food Manufacturing Firms FDA investigators will attempt to contact any on-site FSIS inspectors when they arrive at a plant, invite them to participate in the inspection and discuss with or report any adverse findings involving meat and poultry products to that inspector prior to leaving the premises (225-99-2001).

When report findings are classified "indicated" FDA will provide FSIS with a copy when the plant is also inspected by FSIS.

If the FDA investigator has found unsanitary conditions or otherwise adulterated products, the appropriate FSIS office should be informed by telephone unless the FDA investigator has already reported his findings to the FSIS inspector at the plant.

To any extent possible, consider information provided by FSIS to minimize duplication of effort.

The FDA Liaison Office is the Director, Office of Emergency Operations, HFA-615, (866-300-4374).

The USDA Liaison Office is the Deputy Administrator, Field Operations, Food Safety and Inspection Service (202-720-8803).

3. FSIS and AMS and EPA re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8400).
4. FSIS (NE and SE Regional Offices), DE Department of Agriculture, MD Department of Agriculture, PA Department of Agriculture, VA Department of Agriculture and Consumer Services, WV Department of Agriculture Regarding Regulatory Investigations Involving Drug, Pesticide, and Industrial Chemical Residues in Animal Feeds and Meat and Poultry (225-76-4002).
5. FSIS and GA Department of Agriculture Regarding Regulatory Investigations Involving Drug, Pesticide, and Toxic Chemical Residues in Animal Feeds and in Meat Tissues (225-91-4000).

3.2.1.9 - Science and Education Administration/USDA (SEA)

MOU with SEA Concerning Educational Programs in the Use of Animal Drugs (225-78-1002).

3.2.2 - U.S. DEPARTMENT OF COMMERCE (DOC)

3.2.2.1 - Commerce (DOC)

MOUs with DOC and USDA Concerning Inspection of Industrial Fishery Products Intended for Animal Feed Use.

3.2.2.2 - National Oceanic and Atmospheric Administration (NOAA) - National Marine Fisheries Service (NMFS)

MOU with:

1. NOAA/NMFS Regarding Inspection Programs for Fishery Products (225-76-2001) - The National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA), Department of Commerce, operating under the authority of the Agriculture Marketing Act and the Fish and Wildlife Act is responsible for the development and advancement of commercial grade standards for fishery products and better health and sanitation standards in the industry and for furnishing inspection, analytical, and grading services to interested parties. The major purpose is to encourage and assist industry in improving the quality and safety of its products. This MOU outlines joint responsibilities between NOAA and FDA. See IOM 3.1.3 for guidance on joint inspections when inspecting firms under the voluntary NMFS program.
The FDA Liaison Office is the Policy Guidance Branch, Division of Programs and Enforcement Policy, Office of Seafood, Center for Food Safety and Applied Nutrition, HFS-416 (240-402-2545).
The NMFS Liaison Office is the Seafood Inspection Program, Department of Commerce, NOAA (301-713-2355).
2. NOAA/NMFS Concerning Enforcement of Laws (225-86-2000) - Against Illegal Commerce in Molluscan

Shellfish.

FDA will support NMFS Lacey Act investigations to the extent that regulatory authority and resources allow. This may include conducting food sanitation inspections of suspect shellfish shippers, reviewing interstate shipping records and obtaining affidavits to the extent possible, collecting and analyzing shellfish samples to be used as evidence of violations, and removing adulterated shellfish from the marketplace. Refer to the appropriate Cooperative Agreements manual for further discussion of this MOU.

The FDA Liaison Office is the Policy Guidance Branch, Division of Programs and Enforcement Policy, Office of Seafood, Center for Food Safety and Applied Nutrition, HFS-416 (240-402-2545).

The NMFS Liaison Office is the Seafood Inspection Program, Department of Commerce, NOAA (301-713-2355).

3.2.2.3 - U.S. Patent and Trademark Office (USP&TO) (DOC)

MOUs with:

1. USP and TO/DOC Concerning Orphan Drugs (225-84-8000).
2. USP and TO/DOC to Establish a Product's Eligibility for Patent Term Restoration (225-86-8251).
3. DOD Concerning Food Protection (Food Safety and Food Defense) (225-16-020)

3.2.3 - DEPARTMENT OF DEFENSE (DOD)

FDA has a number of MOUs with DOD and its various elements.

3.2.3.1 - DOD MOUs

1. DOD Concerning Licensure of Military Blood Banks (225-74-1017).
2. DOD Concerning FDA Responsibility for Quality Assurance of DOD Procured Drugs and Biologics (225-97-4000).
3. DOD Concerning Food Protection (Food Safety and Food Defense) (225-16-020).

FDA also has a number of Interagency Agreements (IAG) with DOD to include IAG with:

1. DOD Concerning Investigational Use of Drugs, Antibiotics, Biologics, and Medical Devices by DOD (224-75-3003).
2. DOD Regarding FDA Quality Assurance Responsibility for DOD Contracts for Medical Devices (224-82-4001).

3.2.3.2 - U.S. Army Corps of Engineers (DOD)

MOU with US Army/Corps of Engineers Concerning Consumer Protection During Natural Disasters.

3.2.3.3 – U.S. Army Medical Research and Development Command (DOD)

MOU with U.S. Army Medical Research and Development Command Regarding Quality Assurance Support for Medical Material Having Military Application (225-99-4000).

3.2.3.4 - Defense Personnel Support Center (DPSC)

1. MOU with DPSC Concerning Exchange of Information Regarding Food and Cosmetic Recalls and Hazardous Food Situations (225-82-4003).
2. The Defense Personnel Support Center purchases vast quantities of foods and drugs for use by the Armed Forces. The products are purchased on contract and must meet standards and contract specifications to be accepted. Any products failing to meet these specifications are rejected. These are mentioned in IOM 3.2.3.1 above.

FDA, under the Government-Wide Quality Assurance Program (GWQAP), furnishes information to the military regarding the capabilities of firms bidding or desiring to bid on government contracts. Occasionally Districts may be requested by the OO/OEIO/DCS/Enforcement Systems Branch to make inspections or collect samples in support of the GWQAP. When this is necessary, OO/OEIO/DCS/Enforcement Systems Branch will provide the District with specific procedures and instructions. DoD depots and hospitals must notify their command centers prior to release of their stocks. For this reason, prior to visiting a U.S. Government installation to collect samples of food, drugs or medical devices, Districts should contact OO/OEIO/DCS/Enforcement Systems Branch (see Directory, ORA Headquarters Directory, Office of Enforcement and Import Operations, Division of Compliance Systems).

3.2.3.5 - Department of Navy/Bureau of Medicine and Surgery

MOU with Dept. of the Navy/Bureau of Medicine and Surgery Regarding the Microwave Oven Survey (225-77-1001).

3.2.3.6 - Defense Health Agency (DHA), Public Health Division, Veterinary Services Branch (DHA VS) (DoD)

MOU with DoD Concerning Food Protection (225-16-020) establishes a mutually acceptable understanding between DoD and FDA that aims to strengthen global food protection programs and supports the medical readiness of the US Armed Forces. Both agencies have agreed to develop information-sharing networks and processes to share information on facility audits; recalls and/or advisories, import alerts, adverse food and supplement events, laboratory findings or methods and other food protection

procedures. Both agencies have further agreed to share laboratory data and research related to food protection including Food Emergency Response Network (FERN) and electronic Laboratory Exchange Network. DoD and FDA are collaborating in the development of food protection capabilities that include: joint inspections; training exercises; meetings and conferences; risk communications; and assessment of risk. All activities are coordinated by the agency Liaisons as per IOM section

3.2.3.6.1 – DoD/FDA Liaisons

FDA's MOU with DoD Concerning Food Protection (225-16-020) requires both agencies to identify and provide points of contact (POCs)/liaisons between DoD and FDA for both routine and emergency situations and exercises.

1. DoD designates the Chief, Inter-Agency Coordination (Food Protection) Officer
2. The FDA Liaison to DoD is Kathryn A. Nagy, 404-253-1225.

3.2.4 - DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

This Agency has a number of MOUs with the Department and other HHS units.

3.2.4.1 - HHS MOUs

MOU with USDA and HHS Regarding General War Food Inspection (225-75-8004).

3.2.4.2 - Administration for Children, Youth and Families (ACYF)

A MOU with ACYF to Assure the Feeding Programs in Head Start Centers Conform to Federal Food Safety and Sanitation Responsibilities (225-89-2000).

3.2.4.3 - Centers for Disease Control and Prevention (CDC)

MOU with:

1. CDC Concerning In-Vitro Diagnostics (225-75-5012).
2. CDC Regarding Radiation Emergencies (225-81-6000).
3. CDC Regarding Exchange of Information and Coordination of Actions (225-82-8000).

Additional information is being provided here because of the close working agreement to assure the prompt exchange of information on suspected foodborne outbreaks.

Since it is essential that any suspected outbreaks be reported promptly to CDC, communicate any information you may learn in connection with foodborne outbreaks to your supervisor as soon as possible. Botulism Antitoxin

Shipments - CDC is responsible for maintaining and shipping necessary supplies of botulinum antitoxin. When CDC makes a shipment of botulinum antitoxin, CDC will immediately, regardless of the day or time, phone the Office of Emergency Operations (OEO), HFA-615, (866-300-4374). The OEO contact will immediately phone the consignee District to advise them of the shipment.

1. Outbreaks on Foreign Flag Vessels - If an outbreak involving a foreign flag vessel or a US Flag vessel with an international itinerary comes to your attention, report it to your supervisor immediately who will then report it to OEO 866-300-4374. This situation falls under the jurisdiction of the Vessel Sanitation Program of the Centers for Disease Control and Prevention (CDC) Atlanta, Ga.
2. Outbreaks Involving Interstate Conveyances - Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are the responsibility of FDA.

When a report of illness is received, you are encouraged to share it with state and local public health officials in case they received additional illness reports. Additionally, the procedures outlined in this Subchapter are to be followed including the following 5 items:

3.2.4.3.1 - INTERVIEWS

Interviews with the ill passenger, family members and/or physician (as applicable), should be in-depth enough to hypothesize whether the carrier may be related to the illness. Factors such as time of onset of symptoms, history of eating suspect foods, and other potential exposures should be considered. The carrier should also be contacted to determine whether other reports of illness have been received. The information developed should be evaluated to determine whether further follow-up is necessary (i.e., the carrier suspect). On those carriers where a reservation system is used, the names and phone numbers of passengers should be obtained to determine if other individuals became ill. It may be necessary to contact other passengers to determine if they consumed any food or water on the trip, and if they became ill in the time period associated with the original complaint. When a report of additional related or similar illnesses is received, immediately contact the Office of Emergency Operations, ORO, HFA-615, 866-300-4374 and relay the information. Also contact the state epidemiologist of the affected state to report the details of the illness. It may be advantageous to request assistance from them in the epidemiological investigation, particularly if patient specimens are needed to determine the cause.

3.2.4.3.2 - INFORMATION EXCHANGE AND COORDINATION

Recently FDA revised the MOU between FDA and CDC regarding exchange of information and coordination of actions. This MOU provides a framework for coordination and collaborative efforts between the two agencies. It also

provides the principles and procedures by which information exchanges between FDA and CDC will take place. The new memorandum supersedes the MOU between CDC and FDA dated 4/1/82. When receiving a request for information from the CDC immediately notify the Director of the Office of Emergency Operations, HFA-615, 866-300-4374.

"FDA and CDC agree that the following principles and procedures will govern the exchange of nonpublic information between the two agencies. Although there is no legal requirement the FDA and CDC exchange information in all cases, FDA and CDC agree that there should be a presumption in favor of full and free sharing of information between FDA and CDC. Both agencies recognize and acknowledge however that it is essential that any confidential information that is shared between FDA and CDC must be protected from unauthorized public disclosure. See e.g., 21 USC sec. 331(j); 18 USC sec. 1905; 21 CFR Parts 20 and 21; 42 CFR Parts 5 and 5b; and, 42 USC sec. 301(d). Safeguards are important to protect the interests of, among others, owners and submitters of trade secrets and confidential commercial information; patient identities and other personal privacy information; privileged and/or pre-decisional agency records; and information protected for national security reasons. Any unauthorized disclosure of shared confidential information by the agency receiving the information shall be the responsibility of that agency.

3.2.4.3.3 - ROUTINE REQUESTS FOR INFORMATION

Routine Requests for Information:

1. The requesting agency must demonstrate, in writing, why it is necessary for it to obtain the requested information.
2. The agency receiving the request for information shall, based upon the sufficiency of the need-to-know demonstration described in section 1 above, determine whether it is appropriate to share the requested information with the requesting agency.
3. The requesting agency agrees that:
 - a. It shall limit the dissemination of shared information it receives to internal agency offices and/or individuals that have been identified in its written request and/or have a need-to-know;
 - b. Agree in writing not to publicly disclose any shared information in any manner including publications and public meetings without written permission of the agency that has shared the information;
 - c. If the requesting agency receives a Freedom of Information Act (FOIA) request for the shared information, it will refer the request to the information-sharing agency; and,
 - d. It shall promptly notify ORA's DDP at ORA OSPOT Testimony – Info Sharing Team ORAOSPOTestimony-InfoSharingTeam@fda.hhs.gov when there is any attempt to obtain shared information by compulsory process, including but not limited to a FOIA request,

subpoena, discovery request, or litigation complaint or motion.

- The agency that shares information with the requesting agency shall include a transmittal letter, along with any agency records exchanged, indicating the type of information.

3.2.4.3.4 - EMERGENCY REQUESTS FOR CONFIDENTIAL INFORMATION

In cases in which the requesting agency has a need to obtain certain information as soon as possible due to emergency circumstances, such as a foodborne illness outbreak, FDA and CDC may utilize the following procedures:

- The requesting agency shall indicate orally or in writing to the agency in possession of the relevant information that it has the need to obtain certain identifiable information as soon as possible due to the existence of emergency circumstances and describe what the emergency circumstances are.
- The requesting agency shall verbally agree to protect from unauthorized public disclosure any and all information that is shared, according to all applicable laws and regulations.
- The existence of an actual emergency situation shall warrant, as determined by the agency in possession of the requested records, the waiver of the need-to-know demonstration and determination described in sections 1 and 2 (Routine Requests for Information) above. However, once the requesting agency has obtained the information it seeks, it shall comply with those procedures set forth in section 3 (Routine Requests for Information) above.

3.2.4.3.5 - LIAISON OFFICERS

Liaison Officers

- For FDA:
Office of Commissioner
Contact: Mark Russo, Acting Director, Office of Crisis Management
Food and Drug Administration
12903 New Hampshire Ave.
White Oak, Bldg., 32, Room 1352, HFA-600
Silver Spring, MD 20993
866-300-4374
- For CDC:
Associate Director for Science
Harold W. Jaffee, MD, MA
Centers for Disease Control
Public Health Service
Department of Health and Human Services
Atlanta, GA 30333 404-639-7240

3.2.4.4 - Centers for Medicare and Medicaid Services (CMS)

MOU with Centers for Medicare and Medicaid Services (CMS) Concerning Blood Banking and Transfusion Programs (225-80-4000).

3.2.4.5 - Health Services Administration (HSA)

MOU with HSA Concerning Quality Assurance for Drugs, Biologics, Chemicals and Reagents Procured by HSA (225-75-8002).

3.2.4.6 - National Center for Health Statistics (NCHS)

A MOU with NCHS Regarding Exchange of Information (225-83-6000).

3.2.4.7 - National Institute of Drug Abuse (NIDA)

MOUs with:

- NIDA Regarding Methadone Mutual Responsibilities in Implementing the Jointly Published Narcotic Addict Treatment Regulations (225-81-3000).
- NIDA Concerning Cooperative Interaction in Expediting Domestic Scheduling of Drugs of Abuse (225-85-8251).

3.2.4.8 - National Institutes of Health (NIH)

MOU with:

- NIH Regarding Anticancer Drugs (225-75-3001).
- NIH and USDA Regarding Importation of Biological Specimens under US/USSR Scientific Exchange Agreement (225-74-1010).
- NIH and APHIS Regarding the Care and Welfare of Laboratory Animals (225-83-8400).

3.2.5 - DEPARTMENT OF HOMELAND SECURITY

3.2.5.1 - U.S. Customs and Border Protection

MOU with:

- Customs Service and the FDA Regarding Identifying Roles and Authority Concerning Electronic Products (225-74-6004).
- Customs Service to Establish a Working Relationship for Cooperative Enforcement (225-79-4003).
- Customs Services Regarding the Needs of the Trading Public in Expediting the Collection, Processing and the Use of Import Information (225-91-4003).

3.2.5.2 - Secret Service

The Secret Service operates under the Department of Homeland Security and is charged with the responsibility of protecting the President of the United States and certain other prominent persons. They also enforce the laws and regulations relating to currency, coins, and obligations and securities of the U.S. and foreign governments.

Authority for Secret Service to request FDA assistance, and for FDA to respond, is derived from the "Presidential Protection Assistance Act of 1976", P.L. 94-524 (90 Stat. 2475-7), Sections 1-10. Section six states in part:

"Executive Departments and Executive Agencies shall assist the Secret Service in the performance of its duties by providing services, equipment, and facilities on a temporary and reimbursable basis when requested by the Director and on a permanent and reimbursable basis upon advance written request of the Director; except that the DOD and the Coast Guard shall provide such assistance on a temporary basis without reimbursement when assisting the Secret Service in its duties directly related to the protection of the President or the Vice President or other officer immediately next in order of succession to the office of the President."

Note: At the present time the Agency is not claiming reimbursement from Secret Service until a study of total costs of our support function is completed.

FDA's authority for entry and inspection is derived from Secret Service authority and its request for FDA assistance. When called upon by the Secret Service to assist with a food service function, FDA's response is that of an advisor. Authority for decisions regarding food and beverages to be consumed by protectees is retained by the Secret Service.

Note: Do Not issue a Notice of Inspection - FDA 482 unless the investigation evolves into the collection of a sample for the enforcement of the FD&C Act. You are in the firm under the Secret Service authority.

FDA may initiate action against products encountered which are suspected of being in violation of the FD&C Act or the FPLA.

3.2.5.2.1 - LIAISON

The Secret Service and FDA have an arrangement whereby FDA district officials are alerted by the Secret Service when the President, Vice President or other Protectees are to visit their areas and are to consume prepared meals and Secret Service wants the food service facilities inspected. This is to assure that proper precautions are taken if any meals are to be consumed by these individuals during the stay.

If you are alerted by Secret Service Agents that the President, Vice President or other protectees will visit the area, immediately advise your supervisor in person or by telephone. Since the lead time is often short, the district must be alerted at once so proper arrangements can be made for issuance of inspectional or investigational assignments. Because of security procedures you are not to contact the Secret Service concerning protectee travel prior to notification by them even though you may hear from other sources that a protectee is to visit your area.

As part of this arrangement FDA supplies current rosters, office addresses, and telephone numbers of Regional Food

and Drug Directors, District Directors, Station Chiefs, and Residents to the Secret Service Headquarters for dissemination to their field agents.

3.2.5.2.2 - DEFINITIONS

Definitions:

1. Advanced Prepared Food means food that was prepared on location at the food service establishment prior to arrival of the Lead Investigator.
2. Food Service Function means a public event where food will be provided to a protectee.
3. Lead Advance Agent means the Secret Service Agent in charge of all security arrangements. This person is responsible for all sites to be visited by the protectee, and is a representative of the Office of Protective Operations (Secret Service Headquarters).
4. Lead Investigator means the FDA person designated by the FDA District/region to coordinate the investigational activities at the site of a food service function.
5. Person-in-Charge means the available person in the food service establishment authorized to make necessary changes/decisions such as the general manager, executive chef, banquet manager, caterer's representative or other management person.
6. Pre-prepared Food means potentially hazardous food that was received at the food service establishment in a prepared form. Examples would include chicken salad, liver pate, gefilte fish, hors d'oeuvres, etc. which were prepared at another location, and then transported to the food service establishment providing food for the event.
7. Protectee means any person eligible to receive the protection authorized by law.
8. Protective Detail means a team of Secret Service agents responsible for security surrounding public events to be attended by a protectee during a trip. Protective details are assigned and coordinated by Secret Service Headquarters but may include Secret Service field representatives.
9. District Contact means the Director, Investigations Branch.
10. Site Advance Agent means the Secret Service person responsible for security arrangements at a specific site to be visited by the protectee. This person is part of the protective detail headed by the Lead Advance Agent. Note: the term Site Advance Agent will include any agent designated by the Site Advance Agent to be the contact with the FDA Lead Investigator.
11. Support Personnel means FDA persons deemed necessary by FDA in order to properly inspect a food service function.

3.2.5.2.3 - PURPOSE

FDA's primary purpose in support of Secret Service is to minimize the possibility of the protectee becoming ill from a food intoxication or foodborne infection resulting from inadequate knowledge of food safety requirements by food service personnel, inadequate facilities, improper operating procedures, or carelessness. FDA is further concerned that

food have no visible signs of filth, and that it is prepared in a clean environment.

FDA personnel are not trained to detect deliberate attempts to harm persons by the addition of poisonous or toxic substances to food. The Secret Service retains responsibility for matters involving criminal intent. However, FDA personnel should immediately report to the Site Advance Agent peculiar behavior or suspicious conditions observed during their investigation.

3.2.5.2.4 - CRITERIA FOR REQUESTING FDA ASSISTANCE

The decision to request FDA assistance is made by Secret Service Office of Protective Operations (Headquarters). FDA has provided certain criteria to aid Secret Service in determining how they might derive maximum benefit from FDA. Regardless what criteria are used, FDA should always respond to Secret Service requests for assistance. Secret Service considers factors other than the FDA supplied criteria in making its judgment regarding requests for assistance.

3.2.5.2.5 - SCOPE OF INVESTIGATION

The focus of the FDA investigation should be on the menu items that the protectee will be served, or from which the protectee will make a selection. Food, facilities, personnel, procedures, etc. are only considered by FDA as they relate to the specific food and beverage items which may be consumed by the protectee. Do not conduct a traditional regulatory type food service inspection. The Food Service EIR (FDA 2420) will not normally be part of the report prepared following this special investigation. State/local regulatory authorities have jurisdiction over food establishments and have a primary responsibility for public health protection of the general public or participating members or guests of the organization sponsoring the event.

3.2.5.2.6 - INTERAGENCY COOPERATION

Upon contact by Secret Service and after contacting your supervisor to apprise district management of the Secret Service request, the appropriate state/local regulatory authority should be contacted and encouraged to participate prior to and during the food service function. These officials may offer invaluable assistance because of their familiarity with the establishment and because of their regulation over the establishment on a long-term basis.

3.2.5.2.7 - DISTRICT CONTACT

The district contact should receive Secret Service requests for assistance and initiate the FDA response. If a resident post is contacted directly for assistance, immediately contact your supervisor who will notify the director investigations branch. The director investigations branch will designate the lead investigator and arrange for

assignment of support personnel and equipment as required. The lead investigator could be on district or region staff according to district/region policy.

3.2.5.2.8 - LEAD INVESTIGATOR QUALIFICATIONS

The best suited investigator (criteria optional) assigned to coordinate investigation of these food service functions should be one who:

1. Possesses OPM "Critical Sensitive" security clearance.
2. Is standardized in the use of the FDA Food Code.
3. Is experienced in Secret Service food service functions, if possible. New personnel should accompany experienced personnel before being assigned as Lead Investigator, if at all possible.
4. Is able and authorized to quickly mobilize an investigational team (FDA/State/Local).
5. Is able and authorized to make quick decisions on important food protection/sanitation questions.
6. Has a background in food microbiology.

3.2.5.2.9 - STEPS FOR CONDUCTING A SPECIAL SECRET SERVICE INVESTIGATION

Steps for Conducting a Special Secret Service Investigation (District Contact/Lead Investigator).

Verify the call with the Secret Service and obtain from them:

1. Information about the site advance agent with whom FDA is to coordinate its activities. This should include the name(s) of agent(s) assigned, location(s) and telephone number(s).
2. Information about the firm(s) providing food for the food service function, to include:
 - a. Names of persons-in-charge of food service establishment and caterers.
 - b. Telephone numbers.
 - c. Addresses of firm(s).
 - d. Location where food service function will be held (if different).
 - e. Date of function.
 - f. Time of food events during function.

Obtain through means prearranged and agreed upon by FDA district/region management:

1. FDA support personnel needed.
2. Equipment required to conduct special investigation.

Contact the person-in-charge at the facility to:

1. Introduce the lead investigator.
2. Advise of purpose and scope of special investigation.
3. Arrange for personal interview to discuss menu, food preparation schedule and history (times/specific locations in establishment), and any intended use of pre-prepared foods.
4. Obtain telephone number(s) at the site(s) where FDA lead investigator may be reached while on location.

Contact state and local regulatory agencies responsible for retail food protection and sanitation. Request participation by inspectional personnel of the local office which provides routine inspectional coverage of the facility where the food service function is being held.

Meet with person-in-charge on location, in order to:

1. Be introduced to other key employees who have responsibility for the target meal or kitchen facilities, i.e. banquet manager, executive chef, maintenance supervisor, etc.
2. Inform person-in-charge of the names of other FDA, state, or local regulatory personnel to be involved.
3. Obtain the use of an area within the establishment that will become an FDA base of operations. The location should have convenient access to a telephone but may not be necessary for small functions.

Coordinate with Secret Service command post on location, in order to:

1. Inform site advance agent of the names of other FDA, state or local regulatory personnel to be involved.
2. Determine method for final selection of specific meal(s) to be served to protectee(s).

Carry out investigation by:

1. Basing judgments on the provisions of the FDA Food Code. In consideration of food sources, food protection, personnel, food equipment/utensils, water, waste disposal, vermin control, storage and use of toxic materials, and other code items as they relate to the food items to be served to the protectee.
2. Taking the history of each item on the menu to be served to the protectee. The history for each potentially hazardous food (including advance prepared and pre-prepared Food) must be detailed. Include timetables for preparation and storage, and the names of specific employees involved in its preparation. This will immediately establish parameters needed for FDA to complete a comprehensive, but well focused investigation (See IOM 3.2.5.2.3 above. Though every effort should be made by the lead investigator to help the person-in-charge and the Secret Service in their efforts to assure that preparation and arrangements for the food service function flow smoothly and efficiently, FDA personnel must be aware that their responsibility is for assuring that all prudent steps have been taken to minimize the risk of foodborne illness to the protectee.

3.2.5.2.10 - SAMPLING

Samples shall be collected at the discretion of the lead investigator. Two types of samples should be considered.

1. Typical Meal - In the unlikely event that a protectee (or others) becomes acutely or seriously ill during the hours following a food service function, it could be very helpful to have samples of meals served for analysis. Should this happen, FDA's response should be coordinated with the FDA Office of Emergency Operations at 866-300-4374.

FDA under Secret Service authority should request that two complete meals, including beverages, be randomly selected from the meals being served to the head table. This selection should be made by the same person and at the same time head table meals are selected.

If a reception is a planned part of the event, an example of each type of hors d'oeuvres should also be retained. These meals should be kept intact, covered, and retained under refrigeration by the person-in-charge for 72 hours following the event. Cost of the meals may, at the establishment's option, be invoiced to the organization sponsoring the food service function.

Note: Examples of food items selected in this manner cannot be considered a representative sample of food offered at the function. However, such food examples could be an aid to the FBI and food regulatory personnel, should a suspected food related illness occur.

2. Food Samples - Occasionally, the lead investigator may elect to collect official samples of a food product because of a selected violation of the FD&C Act or for some other reason. When this is done, issue an FDA 482, Notice of Inspection. In these cases, samples should be collected in accordance with procedures outline in IOM Chapter 4.

3.2.5.2.11 - REPORTING

Verbal Report - The lead investigator shall report to the site advance agent in person or by telephone.

1. Significant adverse findings should be immediately reported to the site advance agent during the investigation, if resolution of the finding has the potential for disrupting the smooth flow of the food service function.
2. At the conclusion of the investigation, and prior to leaving the location, notify the site advance agent of FDA conclusions and recommendations. One of the following responses would be normal:
 - a. No restrictions recommended. Protectee should be permitted to consume any food or beverage being offered.
 - b. A recommendation that the protectee be advised that one or more specifically named items available should not be selected or consumed.
 - c. In unusual cases, it may be necessary to recommend that the protectee not eat food prepared for the event, or not drink the water provided.

Narrative Report - Following each special investigation conducted for the Secret Service, write a Memo of Investigation for your supervisor's endorsement. The report is for FDA's internal use and should be a chronological accounting beginning with how and when the Secret Service request was received and concluding with recommendations tendered to the Secret Service, and any F/U actions recommended to or planned by participating State/local food protection agencies. The narrative report should include time frames, contact persons, a copy of the menu, a description of the investigational process used, adverse findings, corrective steps taken, the selection and retention of typical meals, and how and why official samples

(if any) were collected and submitted, and a discussion of other matters of significance in your opinion.

Each narrative report must contain:

1. Total time on location.
2. Total time of inspection including, time on location and time necessary for making arrangements in advance, and preparation and submission of required reports. It does not include travel time.
3. Total travel time and mileage.

3.2.6 - DEPARTMENT OF JUSTICE

3.2.6.1 - U.S. Attorney

You may be contacted by the U.S. Attorney's office to discuss possible or pending cases or other matters pertinent to FDA. Notify your supervisor of these contacts. You may be accompanied by your supervisor or a compliance officer. If you are contacted by the U.S. Attorney's Office regarding any criminal issues, this is to be referred immediately to the appropriate OCI Office.

During any discussion with the U.S. Attorney, inform him that you are qualified to report the facts of whatever case or item being discussed, but inform him that you are a fact witness only and not qualified as an "expert".

3.2.6.2 - Drug Enforcement Administration (DEA) (Formerly: Bureau of Narcotics)

You should follow the procedures outlined in the Information Disclosure manual if you receive a request to share information with another Federal agency.

3.2.6.3 - Federal Bureau of Investigation (FBI)

The FBI, USDA and FDA are authorized to investigate reported tampering of FDA regulated consumer products under the Federal Anti-Tampering Act (FATA), Title 18, USC, Section 1365. In most cases, FDA's authority for such investigations is also found in the FD&C Act.

USDA and the FBI share enforcement of the FATA with FDA as described below:

1. FBI Responsibility - FDA understands that the FBI's primary response in FATA matters will be to investigate particularly those cases that involve a serious threat to human life or if a death has occurred. The FBI will also investigate FATA matters involving threatened tamperings, and actual or threatened tamperings coupled with an extortion demand. The FBI will rely on FDA to determine if tampering with FDA products has occurred.

2. USDA Responsibility - The USDA will investigate and interact with the FBI on tampering with products regulated by USDA.

For complete information regarding FBI/FDA actions under FATA, [see IOM 8.1.5.9.3.](#)

3.2.6.4 - U.S. Marshals Service

The U.S. Marshals Service (USMS) is the enforcement arm of the federal court. The USMS is primarily responsible for the service of civil process. In other words, when FDA takes an action, such as seizure the U.S. Marshal actually serves the complaint for forfeiture and "arrests" the goods. FDA employees typically accompany the U.S. Marshal to assist in identifying the goods which are to be seized. The USMS is also responsible for ensuring the safe conduct of judicial proceedings and protecting federal judges, jurors and other members of the federal judiciary. District Offices may find it useful to contact the local U.S. Marshals when preparing a situation plan to deal with issues of personal safety while conducting inspections or other operations. See IOM 5.2.1.2.2. and <http://www.usmarshals.gov/>

3.2.7 - DEPARTMENT OF LABOR: OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

The MOU with OSHA Concerns Standards for Electronic Product Radiation (225-74-6008).

3.2.8 - TREASURY DEPARTMENT

Many different agencies operate under the direction of this department. These include the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau. Agreements and MOUs with the Treasury Department will be discussed below.

3.2.8.1 - Alcohol and Tobacco Tax and Trade Bureau (TTB)

FDA and TTB share jurisdiction over alcoholic beverages. The MOU between FDA and TTB (formerly the Bureau of Alcohol, Tobacco and Firearms (ATF)) delineates the enforcement responsibilities of each agency with respect to alcoholic beverages (MOU 225-88-2000). This MOU, among other things, confirms that TTB will be responsible for testing alcoholic beverages to determine the extent of an adulteration problem and that when FDA learns or is advised that an alcoholic beverage is or may be adulterated, FDA will inform TTB. FDA will also provide laboratory assistance and health hazard evaluations at TTB request. TTB generally has responsibility for alcoholic beverage labeling; however, FDA also has jurisdiction over the labeling of wine with less than 7% alcohol by volume (such as alcoholic ciders and most wine coolers), and beer described in the TTB's

Ruling 2008-3

(<https://www.ttb.gov/images/pdfs/rulings/2008-3.pdf>) as not being a “malt beverage” (also see FDA Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration, (<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm166239.htm>)). Labeling questions for these alcoholic beverages that are under FDA’s jurisdiction should be directed to Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, 240-402-2373.

Based on this MOU (225-88-2000), FDA should refer all complaints involving alcoholic beverages (distilled spirits, wines, and malt beverage products except for labeling issues related to wine with less than 7% alcohol by volume and beer described in the TTB’s Ruling 2008-3 as not being a “malt beverage”) to TTB using the procedure outlined below. When a complaint is received from a consumer, it should be entered into FACTS with the disposition “referred to other Federal agency”. If the complaint is reporting a suspected tampering, it should be referred to the home district and OCI for follow up. In all cases, a copy of the FACTS consumer complaint report should be forwarded directly to the TTB Market Compliance Office with a copy to the FDA liaison officer to facilitate appropriate follow up between the two agencies at the headquarters level.

TTB Market Compliance Office can be reached at 202-453-2251 (Email: Market.Compliance@ttb.gov; Fax: 202-453-2873). The FDA Liaison Officer (Office of Food Safety, Center for Food Safety and Applied Nutrition) can be reached at 240-402-1700 (Email: FDA-TTB-Liaison-Officer@fda.hhs.gov; Fax: 301-436-2632).

3.2.8.2 - Internal Revenue Service (IRS)

MOU with IRS Concerning Legal Actions Taken by FDA Against Alcoholic Beverage Firms for Under filling of Containers (225-71-2006).

The FDA Liaison Office is the Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, HFS-605 (240-402-2094).

The ATF Liaison Office is the Chief, Industry Compliance Division (202-927-8100).

3.2.9 - DEPARTMENT OF VETERANS AFFAIRS VETERANS ADMINISTRATION (VA)

MOU with the VA are:

1. Concerning Exchange of Medical Device Experience Data (225-75-5011).
2. Concerning Communications and Cooperation Regarding Clinical Research with Investigational New Drugs and Devices, Including Biologicals (225-82-8400).

3. To promote cooperation and coordination between the Food and Drug Administration and the Veterans Health Administration for the purpose of enhancing food safety and sanitation in food operations serving health care facilities of the Department of Veterans Affairs (225-93-2000).

IAGs with the VA are:

1. VA Concerning FDA Responsibility for Quality Assurance for Drugs, Biologicals, Chemicals and Reagents Procured by VA (224-76-8049).
2. VA Regarding FDA Quality Assurance Responsibility for VA Contracts for Medical Devices (224-82-4002).
3. To provide mammography inspections, pursuant to Public Law 102-539 and Public Law 104-262, to Veterans Health Administration facilities.

3.2.10 - CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

MOUs with CPSC are:

1. CPSC Concerning CPSC Use of FDA Documents (225-74-8001).
2. CPSC Regarding Jurisdiction with Respect to Food, Food Containers, and Food Related Articles and Equipment (225-76-2003).

3.2.11 - ENVIRONMENTAL PROTECTION AGENCY (EPA)

The EPA administers many Acts one of them is the National Environmental Protection Act (NEPA). FDA must be guided by this Act when assisting in voluntary destructions, disposal of laboratory wastes, etc.

Do not condone the wanton pollution of waterways, uncontrolled burning, the creation of a public nuisance or other questionable disposal practices. Note that certain products should not be disposed of in a conventional manner (e.g., sanitary landfill, flushing down the drain, etc.). In particular, certain products that have been banned in the past (chloroform, methapyrilene, hexachlorophene, PCB, etc.), are classified by EPA as hazardous and toxic substances and may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of without prior consultation by the firm with the U.S. Environmental Protection Agency and/or the regulating state authority. Refer to [21 CFR 25](#) and the National Environmental Protection Act for guidance regarding the environmental impact of voluntary destructions.

3.2.11.1 - EPA MOUs

MOUs with:

1. EPA Regarding Matters of Mutual Responsibility Under Federal FD&C Act and Federal Insecticide, Fungicide and Rodenticide Act (225-73-8010).

2. EPA Regarding Potable Water on Interstate Conveyances (225-78-4006).

The EPA administers a regulatory program in this area, but FDA has the responsibility of notifying the ICC headquarters when problems are found. FDA will, if deemed appropriate include conveyances in their inspection/monitoring schedule. Both agencies will coordinate enforcement efforts, thereby avoiding duplication of efforts.

3. EPA Concerning Control of Drinking Water (225-79-2001).

FDA has responsibility for water, and substances in water, used in food and for food processing and bottled drinking water.

FDA will take appropriate regulatory action to control bottled drinking water and water and substances in water, used in food and for food processing.

The FDA Liaison Office is the Division of Programs and Enforcement Policy, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, HFS-305 (240-402-1488).

The EPA Liaison Office is the Drinking Water Technologies Branch, Drinking Water Standards Division (202-260-3022).

4. EPA and USDA (FSIS and AMS) re: Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods (225-85-8400).

New York, NY 10278
212-264-7662

Charles J. Walters
EPA Region III
841 Chestnut Bldg
Philadelphia, PA
19106
215-597-7291
303-294-1063

Robert E. Safay
Air & Waste Mgmt Div.
Region IV
345 Courtland St.
Atlanta, GA 30365
404-347-1847

Louise A. Fabinski
Emerg. & Remedial Br.
EPA Region V (M-SHS-6)
77 W. Jackson Blvd
Chicago, IL 60604
312-886-0840

Kansas City KS 66101
913-551-7692

Glenn J. Tucker
ATSDR Region VIII (8HWM-FF)
Waste Management Div.
Suite 500
999 18th St.
Denver, CO 80202

William Q. Nelson
ATSDR Region IX
75 Hawthorne St
Rm 09261
San Francisco, CA 94105
415-744-2194

George Thomas
EPA Region X (MSHW113)
1200 6th Ave.
Seattle, WA 98101
206-553-2113

Some situations where ATSDR guidance is indicated are mentioned below.

In wrecks the physical impact usually causes most damage. Toxic items in the same load, this is illegal, may rupture and add to the contamination. In train wrecks, other railcars loaded with chemicals, oils or other contaminating materials may rupture and contaminate food and drug products in otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Do not overlook the possibility that runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms under FDA jurisdiction.

Chemical spills occurring on land or water can pose a serious threat to the environment and contaminate FDA regulated products both directly and indirectly.

Hazardous waste sites also pose a hazard to the immediate environment, as well as offsite, if runoff contaminates nearby surface waters or if leachate contaminates ground water supplies.

3.2.12 - AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

The ATSDR (formerly CDC Superfund) staff has been designated as the lead agency for the DHHS response to chemical emergencies. The CDC ATSDR Public Health Advisors are located at the EPA Regional Offices. These advisors would not only alert your office of chemical emergencies but would be invaluable in answering questions concerning the severity of the problem and discussing protective measures. Under no circumstances, are FDA employees to enter areas designated as hazardous.

If it is necessary to contact ATSDR employees, their addresses and phone numbers are listed below:

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (FORMERLY KNOWN AS SUPERFUND)

Louise A. House
EPA Region I
ATSDR
EPA Bldg
60 Westview St.
Lexington, MA 02173
617-860-4314

George Pettigrew
EPA Region VI (6HE)
1445 Ross Ave.
Dallas, TX 75202
214-655-8361

Arthur Black
EPA Region II
Rm 3137C
26 Federal Plaza

Denise Jordan-Izaguirre
EPA Region VII
Waste Management Branch
726 Minnesota Ave

3.2.13 - FEDERAL TRADE COMMISSION (FTC)

The MOU with FTC Concerns Exchange of Information (225-71-8003).

3.2.14 - U.S. NUCLEAR REGULATORY COMMISSION (NRC)

The U.S. Nuclear Regulatory Commission and the U.S. Department of Health and Human Services, Food and Drug Administration signed a MOU (225-03-4001) on August 26, 1993 (FR Vol. 58, No. 172, 09/08/93, 47300-47303). The purpose of the MOU is to coordinate existing NRC and FDA regulatory programs for medical devices (including utilization facilities used for medical therapy), drugs, and biological products utilizing byproduct, source, or special nuclear material regulated under the Atomic Energy Act of 1954, as amended. These regulatory programs include activities for evaluating and authorizing the manufacture, sale, distribution, licensing, and labeled intended use of such products.

Medical devices affected by this MOU include but are not limited to: in vitro diagnostic kits (radioimmunoassay); utilization facilities licensed to perform medical therapy; and teletherapy and brachytherapy sources, systems, and accessory devices. Biologicals include, but are not limited to, licensed in vitro diagnostic kits (radioimmunoassay), and certain radiolabeled biologics for in-vivo use. Drugs include all those that contain byproduct, source, or special nuclear material.

The organizations in FDA that are responsible for regulating these products are CDRH, CDER, and CBER.

The FDA Liaison Offices are the Center for Devices and Radiological Health, Director, Office of Regulatory Programs(301-796-5895), Center for Drug Evaluation and Research, Director, Office of Compliance, HFD-300 (301-796-3100), and the Center for Biologic Evaluation and Research, Director, Office of Compliance and Biologics Quality, HFM-600 (301-827-6190).

The NRC Liaison Office is the Director, Office of Nuclear Material Safety and Safeguards (301-504-3352).

3.2.15 - U.S. POSTAL SERVICE (USPS)

FDA cooperates with postal authorities in areas of mutual concern. If contacted by postal authorities, extend courtesy and cooperation. In any doubtful situation or incidents involving excessive expenditure of time and/or resources, check with your supervisor

3.2.15.1 - Change of Address Information

At times during an investigation or inspection it may become necessary to visit local post offices to obtain new or forwarding addresses of individuals involved. Procedure:

1. Introduce yourself and display your credentials to the local P.O. clerk or official.
2. State the information desired.
3. Present the clerk or official on duty the statement in writing on FDA letterhead using the wording from IOM Exhibit 3-3 which may be reproduced or typed on district letterhead.
4. If you are still refused information or delayed in any manner, contact the nearest U.S. Postal Inspector to handle the matter.

5. At this time there is no charge for providing this information to a Federal Agency. The regulation promulgating a fee has been stayed.

3.2.15.2 - Postal Box Information

At times during an investigation or inspection it will become necessary to obtain the name and address of the holder of a postal box (PO Box).

Procedure:

1. Introduce yourself and display credentials to the local P.O. clerk or official.
2. State the information you desire.
3. Present the clerk or official the statement in writing on FDA letterhead using the wording from IOM Exhibit 3-3 which may be reproduced or typed on district letterhead.
4. At this time there is no charge for providing this information to a Federal Agency. The regulation promulgating a fee has been stayed.
5. If you are still refused the information or are delayed in any manner, contact the nearest U.S. Postal Inspector to handle the matter.

3.2.15.3 - Authority

The authority for providing forwarding address information to government agencies is defined in [39 CFR 265.6\(d\)\(5\)\(i\)](#) which states as follows:

(5) Exceptions. Except as otherwise provided in these regulations, names or addresses of postal customers will be furnished only as follows:

(i) To a federal, state, or local government agency upon prior written certification that the information is required for the performance of its duties.

Additionally, [39 CFR 265.6\(d\)\(7\)](#) may apply: Address verification. The address of a postal customer will be verified at the request of a federal, state, or local government agency.

3.2.16 - FIRM LOCATIONS

Many firms FDA is required to inspect are difficult to locate, including growers, farms, and other types of operations in rural areas. Directions to these firms can be obtained from many sources, including:

1. Visits to Post Offices.
2. If the envelope has a postal meter number and no return address, check with the USPS to determine the name of the firm or holder of that "PB Meter" number.
3. Visits to local health departments.
4. Visits to county extension services.
5. Visits to USDA - Agricultural Stabilization and Conservation Offices of Soil Conservation Service Offices.

Many of these offices have maps of the counties, municipalities, etc. which can be purchased or copied and used with their guidance to find the firms.

After the directions are obtained or the maps copied, copies of the maps with directions can be included in the factory jacket.

3.2.17 - FEDERAL FOOD SAFETY COALITION

In August 1999, FDA began an interagency Federal Food Safety Coalition with other federal agencies in an effort to focus on food protection of high-risk populations. The group's objective is to promote the development of effective public health protection systems for food safety within federal programs using the FDA Model Food Code, emphasizing foodborne illness interventions, to reduce the occurrence of the five leading illness risk factors. A formal MOU or partnership has not yet been developed. The agency members are as follows:

1. Dept. of Veterans Affairs, Veterans Health Admin.
2. United States Department of Agriculture, Food and Nutrition Service Child Nutrition Division
3. Dept. of Justice, Bureau of Prisons
4. Dept. of Health and Human Services:
 - a. Head Start Program
 - b. Administration on Aging
 - c. Indian Health Services
 - d. Centers for Medicare and Medicaid Services
 - e. Food and Drug Administration, Center for Food Safety and Applied Nutrition
5. CDC – Vessel Sanitation Program
6. Department of Defense:
 - a. US Air Force
 - b. US Army
 - c. US Coast Guard
 - d. US Navy
7. Department of Interior, National Park Service
8. US Congress, Office of the Attending Physician

SUBCHAPTER 3.3 - STATE OPERATIONAL AUTHORITY

3.3.1 - STATE OPERATIONAL AUTHORITY

Establishment Inspections - All state and local officials have some type of jurisdiction over the food and drug establishments located within their state or local boundaries, regardless of the interstate movement or origin of the products involved. Some states divide the responsibility for food, drugs, etc., among the various agencies within the state. See IOM 3.3.3¹.

Samples - All state laws provide authority to collect samples of food, drug, and other products within the state.

Embargoes - FDA does not have embargo authority. Some states have embargo and detention authorities, these

authorities are specific within each state. FDA does have administrative detention authority for medical devices and food. Administrative detention for medical devices and food can be used when the Agency has reason to believe that the article is adulterated, misbranded, or presents a threat of serious adverse health consequences to humans or animals. See [FD&C Act section 304\(g\)](#) and [\(h\)](#), IOM 3.2.1.3, 2.2.10, and 2.7.1 for administrative detention information.

Some state laws empower their inspectors to place an immediate embargo on products that are, or are suspected of being, adulterated or misbranded or otherwise in violation of their laws. As a cooperative measure most state agencies will have their inspectors place an embargo at the request of an FDA representative. Do not routinely request such embargo. District assignments may include instructions relative to cooperative embargoes.

In all instances, exercise care in requesting embargoes. In accordance with [Field Management Directive 50 \(FMD 50\)](#), the appropriate state agency should be notified of pending or recommended compliance/enforcement actions within five working days. When a state institutes an embargo at FDA's request, the District must assure that cooperating officials are kept informed of the status of the resulting administrative or legal action. The District must promptly notify state officials when the resulting action is final so that the state can update records and issue required releases for the lot. This helps prevent inordinately long holding times by the state.

Embargoes should not be considered as a mere convenience to the Food and Drug Administration but as an important and effective cooperative measure to be applied only when circumstances indicate such action.

Disaster Operations - Following major disasters, FDA regional directors and District directors will arrange for close cooperation with local and state food and drug officials, Health Departments, the Public Health Service and other agencies engaged in comparable work. When requested to do so, FDA District personnel will assist local and state officials during such emergencies. At such times FDA personnel may be temporarily commissioned by local or state authorities and provided the authority to place embargoes ([See IOM 8.1.5.8.6](#)).

3.3.1.1 - FDA Personnel with State Authority

Certain states have designated selected FDA employees as special representatives or agents of the particular state agency. In these cases, they have furnished the FDA individuals with official state credentials. The FDA representatives given this authority will receive instructions and training, by their District, in the proper exercise of the powers conferred on them and must operate within the guidelines established by their District to monitor this authority. This is particularly important whenever state embargo powers may be used.

3.3.1.2 - Joint Inspections

Joint inspections with state or local inspectors are arranged by the District supervisory personnel. Joint inspections are conducted in the same manner as inspections by FDA alone and findings are discussed with the accompanying inspector. The cooperating inspector may wish to take action against the merchandise or the firm under pertinent local or state laws.

3.3.1.3 - FDA Commissioned State Personnel

Qualified state regulatory officials may be commissioned under section 702(a)(1)(A) of the FD&C Act to conduct examinations and investigations, which can include conducting inspections, collecting samples, copying and verifying records and carrying out an administrative detention order (following approval by the FDA District Director) under the FD&C Act.

3.3.2 - STATE MEMORANDA OF UNDERSTANDING

The FDA has entered into agreements with various state and local agencies covering a variety of issues and work sharing agreements. At the present time not all the states have entered into agreements with FDA. A listing of current MOUs for states, the District of Columbia, and the Commonwealth of Puerto Rico are on [FDA's MOU page](#).

3.3.3 - STATE AUTHORITIES AND PHONE CONTACT NUMBERS

This section contains information regarding various state enforcement authorities. Some states operate under state laws patterned after the FD&C Act of 1906 or the current FD&C Act. However, most of the states operate under a "Uniform FD&C Act" which was developed by the Association of Food and Drug Officials (AFDO).

States that have adopted the Uniform FD&C Act as their legal guideline have in most cases adopted the entire act. The food authority in most cases includes among other things the adoption of the food and color additive provisions, pesticide residue amendments, enrichment guidance, etc. The Uniform FD&C Act also includes a provision for automatic adoption of changes in the FD&C Act. Some state legislatures have also included this provision in their laws. Some other provisions of the Uniform Act adopted by state include the new drug provisions, medical device laws, and cosmetic requirements.

Some states have also adopted the Association of American Feed Control Officials (AAFCO) model bill as their legal guideline for feed inspections.

In most cases the contact for "Consumer Protection Issues" would be located in the Office of the State Attorney General

and would usually cover consumer fraud and other consumer protection issues. The State Attorney General's staff usually has mechanisms to deal with health fraud issues not efficiently dealt with by traditional FDA approaches. Contact your District Health Fraud Monitor for guidance in cooperative efforts with the State Attorney General's staff.

A complete listing of the personnel and programs at the state and local level may be found in the FDA Internet Directory of State and Local Officials which was prepared by the Office of Partnerships (HFC-150) at <https://www.fda.gov/ForFederalStateandLocalOfficials/default.htm> or <http://www.afdo.org/>

3.3.3.1 - Alabama (AL)

Alabama has adopted the FD&C Act of 1906 and the 1970 AAFCO as their legal guideline. The control agencies are Agriculture and Health. They have not adopted the new drug provisions, the medical device law, nor the automatic adoption provisions.

3.3.3.2 - Alaska (AK)

Alaska has adopted the Uniform FD&C Act without the automatic adoption provision and have not adopted either AAFCO feed bill. The controlling agencies are Health, Social Services, and Environmental Conservation. Alaska has adopted the various provisions of the Uniform bill.

3.3.3.3 - Arizona (AZ)

Arizona operates under the Uniform FD&C Act and the 1970 AAFCO Feed Bill. The controlling agencies are Health, Pharmacy and the State Chemist. They have not adopted the medical device law, cosmetics law, nor the automatic adoption provisions of the Uniform FD&C Act.

3.3.3.4 - Arkansas (AR)

Arkansas operates under the Uniform FD&C Act and the 1970 AAFCO Feed Bill. The agencies in control are Health and the Plant Board. They have not adopted the new drug provisions or the automatic adoption provision.

3.3.3.5 - California (CA)

California has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.6 - Colorado (CO)

Colorado has adopted the Uniform FD&C Act and the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted either version of the AAFCO Feed Bill.

3.3.3.7 - Connecticut (CT)

Connecticut has adopted the FD&C Act, the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Consumer Protection.

3.3.3.8 - Delaware (DE)

Delaware has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health, and Pharmacy. They have not adopted the food and color additive amendments, the pesticide residue amendment, enrichment amendment, new drug provisions, medical device law, and the cosmetics law.

3.3.3.9 - Florida (FL)

Florida has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.10 - Georgia (GA)

Georgia has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the food additive, color additive or pesticide residue amendments.

3.3.3.11 - Hawaii (HI)

Hawaii has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health and the Attorney General.

3.3.3.12 - Idaho (ID)

Idaho has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill and has not adopted the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health and Pharmacy. They have not adopted the food additive, color additive or pesticide residue amendments of the Act.

3.3.3.13 - Illinois (IL)

Illinois has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.14 - Indiana (IN)

Indiana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Health and the State Chemist.

3.3.3.15 - Iowa (IA)

Iowa has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the FD&C Act. The controlling agencies are Agriculture, Health and Appeals, and Pharmacy.

3.3.3.16 - Kansas (KS)

Kansas has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill and has not adopted the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.17 - Kentucky (KY)

Kentucky has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Human Resources, Pharmacy, and the University of Kentucky Registration Services.

3.3.3.18 - Louisiana (LA)

Louisiana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the provisions of the medical device law.

3.3.3.19 - Maine (ME)

Maine has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the food and color additive amendments nor the new drug provisions or the medical device law.

3.3.3.20 - Maryland (MD)

Maryland has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.21 - Massachusetts (MA)

Massachusetts has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption

provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions of the Act.

3.3.3.22 - Michigan (MI)

Michigan has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce, Licensing and Registration. They have not adopted the enrichment provisions or the cosmetics law.

3.3.3.23 - Minnesota (MN)

Minnesota has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the enrichment provisions, the new drug provisions, the medical device law, nor the cosmetic law.

3.3.3.24 - Mississippi (MS)

Mississippi has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce and the State Chemistry Lab. They have not adopted the food additive, color additive, and pesticide residue amendments, nor the new drug provisions or cosmetic law.

3.3.3.25 - Missouri (MO)

Missouri has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.26 - Montana (MT)

Montana has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.27 - Nebraska (NE)

Nebraska has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions nor the medical device and cosmetic laws.

3.3.3.28 - Nevada (NV)

Nevada has adopted the Uniform FD&C Act but not the automatic adoption provisions of the Uniform FD&C Act. They have not adopted either version of the AAFCO Feed Bill. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions of the Act.

3.3.3.29 - New Hampshire (NH)

New Hampshire has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.30 - New Jersey (NJ)

New Jersey has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the pesticide residue amendment.

3.3.3.31 - New Mexico (NM)

New Mexico has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Environment, Health and Pharmacy. They have not adopted the food additive or color additive amendments.

3.3.3.32 - New York (NY)

New York has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Markets, Health, and Pharmacy. They have not adopted the cosmetics law.

3.3.3.33 - North Carolina (NC)

North Carolina has adopted the Uniform FD&C Act and both versions of the AAFCO Feed Bills along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture. They have not adopted the enrichment provisions of the Act.

3.3.3.34 - North Dakota (ND)

North Dakota has adopted the Uniform FD&C Act and neither version of the AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Consolidated Laboratories, Health and Pharmacy.

3.3.3.35 - Ohio (OH)

Ohio has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

3.3.3.36 - Oklahoma (OK)

Oklahoma has adopted the Uniform FD&C Act but neither version of the AAFCO Feed Bills nor the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the food additive or color additive amendments, the enrichment provisions nor the new drug provisions.

3.3.3.37 - Oregon (OR)

Oregon has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the cosmetics law.

3.3.3.38 - Pennsylvania (PA)

Pennsylvania has adopted the 1906 FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the food additive, color additive, and pesticide residue amendments nor the enrichment provisions.

3.3.3.39 - Rhode Island (RI)

Rhode Island has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Environmental Management and Health.

3.3.3.40 - South Carolina (SC)

South Carolina has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health.

3.3.3.41 - South Dakota (SD)

South Dakota has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Commerce and Regulations. They have not adopted the new drug provisions, medical device law, nor the cosmetics law.

3.3.3.42 - Tennessee (TN)

Tennessee has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture.

3.3.3.43 - Texas (TX)

Texas has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Health and the State Chemist.

3.3.3.44 - Utah (UT)

Utah has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the new drug provisions.

3.3.3.45 - Vermont (VT)

Vermont has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Health. They have not adopted the enrichment provisions.

3.3.3.46 - Virginia (VA)

Virginia has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

3.3.3.47 - Washington (WA)

Washington has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy.

3.3.3.48 - West Virginia (WV)

West Virginia has adopted the 1906 FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agencies are Agriculture, Health and Pharmacy. They have not adopted the food additives or color additive amendments, the new drug provisions, the medical device law and the cosmetics law.

3.3.3.49 - Wisconsin (WI)

Wisconsin has adopted the Uniform FD&C Act and the 1958 AAFCO Feed Bill along with the automatic adoption

provisions of the Uniform FD&C Act. The controlling agencies are Agriculture and Pharmacy. They have not adopted the enrichment provisions, the new drug provisions, the medical device law, and the cosmetics law.

3.3.3.50 - Wyoming

Wyoming has adopted the Uniform FD&C Act and the 1970 AAFCO Feed Bill but not the automatic adoption provisions of the Uniform FD&C Act. The controlling agency is Agriculture.

SUBCHAPTER 3.4 - INTERNATIONAL ARRANGEMENTS

3.4.1 - INTERNATIONAL ARRANGEMENTS

The Agency has over the years entered into agreements with foreign governments regarding the quality of foods, drugs, and other products exported to the United States. Refer to FDA's website at

<https://www.fda.gov/international-programs/international-arrangements/cooperative-arrangements> for additional information.

3.4.2 - MUTUAL RECOGNITION AGREEMENTS

3.4.2.1 - European Community

Changes in FDAMA have required that FDA begin the process of acceptance of mutual recognition agreements relating to the regulation of FDA regulated commodities, facilitate commerce between the US and foreign countries and other activities to reduce the burden of regulation and to harmonize regulatory requirements. See [Section 410 of FDAMA](#). Additional specific information is available at <https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra>.

3.4.2.2 - Food Products

In July 1999, the United States and the EC signed the "AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN COMMUNITY ON SANITARY MEASURES TO PROTECT PUBLIC AND ANIMAL HEALTH IN TRADE IN LIVE ANIMALS AND ANIMAL PRODUCTS". This agreement is very much like a mutual recognition agreement and is based on the equivalence process. It covers a very wide range of human food products, all of animal origin, such as milk and dairy products, seafood, honey, wild game, snails, frog legs and canned pet food. For purposes of this agreement, the EC is considered one "party" and not 15 Member States. Activities to begin assessing equivalence are underway.

SUBCHAPTER 3.5 - NON-GOVERNMENT AGREEMENTS

The Agency has entered agreements with various non-governmental groups to formulate various programs and guidance See [FDA's Cooperative Agreements page](#).

3-1 FDA/USDA JURISDICTION

This table summarizes information concerning jurisdiction overlap for commercial products regulated by either or both FDA and USDA. It does not cover products made for on-site consumption such as pizza parlors, delicatessens, fast food sites, etc.

FDA JURISDICTION	USDA JURISDICTION		
<p>21 USC 392(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals and all members of the deer family including elk (wapiti) and moose)). FDA responsible for all non-specified birds including wild turkeys, wild ducks, and wild geese.</p>	<p>The Federal Meat Inspection Act regulates the inspection of the following amenable species: cattle, sheep, swine, goats, horses, mules or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory Inspection of Ratites and Squab (including emu) announced by USDA/FSIS April 2001</p>	<p>The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA. Mandatory Inspection of Ratites and Squab announced by USDA/FSIS April 2001</p>	<p>The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose or guinea. Voluntary grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs.)</p>
<p>Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or less than 30% fat, tallow or meat extract, alone or in combination.</p> <p>Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat and poultry meat (limited to less than 2%) in any combination. *</p> <p>Closed-face sandwiches.</p>	<p>Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or 30% or more fat, tallow or meat extract, alone or in combination. *</p> <p>Open-face sandwiches.</p>	<p>Products containing 2% or more cooked poultry; more than 10% cooked poultry skins, giblets, fat and poultry meat in any combination. *</p>	<p>Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction.</p>
<p>FDA is responsible for shell eggs and egg containing products that do not meet USDA's definition of "egg product." FDA also has jurisdiction in establishments not covered by USDA; e.g. restaurants, bakeries, cake mix plants, etc.</p> <p>Egg processing plants (egg washing, sorting, packing) are under FDA jurisdiction.</p>			<p>Products that meet USDA's definition of "egg product" are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, eggnog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction.</p>
<p>Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3% red meat), meat flavored spaghetti sauce with mushrooms, (2% meat), pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor</p>	<p>Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie</p>	<p>Chicken sandwich (open face), chicken noodle soup</p>	<p>Homogeneous cheese and meat products, e.g., cheese balls with pepperoni, must contain more than 50 percent meat to be amenable to USDA inspection. Cheese products that contain 50 percent or less meat are considered products of the dairy food industry and, thus, are exempt from USDA inspection. When cheese and meat are separate components in a package, the packaged product is amenable,</p>

			provided, it contains 2 percent cooked meat.
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Jurisdiction for products produced under the School Lunch Program, for military use, etc. is determined via the same algorithm although the purchases are made under strict specifications so that the burden of compliance falls on the contractor. Compliance Policy Guide 565.100, 567.200 and 567.300 provide additional examples of jurisdiction. IOM 3.2.1 and 2.7.1 provide more information on our interactions with USDA and Detention Authority.

* These percentages are based on the amount of meat or poultry product used in the product at formulation.

HISTORY OF MENU ITEMS

DATE
4/25/03

PLACE
Hyatt Hotel
St. Louis, MO

MENU ITEM	SUPPLIER	DATE REC' D	PRE-PARED	ADVANCE PREPARED	LOCATION	STEPS IN PROCESS	TEMP OF	TIMES	EMPLOYEE(S) INVOLVED
Egg Rolls (Appetizer)	Independent Foods St. Louis, MO	4/20	yes		freezer	bake	5°-230°F	1600-1730	R. Brown
Ravioli (Appetizer)	ITAL-AMER Foods St. Louis, MO	4/21	yes		freezer	deep fry	5°-300°F	1700 - 1730	B. Black
Cheeses (Appetizer)	Fox Dairy St. Louis, MO	4/24	yes		cooler	slice	40°F	1350 - 1450	C. White
Pate (Appetizer)	Joe' s Butcher Shop E. St. Louis, IL (liver)	4/10		yes 4/10 Chef Welsh	freezer	thaw slice plate	5°-40°F 40°F 40°F	?-1600 1600-1630 1630-1700	K. Green " " " "
Produce (Salad)	Lombardi' s St. Louis, MO	4/24			cooler	wash plate cool	55°F 75°F 75°-40°F	0730 0845-0945 0945-1730	B. Black & K. Green
Crown Potatoes	"	"			"	slice bake plate	75°F 75°-225°F 200°F	0900-1030 1030-1200 1700-1730	R. Brown & A. Smith
Prime Rib	Joe' s Butcher Shop E. St. Louis, IL	4/24			"	roast slice plate	36°-140°F 135°F 130°F	1500-1800 1800-1830 1930-1900	Chef Welsh C. White Chef Welsh
Wine Chateau St. Juan 2001 2000 Marion Cabernet	Sonoma Valley CA "								

HISTORY OF MENU ITEMS

DATE **PLACE**

MENU ITEM	SUPPLIER	DATE REC' D	PRE-PARED	ADVANCE PREPARED	LOCATION	STEPS IN PROCESS	TEMP OF	TIMES	EMPLOYEE(S) INVOLVED



To: Postmaster

Agency Control Number:

Date:

ADDRESS INFORMATION REQUEST

Please furnish this agency with the new address, if available, for the following individual or verify whether or not the address given below is one at which mail for this individual is currently being delivered. If the following address is a post office box, please furnish the street address as recorded on the boxholder's application form.

Name:

Last Known Address:

I certify that the address information for this individual is required for the performance of this agency's official duties.

(Signature of Agency Official)

(Title)

FOR POST OFFICE USE ONLY

<input type="checkbox"/> MAIL IS DELIVERED TO ADDRESS GIVEN	NEW ADDRESS
<input type="checkbox"/> NOT KNOWN AT ADDRESS GIVEN	_____
<input type="checkbox"/> MOVED, LEFT NO FORWARDING ADDRESS	_____
<input type="checkbox"/> NO SUCH ADDRESS	
<input type="checkbox"/> OTHER (SPECIFY):	BOXHOLDER'S STREET ADDRESS
_____	_____
_____	_____
Agency return address	Postmark/Date Stamp

Under the authority of 39 CFR 265.6(d)(5)(i) and (d)(7)

265.6 Availability of records.

(d) Disclosure of names and addresses of customers. Upon request, the names and addresses of specifically identified [Postal Service](#) customers will be made available only as follows: (5) Exceptions. Except as otherwise provided in these regulations, names or addresses of [Postal Service](#) customers will be furnished only as follows: (i) To a federal, state or local government agency upon prior written certification that the information is required for the performance of its duties. The [Postal Service](#) requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked 'OTHER'. A copy of PS Form 1093 may be provided.

(7) Address verification. The address of a postal customer will be verified at the request of a Federal, State, or local government agency upon written certification that the information is required for the performance of the agency's duties. "Verification" means advising such an agency whether or not its address for a postal customer is one at which mail for that customer is currently being delivered. "Verification" neither means nor implies knowledge on the part of the [Postal Service](#) as to the actual residence of the customer or as to the actual receipt by the customer of mail delivered to that address. The [Postal Service](#) requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked "OTHER".

U.S. Food and Drug Administration

www.fda.gov

INSTRUCTIONS FOR COMPLETING IOM EXHIBIT 3-3

If you have already attempted to locate the individual or firm by sending mail marked on the outside of the envelope "DO NOT FORWARD. ADDRESS CORRECTION REQUESTED", without results, then proceed with this form according to the instructions below.

INSTRUCTIONS

1. Address the request to the Postmaster at the post office of the last known address.
2. Insert FEI # if known; or assignment or sample number for Agency Control number.
3. On the lines provided, give the name and last known address, including zip code, of the individual or firm. Do not include any other identifying information such as race, date of birth, social security number, etc.
4. The Postal Service provides the service of address verification to Government agencies only. For this reason, the Postal Service requires the signature and title of an agency official to certify that the address information requested is required in the performance of the agency's official duties. The agency official should be if possible, the chief of the office requesting the information. In the interests of efficiency, the signature may be preprinted or rubber-stamped.
5. Type or stamp the agency's return mailing address in the space provided at the bottom of the request. Include your full name and title or the appropriate person's full name and title to whom the form should be returned to. Mail or deliver the request to the Postmaster at the post office of the last known address.

You are not required to submit this request in duplicate or to furnish a return envelope.