CHAPTER 1 – ADMINISTRATION

CONTENTS

SUBCHAPTER 1.1 - ENGLISH LANGUAGE REQUIREMENT FOR FDA DOCUMENTS

Definition: the term **document** applies to official records which are considered to be U.S. Government property regardless of the media e.g. Regulatory notes (electronic and hardcopy), memoranda, inspection reports, e-mails, and official government forms (e.g. SF-71, FDA-482, FDA-483, etc.)

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

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

SUBCHAPTER 1.2 - TRAVEL

All official travel must be authorized and approved with a valid travel order (T.O.) using FDA's online travel management program GovTrip. Emergency travel can be approved and the travel order prepared and authorized after the fact. "After the fact" T.O.s should be utilized on a very limited basis.

The federal travel regulations contained in 41 CFR 301, Department of Health and Human Services (DHHS) Travel Manual, and the Food and Drug Administration (FDA) supplements thereto, govern official travel. Become familiar with these documents. All material contained in the Investigations Operations Manual (IOM) must be used in conjunction with, and subject to, federal travel regulations. Additional travel information can be obtained from the Office of Financial Management (OFM) Intranet home page.

For foreign travel, be aware that there are differences in reporting requirements and reimbursable expenses. See the Guide to International Inspections and Travel, Chapter 1, Subchapter 110 - Travel, for specifics.

Effective March 1, 2000, federal employees must put most official travel-related charges on government-issued credit cards, with exceptions only for expenses that are either relatively minor or inconvenient for credit card usage such as parking, local transportation, tips, phone calls, and certain expenses for which credit cards are not accepted.

FDA selected Northrop Grumman's GovTrip as their E-Government Travel Service. GovTrip is accessed at www.govtrip.com. GovTrip will enable FDA travelers and travel preparers to make travel reservations, book hotel accommodations and rental car reservations, and create authorizations and vouchers (including local travel vouchers) in a single web-based system. In addition, GovTrip will interface with the Unified Financial Management System (UFMS) for obligation and payment of travel vouchers. Payments will include direct payment to US Bank for expenses charged to the individual's official government travel credit card. The system incorporates Federal Government travel policies which include the city pair airfare contract program and Federal Travel Regulations and is structured to require justification if you want to deviate from General Services Administration's (GSA) regulations. A policy has been established with the FDA so that your government-issued credit card will be your primary method of billing and payment when you book flights, make hotel reservations, or reserve a rental car. Additional information can be obtained by contacting your Administrative Officer (AO) or visiting OFM's website.

1.2.1 - COMMON CARRIER

Request round-trip tickets when it can be expected you will use them. This reduces paperwork costs, even though there may be no savings on the tickets themselves.

You should cancel reserved tickets if you will not be using them. Failure to do so may result in charges levied by the carrier. Note the date, time of your cancellation, and the name or code number of the agent that you advised. Unused tickets must be returned to your AO or Travel Management Center.

Requirements which authorize you to use cash payments for procurement of common carrier transportation and related expenses, in lieu of your government-issued credit card, or centrally billed account, are specified in 41 CFR 301-72.200 and 301-51.100. Cash payments are generally permitted:

1. To obtain passenger transportation services, in an emergency, for any amount when authorized by your District Director (DD) and documented on your T.O. Otherwise, cash and personal credit cards may not be used for transportation expenses exceeding $100.00.
2. To pay air excess baggage charges up to $15.00 for each leg of a trip.

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

1.2.1.1 - Air

It is FDA's policy to require all travelers to use coach class service for official travel. A contract air carrier must be used unless one of three approved exceptions is met and your District Director approves another carrier. See your fiscal clerk for further information. Justification for use of non-contract carriers must be approved on the Travel Order by the Regional Food and Drug Director (RFDD), DD or Administrative Officer, or on the voucher, if "after the fact." Refer to Federal Travel Regulation (FTR) 301-10.107 and 301-10.108 for the mandatory use of a contract city-pair fare.

Exceptions to using City Pair Program are:

1. Contract service is not available in time to accomplish the purpose of your travel
2. Use of contract service would require you to incur unnecessary overnight lodging costs that would increase the total cost of the trip
3. Contract service is outside normal working hours
4. A non-contract carrier offers a lower fare (available to the general public), the use of which will result in a lower total trip cost to the Government
5. Cost effective rail service is available and is consistent with mission requirements

The Associate Commissioner for Management must authorize First Class travel. The use of first class travel must be pre-approved, and such approval will not be granted, even for medical reasons, unless business class is not available.

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

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

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

Please see the FTR on the GSA website for additional information.

1.2.1.2 - Auto Rental

GSA and the Department of Defense (DOD) both provide employees with a nationwide commercial auto rental program. The Federal Travel Directory, published monthly on floppy diskette, contains a list of vehicle leasing companies participating in this program. Agency policy dictates leasing the least expensive auto to satisfy the transportation requirements.

Commercial auto rental is available when specifically authorized by a special or blanket T.O. You will be reimbursed for rental expense when it is properly vouchered and your receipt is attached to your travel voucher.

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

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

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

1.2.1.3 - Taxi

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

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

1.2.1.4 - Accident Insurance

The government will not pay or reimburse you if you purchase accident insurance. Obtaining accident insurance is at your expense since you are covered while on official business by workmen's compensation insurance. See IOM 1.2.1.2 for payment of insurance on rental cars.

Many insurance policies will not cover you if you perform any duties connected with your job while on an interstate transportation carrier. This could affect you if you perform on-board inspections under the Interstate Travel Sanitation Program during a trip.

1.2.1.5 - Gainsharing

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

1.2.2 - GOVERNMENT FURNISHED VEHICLES (GFVs)

GFVs are provided for official purposes only. The term "official purpose" shall be interpreted strictly, and not construed to mean mingling of official business with non-official business. Using a GFV for sightseeing, personal business, personal convenience or preference will be construed as unauthorized use of a GFV. The distance involved in any such misuse is irrelevant. The following is an excerpt from the DHHS Travel Manual Appendix A 1-2.6a., dated May 31, 1988 which further defines official purpose:

"Use of Government-furnished Vehicles."

a. "Use limited to official purposes - When a Government furnished vehicle is used by an employee for official travel, its use shall be limited to official purposes (31 U.S.C. 638a) which include transportation between places where the employee's presence is required incident to official business; between such places and places of temporary lodging when public transportation is unavailable or its use is impractical; and between either of the above places and suitable eating places, drug stores, barber shops, places of worship, cleaning establishments, and similar places necessary for the sustenance, comfort, or health of the employee in order to foster the continued efficient performance of Government business."

You are responsible at all times for the proper care, operation, maintenance, and protection of a GFV. If you willfully or knowingly use or authorize the use of a GFV for other than official purposes, you are subject to suspension or removal.

1.2.2.1 - Interagency Motor Pool

GFVs for district operations are furnished by the regional GSA motor pool. Be guided by the district operating procedures in effect for the appropriate regional pool.

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

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

Purchase gas and oil for your GFV with GSA Credit Cards. Make emergency purchases with cash only when the GSA Credit Card is refused. Your receipts are required by the GSA motor pool. Provide for the safe and proper overnight storage of GFVs while you are in travel status, and put the charges on your travel voucher.

You are responsible for all traffic violations, including parking fines, you incur during the use and operation of a GFV. See DHHS Material Management Manual Section 103-38-052.1.

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

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

1.2.2.2 - Accidents

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

1.2.2.2.1 - INFORMATION TO BE OBTAINED

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

1.2.2.2.2 - REPORTING

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor and the chief of the motor pool from which the vehicle is assigned, unless your supervisor advises you the district will handle it.

1. Complete the following forms and submit as required:
   a. "Motor Vehicle Accident Report" (SF-91)
   b. Copy of an traffic regulations or ordinance which was violated
   c. Results of any trial or disposition of summons if any arrests were made or charges preferred.
   d. "Claim for Damage, Injury or Death" (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.) To be completed by claimant/non-government employee.
   e. Investigation Reports and Policy Reports
   f. Statement of Witness (SF-94)
   g. Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
   h. Statement listing date of purchase, purchase price and salvage value where repair is not economical
   i. Photographs of damage and/or scene of accident if available
2. File reports to comply with all local and state laws dealing with accident reporting. Keep copies of all reports made and attach them to the federal accident report.
3. Check with your personal insurance carrier for their requirements.
4. Immediately submit to your supervisor any notice, summons, legal paper or claim, which may subsequently arise from the accident.
5. Check with your district safety officer to determine if additional reports or information are needed.

1.2.2.3 - Liability

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

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

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

Claims should be submitted through your Administrative Office to the Office of Shared Services, Fleet Manager, HFA-720, 12345 Parklawn Drive, Rockville, MD 20857. The claim will be reviewed and forwarded to Program Support Center (PSC) for processing.

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

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

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

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

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

Motor Vehicle Accidents - See IOM 1.2.2.2

1.2.2.3.2 - TORT CLAIMS

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

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

1.2.2.3.3 - REFERENCES

FDA Staff Manual Guide 2260.1

Military Personnel and Civilian "Employees' Claims Act of 1964 Directive 495.1 - Claims Under The Military Personnel And Federal Tort Claims Act http://www.law.cornell.edu/uscode/html/uscode28/usc_sup_01_28_10_VI_20_171.html

HHS and PHS General Administration Manuals (Chapters 4-00, 4-10, 4-30, 40-35)

1.2.2.4 - Use of a GFV between Your Residence and Place of Employment

Use of government owned, or leased autos between your residence and place of employment, is approved by the Secretary, DHHS, for certain job series as stated in FDA Staff Manual Guide (SMG) 2173.1. The use of a DHHS-16 "Request to use Government Furnished Vehicle for Transportation between Domicile and Place of Employment" is no longer required, however, local management may continue to use the form or establish a verbal approval process, if desired. The Daily Log of Government Vehicle (Form FDA-3369) must be maintained by all approved persons using a GFV, assuring that all items indicated on the form are completed for each trip. The DHHS now requires that each person taking a GFV home, in order to perform field work, must indicate in Column 10 on the Form 3369, the location of their residence. The Daily Log must be kept for at least a period of three years and must be available for audit purposes. The use of Form DHHS-17 "Quarterly Report on use of Government-Owned or Leased Vehicles between Domicile and Place of Employment" is no longer required.

1.2.2.5 - Care & Custody of U.S. Vehicles

GSA has issued instructions on the use and protection of U.S. Government vehicles, Government National Credit Cards, and car keys. The parts of these instructions applicable to you while the car is in your custody are:
1. The car should be locked when parked in public areas, in private lots, or in open government parking areas.
2. The operator is responsible for the keys and the credit card. They should be removed from the vehicle and carried whenever the vehicle is parked.
3. The keys and credit card are returned to the motor pool office when the vehicle is returned. These items should be kept in a safe place at the office if the vehicle is stored at other than a motor pool location.
4. The credit card must be removed when a vehicle is left at a garage or service station and the keys remain with the garage or station attendant.
5. The credit card may only be used to purchase fuel and lubricants or other items listed on the back of the card for the vehicle identified, and not used for other vehicles.
6. Before signing a service ticket, check for accuracy. Be sure the imprinted address is legible, and write the vehicle mileage (odometer reading) on the ticket.

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

1.2.3 - PRIVATELY OWNED VEHICLE (POV)

On official business, you may use your POV instead of a GFV, if authorized. However, reimbursement for mileage will not exceed the cost of using a GFV. You should carry a set of government accident reporting forms whenever you use your POV for official business. See IOM 1.2.2.2.2 for accident reporting requirements.

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

1.2.3.1 - Accidents

The Federal Employee’s Compensation Act (Workmen’s Compensation) protects employees against losses due to

personal injuries received while operating POVs on official business.

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

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

If the accident is determined not to have been caused by your negligence, the provisions of the Military Personnel and Civilian Employees Claims Act (31 U.S.C. 240-243) would be applicable. Under this Act, you would be reimbursed for the deductible portion of the repair not covered by your own automobile insurance policy, up to a maximum of $250.00 deductible. (You may also collect from the other party's insurance.) Form DHHS-481, Employee Claim for Loss or Damage to Personal Property, should be obtained from, completed, and submitted to the Office of Shared Services, Fleet Manager, HFA-720, 12345 Parklawn Drive, Rockville, MD 20857, with evidence establishing that the use of a POV was authorized for official purposes and that the accident was not caused by your negligence.

Employee Liability - see IOM 1.2.2.3.

Reporting - Report vehicle accidents as instructed in IOM 1.2.2.2.

1.2.4 - PER DIEM AND SUBSISTENCE

Subsistence is the cost of lodging, meals, tips, and the miscellaneous expenses you incur while in travel status. Per Diem is based on the actual cost of lodging, plus a set amount for "Meals and Incidental Expenses" (M&IE), not to exceed the maximum rate for the prescribed city or area. Note: For domestic travel only, report lodging taxes separate from lodging expenses and claim them in the "Other" column on your travel voucher. Foreign travel taxes still remain a part of your lodging expenses.

Lodging expenses should be paid using your government-issued credit card, when possible. The credit card bill will be mailed directly to you. It is your responsibility to pay the bill on time. The FDA will reimburse late charges on your bill only when you can show the late payment was due to late reimbursement of funds by the FDA.

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

Administrative Notes - Your regulatory notes (See IOM 2.1) should not contain notes of a purely administrative nature (documentation of travel, expenses [tolls, sample costs, etc.], fiscal data, mileage, etc.) These administrative notes can be documented in some kind of an administrative diary. They do not need to be kept in a permanent record other than the completed Travel Voucher, Claim for Reimbursement for Expenditures on Official Business, Receipt for Samples, etc. Follow your district's requirements for maintaining this information.

1.2.4.1 - Per Diem Rates

Consult your supervisor or administrative personnel for specific rates for specific locations or at the ERIC website.

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

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

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

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

1.2.4.2 - Hospitalized In Travel Status

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

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

1.2.5 - CHANGE OF OFFICIAL STATION

Effective January 11, 2004, the Office of Financial Services, OSS, centralized FDA relocation services with Prudential Relocation Services. Services provided include: entitlement counseling, transportation of household goods, and travel voucher review and preparation. Access the ERIC website to view the online "Agency-wide Relocation Policy Guide" which provides basic administrative

information for employees transferring from one duty station to another within the FDA.

1.2.6 - ADVANCE OF FUNDS

You will use your government-issued credit card to obtain a cash advance from an ATM machine, for official government business only. Ensure your Travel Authorization contains a statement that you are authorized to use an ATM to obtain cash advances and the amount authorized. ATM cash advances may be used to purchase samples. There are usually two fees associated with an ATM cash advance. The "Terminal Fee" assessed by the ATM terminal's owner/supplier and the "Cash Advance Fee" assessed by the bank. Currently, the Cash Advance Fee is 1.5% of the total ATM advance; or 1.5% x $(Cash advance amount + ATM Terminal Fee). The Cash Advance Fee is described in your credit card agreement. These amounts must be included on the Travel Authorization/Voucher along with receipts before reimbursement can be made.

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

1.2.7 - CLAIMS FOR REIMBURSEMENT

Within five days after each trip, submit your electronic claim for reimbursement (Travel Voucher) using GovTrip. Expenses for local travel for meetings and/or field work are also claimed using GovTrip. All travel vouchers are processed electronically. See www.govtrip.com for web-based training information.

Travel Voucher Preparation - Clerical procedures vary from district to district, so consult your supervisor or administrative officer for instructions. State all items in chronological order. Show your mode of transportation and if accompanied, the names of the other travelers.

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

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

Leave Taken in Travel Status - If you take any type of leave while in travel status, include a statement on your travel voucher that you apprised your timekeeper of the amount and type of leave taken. The timekeeper must initial your voucher to show that the leave has been recorded.

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

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

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

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

1.2.8 - TELEPHONE COMMUNICATIONS

Commercial - Local, official telephone calls are reimbursable. When placing an official call from a non-government phone, use your government-issued calling card, call collect if permitted by your District's policy, or call commercially and claim reimbursement on your travel voucher.

Commercial calls from hotels or motels should be made using your government-issued calling card, whenever possible. If not possible, they should be claimed on your travel voucher and be supported by the phone bill. Calls made using a personal credit card or similar billing arrangements should be claimed on your travel voucher if a receipt is available at the time of voucher preparation. Otherwise, a follow-up petty cash voucher should be submitted, supported by a copy of your itemized phone bill, and certification the charge was for official government business.

Calls To Residence - FDA has established the following guidelines under which an employee in travel status for more than one night within the U.S. may be reimbursed for telephone calls home:

1. Calls should be made as economically as possible.
2. Calls should be made on the FTS network when possible. If not possible, calls should be made using your government-issued calling card. Telephone calls made with government-issued calling cards are automatically billed to the FDA. You are reimbursed through the

voucher system when a surcharge is imposed for credit card calls from the traveler's motel/hotel room. Refer to Staff Manual Guide 2343.2 to determine the maximum allowable reimbursement for telephone calls home.

Districts that have differing union-negotiated agreements regarding telephone calls home while in travel status should be guided by those agreements.

1.2.9 - ITINERARIES

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

SUBCHAPTER 1.3 - LEAVE

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

If it is necessary for you to take leave while in travel status, notify your supervisor immediately. Include a specific statement on your travel voucher that you did so.

Refer to the NTEU Collective Bargaining Agreement dated 10/1/99 or the agreement negotiated at your local site for additional information regarding leave issues.

More leave information is also available at http://www.opm.gov/oca/leave/index.asp compensatory time at http://www.opm.gov/oca/pay/html/comp.htm and credit time at http://www.opm.gov/oca/worksch/html/cred_hrs.htm. Information for Commissioned Corps is located in the officers handbook under Leave and Work Schedules on pages 97-100 at http://dcp.psc.gov/eccis/documents/PAM62.pdf.

SUBCHAPTER 1.4 - DISCLOSURE OF OFFICIAL INFORMATION

You are not to release or divulge any information obtained during FDA investigative or inspectional operations, unless you are authorized to do so and the sharing (regardless of the manner) complies with FDA's information disclosure laws and procedures. This includes information contained in diaries and field notes, except for official issuance of forms or documents to addressees. Do not release any originals or copies of reports, memos, diaries, forms (e.g.: FDA-483, 484, 464, etc.), or similar investigational documents to anyone outside the Agency without express concurrence of district or regional management and without following FDA's laws and procedures (21 CFR 20.85 - federal, 21 CFR 20.88 - state/local, 21 CFR 20.89 -foreign, 21 CFR Part 20 - Freedom of Information Act (FOIA), and 21 CFR Part 21 - Privacy Act). See IOM 1.4.4.

1.4.1 - SUBPOENA

If you are served a subpoena (commanding your appearance in court) or a subpoena duces tecum, (commanding the production of any record or testimony, or the giving of information relating to official FDA matters), immediately advise your supervisor. You will be instructed by your District officials as to the proper procedures and actions on your part in complying with the subpoena. See 21 CFR 20.1, 20.2 and the Regulatory Procedures Manual (RPM) chapter 10-9, "Testimony; Production of Records; Certification of Records."

1.4.2 - REQUESTS BY THE PUBLIC, INCLUDING TRADE

Be guided by IOM 1.4.4 on requests for information desired by the public under the Freedom of Information Act (FOIA). Refer to FDA's "Information Disclosure Manual" (IDM) for procedures for sharing non-public information with federal, state, local, or foreign government officials. (See IOM 1.4.3).

In the case of complaints where a sample has been collected from the complainant, your District may inform the complainant of FDA's findings when an examination is actually made of the sample. When you collect a sample from a complainant, and he asks for analytical results, he may be told that the FDA will advise him by letter of the general nature of the findings. See IOM 4.1.7 and IOM 4.4.6.3 for cautions on collecting this type sample.

1.4.3 - SHARING NON-PUBLIC INFORMATION WITH OTHER GOVERNMENT OFFICIALS

If you receive requests for non-public information from officials of other federal agencies or from state, local or foreign government officials, be guided by the current IDM published by the Division of Compliance Policy (DCP) (HFC-230). You may not share FDA non-public information with such officials without being authorized to do so under FDA's procedures.

The procedures contained in the IDM on disclosing information to the public or sharing non-public information with officials from other federal agencies, or from state, local, or foreign governments were formerly found in Chapter 8 of the FDA's RPM. With the publication of the IDM, this material no longer appears in the RPM.

The most current IDM is available on the FDA Intranet by visiting the Office of Enforcement's website. Relevant

sections on non-public disclosure may be found in the IDM, Section 4 as follows:

1. Sharing Non-Public Information with Foreign Government Officials,
2. Sharing Non-Public Information with Federal Government Officials,
3. Sharing Non-Public Information with State and Local Government Officials

1.4.4 - FREEDOM OF INFORMATION ACT

Public Law 89-487, the Public Information section of the Administrative Procedures Act, more commonly known as the FOIA, adopts a general rule that, except where specifically exempt, all documents in government files shall be made available to the public. There are various exemptions in certain areas, and it is these that mostly affect your operations in FDA. The regulations exempt certain information, such as personal privacy, deliberative process, open investigatory, as well as a company's trade secrets or confidential commercial information.

1.4.4.1 - Procedures

Study and become familiar with the general provisions of the FOIA and the regulations in the Code of Federal Regulations (CFR) regarding the release of information to the public. In particular, study 21 CFR Parts 20 and 21, 21 CFR 71.15, 171.1, 314.430, 514.11, 514.12 and others, all of which contain provisions regarding confidentiality in various FDA records and documents. Also, see the IDM.

In addition to the FOIA, various other Acts such as the Federal Food, Drug, and Cosmetic (FD&C) Act, the Public Health Services (PHS) Act, and 18 U.S.C. 1905 each contain information relating to the confidentiality of information in government files, and are of particular interest. Special care should be taken to protect the identity of confidential sources. See IOM 5.2.9 for further guidance.

1.4.4.2 - Requests for Documents

No field FDA employee has authority to deny any request for documents, no matter what form the request takes. Authority to deny requests rests with the Associate Commissioner for Public Affairs.

Each field and district office is responsible for the internal handling of requests. Information disclosure personnel, e.g. FOI Officers, designated by their respective RFDD's, are responsible for coordinating the implementation of the regulations, for development of procedures within their organization to handle requests, and for adherence to Fad's laws and procedures regarding the maintenance of confidentiality of non-public information. If you receive a request for information under the FOIA, advise the requester to write to the Food and Drug Administration, Division of Freedom of Information (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. See DFOI's website at http://www.fda.gov/foi/default.htm.

1.4.5 - INTERNAL FDA DOCUMENTS

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

Work Plans - Do not divulge district work planning operations without authority from your supervisor.

If you receive requests for internal documents or for parts of them, refer to IOM 1.4.4 and IOM 1.10.2.7.

SUBCHAPTER 1.5 - SAFETY

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

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

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

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

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

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

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

If you do not have the specific personal protective equipment recommended by the firm's management, have your District furnish what you need. In some cases, the firm may be willing to provide the necessary personal protective equipment, however if respiratory protection is required, you should not wear any respiratory protection unless your District has a written Respiratory Protection Program and you have been certified by your District's Respiratory Protection Program Administrator as having currently met the requirements of this program. See IOM 1.5.1. It is ultimately your responsibility to ensure that you do not expose yourself to any hazard.

Disaster conditions present inherently dangerous situations. See IOM 8.5.

Operations in the radiological area also pose special dangers. See IOM 1.5.4.2.3. Obtain advice on protective measures from regional radiological health personnel.

1.5.1 - PROTECTIVE EQUIPMENT

1.5.1.1 - Eye Protection

Wear safety glasses during all inspectional activities in which there is a potential for physical or chemical injury to the eye. These glasses should, at a minimum, meet the American National Standard Z87.1-1989 standard for impact resistance. Guidance should be provided by the management of the facility being inspected as to additional eye protection required. Unvented goggles should be worn whenever there is the potential for a chemical splash or irritating mists. Additional eye protection may be required in facilities that use exposed high intensity UV lights for bacteriostatic purposes, tanning booth establishment inspections (EIs), etc. Follow the manufacturer's recommendation regarding eye protection for any instrumentation generating light in the UV or higher energy wavelength range.

1.5.1.2 - Hearing Protection

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

1.5.1.3 - Protective Clothing

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

1.5.1.4 - Respiratory Protection

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

1.5.1.4.1 - PROGRAM PROVISIONS

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

1. Procedures for selecting respirators for use in the workplace, and annual fit testing of each employee wearing the selected respirator(s)
2. Medical evaluation of employees required to use a respirator prior to the employee's use of a respirator, and repeated as specified in the Respiratory Protection Program. A medical evaluation can be obtained by

contacting your local Industrial Hygienist or Ann Gallman, SERL, phone (404) 253-2214.
3. Procedures for using respirators in routine and reasonably foreseeable emergency situations
4. Procedures for maintaining respirators
5. Training of employees in the hazards to which they are potentially exposed during routine and emergency situations, and in the proper use of respirators including limitations of their use and fit checking procedures each time the respirator is donned
6. Procedures for regularly evaluating the effectiveness of the program. OSHA requires each employer perform an evaluation of any workplace which may contain respiratory hazards. If these respiratory hazards cannot be removed through engineering controls, the employer must provide respirator protection. Do not enter any area you suspect may contain an unevaluated respiratory hazard. Your training should include a determination of the minimum respiratory protection for each type of inspection you may perform. Your regional Industrial Hygienist or the ORA Safety and Occupational Health Manager may be consulted for guidance in the type of respirator, type of cartridge or filter, and the useful life of the cartridge or filter.

1.5.1.4.2 - FIRMS WITH POTENTIAL RESPIRATORY HAZARDS

The following list includes situations, which have been identified as having the potential for respiratory hazards:
1. Feed or drug plants where there is a possible inhalation hazard due to airborne particulates.
2. Fumigation or storage facilities where treated grain or produce is encountered, including trucks, vessels, railroad cars, fumigation chambers.
   a. Do not enter any structure or conveyance or sample any product that is being treated with the fumigants Methyl Bromide or Phosphine. If a sampling area is suspected of having been fumigated with methyl bromide or phosphine, and has not been cleared according to the EPA requirements, contact your local industrial hygienist for guidance as to how to ensure that the area is safe to enter. Do not enter the area until it is appropriately aerated and tested. If entry is required using personal protective equipment, you local industrial hygienist can provide guidance to ensure you are using the appropriate respirator and cartridge, and any other protective equipment necessary based upon the fumigant concentration. See IOM 1.5.3.4, Asphyxiation Hazards, and IOM 1.5.4.2 Factory Inspections, for additional cautions related to fumigants.
   b. Areas and/or products being treated with fumigants are required by Environmental Protection Agency (EPA) to be placarded, and the placards not removed until the treatment is complete (usually 12 hours to 4 or more days) and the areas and/or products are clear of fumigant gases (phosphine <0.3 ppm and methyl bromide <1 ppm).
   c. Self-contained breathing apparatus (SCBA) is generally the only respiratory protection gear approved for use in areas being fumigated. It is necessary to follow many other precautions when working around fumigants. See Note on Methyl Bromide and Phosphine at the end of this section for additional information.
3. Facilities using ozone, or where ozone is produced as a by-product of the manufacturing operation.
4. Facilities where sterilizers utilize ethylene oxide gas (EO) - See IOM 1.5.4.2.2 Factory Inspection
5. Grain elevators or other grain storage facilities that potentially contain aflatoxin in the dust.
6. Spice grinders and repackers that potentially produce airborne respiratory irritants such as pepper.
7. Any rodent-infested area. - See IOM 1.5.5.4 Hantavirus Associated Diseases

1.5.1.5 - Health and Hygiene

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

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

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

If any firm management demands evidence of recent physical examination before permitting inspection, consult your supervisor. A mere request to examine your hands

for sores, etc., is not unreasonable. However, do not accede to a physical examination.

1.5.2 - AUTOMOBILE SAFETY

Automobile Condition - See IOM 1.6.2.

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

Ensure all volatile solvents, either in the sample collection kit or contained in a sampled material, are sealed to prevent contamination of the air in a closed vehicle. Be especially aware of the hazard of transporting dry ice in a closed vehicle. The concentration of carbon dioxide gas can cause drowsiness, or even an asphyxiation hazard, if the dry ice is carried in an unventilated vehicle. See IOM 1.5.3.4 Asphyxiation Hazards.

1.5.3 - SAMPLING

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

1.5.3.1 - Sample Fumigation and Preservation

Follow safety precautions when fumigating and/or preserving samples. Guidance is as follows:
1. Whenever possible, freeze the sample. If freezing is not practical, contact your servicing laboratory for alternative fumigants and preservatives.
2. When fumigants or preservatives are used, exercise care to limit your exposure to these chemicals. Contact your servicing laboratory for the appropriate precautions necessary with these chemicals.
3. Material Safety Data Sheets (MSDS) for each of these chemicals must be available at each duty site (e.g., District office, resident posts), and can be obtained from your servicing laboratory. These sheets list the hazards involved with these chemicals and precautions to take for use. You must read and follow the instructions in the MSDS prior to using the chemical. If a measured amount of chemical fumigant or preservative is present at the time of shipping, enclose a copy of its MSDS with the shipped sample. Again, if you have any questions, contact your servicing laboratory.
4. Avoid excessive heat and open flame.
5. Use glass vials or jars with lined lids whenever possible. Depending on the type of fumigant used, some polypropylene containers can also be used.

1.5.3.2 - Electrical Hazards

Many samples are collected in poorly lighted areas, or in older poorly wired buildings. Be alert for low hanging wires, bare, exposed, or worn wires, and broken or cracked electrical outlets.

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

1.5.3.3 - Physical Hazards

Be alert for dangerous conditions on all sampling operations. If it is necessary to use a flame to sterilize sampling equipment, use extreme care.

All flammable liquids in your sampling kits must be in metal safety cans. See IOM 4.3.6.1.2

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

1.5.3.3.1 - RAILCARS

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

1.5.3.3.2 - GRAIN ELEVATORS

Grain Elevators:
1. Prior to use, make sure man lifts are operating properly.
2. Make sure cross-rungs on ladders are safe.

3. When stepping off ladders or man lifts, be sure the floor is actually a floor and not a bin covered with canvas, cardboard, or other temporary non-supportive cover.
4. Make sure walkways between bins are sturdy.
5. Use caution when sampling from high bins or tanks. Wet or icy conditions may prevail, so check these conditions.
6. When brass grain bombs are used to collect bin samples, do not drop the bomb to the surface of the grain. This could cause sparks if it hits the bottom or side of a bin. Lower the bomb gently to the grain surface, then raise it four to five feet and let it fall to the grain surface to collect the sample. Do not use steel grain bombs; use only brass bombs for sampling.
7. Do not use flash units in dusty areas because of the possibility of explosion hazard. See IOM 5.3.4 for additional information.

1.5.3.3.3 - CLOTHING

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

1.5.3.3.4 - TRUCKS

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

1.5.3.4 - Asphyxiation Hazards

1. Prior to entering closed areas, ascertain if they have been fumigated and, if so, air them out prior to entering.
2. When sampling or inspecting at rendering plants or fishmeal plants, be alert to possible hydrogen sulfide accumulations in dump pits and other areas. These fumes can be deadly.
3. Be alert and take proper safety precautions in plants, silos, bins, pits, and any closed areas where semi-solid buttermilk or other liquid dairy products, silage, or other bulk products are stored. If not properly stored, improperly handled, or decomposing, certain products can produce dangerous amounts of carbon dioxide, or other gases, or may deplete the oxygen supply in these areas.
4. When transporting dry ice or packages containing dry ice in your car, have some external ventilation (See IOM 1.5.4.2.1, 4.5.3.5, and 8.5.3 for additional dry ice cautions).
5. When sampling from the top of a grain elevator, do not jump down on top of grain. There may be a cavity caused by crusted grain which could break and result in you being buried in grain, or being in an atmosphere of fumigating gas.
6. Be alert when entering storage areas having controlled atmospheres, e.g., where oxygen has been replaced by carbon dioxide to prolong fruit storage, added sulfur dioxide for preservation purposes, etc. These areas must either be aerated prior to entering, or Oxygen Breathing Apparatus (OBA) must be used.

1.5.3.5 - Radioactive Product Sampling

The sampling and viewing of radiopharmaceuticals may be accomplished working through a lead shield or viewing through lead glass and using protective clothing latex gloves and tongs to prevent exposure to "unnecessary" radiation.

1.5.3.6 - Chemical Hazards

You may be assigned to collect samples of FDA regulated products involved in a wreck where chemicals pose a threat, or in areas of chemical spills or hazardous waste sites. In such instances, unprotected personnel are not permitted into hazardous zones. You will be permitted into those areas deemed safe, however, consult with the on-site DHHS Coordinator, usually an employee of the Agency For Toxic Substances and Disease Registry (ATSDR), to ascertain if any safety precautions are necessary on your part. Follow instructions provided. See IOM 3.2.12 for further information and for the address and phone numbers of the ATSDR contacts.

1.5.3.7 - Carbadox Sampling

Concentrated Carbadox (above 95%) has a severe dust explosiveness rating, is a flammable solid, and is also carcinogenic. The only approved source of Carbadox in the US is "Mecadox 10", a medicated pre-mix at a 2.2% concentration.

High concentrations of Carbadox (up to 99%) have been found during investigations of illegal bulk drugs. Some have been falsely labeled as Mecadox. Carbadox, in its pure form, is a minute yellow crystal. It is considered dangerous. Do not collect physical samples of any bulk substance identified or represented as Carbadox or Mecadox. The Center for Veterinary Medicine (CVM) will take action on documentary samples.

If there is no labeling and/or a dealer refuses to identify any yellow powder, inform the dealer of the hazards of Carbadox. Contact your supervisor before collecting any samples of suspected Carbadox. If instructed to collect a sample, use extreme caution and proceed as follows:
1. Wear disposable gloves
2. Use a respirator or other effective means to avoid breathing the dust. Paper masks are not adequate
3. Use goggles
4. Do not sample in drafty places
5. Use only plastic bottles with plastic caps
6. Collect only 1-2 oz. per sub

7. Cover material collected with at least an equal amount of distilled or deionized water and gently mix. It is preferable to use too much water than not enough
8. Note on collection report (CR) the approximate amount of water added to the bottle of suspect product
9. Protect subs from excessive heat and do not store in the trunk of car in the sun
10. Store in insulated cartons with ice, if necessary
11. Flag the CR as to possible presence of Carbadox

Notify the receiving laboratory of sample collection.

1.5.4 - INSPECTIONS

Many firms pose safety hazards or problems. Some include:
1. Flying glass in bottling plants
2. Explosion hazards from dust
3. Man-lifts which do not operate properly
4. Asphyxiation problems in rendering plants, fish meal plants, fumigated bins in elevators, fumigation chambers and any closed bins or areas
5. Forklifts and other power equipment operated in the plant. Be alert for their presence and avoid being hit.

1.5.4.1 - Man Lifts and Ladders

Many firms have either power or hand driven man lifts for movement between floors. Do not use the man lift if company policy forbids non-employees using them.

Before riding mechanical lifts, make sure safety equipment is installed and operating properly.

When riding power lifts, observe the following safety precautions:
1. Determine ahead of time what floors are serviced by the lift and at which floor you intend to get off
2. Determine safety devices, and how they operate. Check lift for automatic cut off at the top or a safety stop cord
3. Always face the belt when riding the lift
4. Never carry excess equipment or items that protrude and could get caught between floors.

When using hand powered lifts, remember to:
1. Check the foot brake for proper operation
2. Check if control rope is firmly fastened at the bottom
3. If lift has a stop pin which must be removed prior to use or after use, determine how it is used and use it
4. Check counterbalance of lift, and add or remove weights if necessary
5. Never free-fall on the lift when descending; always keep descent in control by using the brake
6. Use gloves to avoid rope burns or slivers from the hemp or metal pull ropes.

Never over-extend a ladder. If possible, have the bottom held by someone while you are using it. Use blocks on base of portable Grain Car Ladders to hold base away from car wall to provide foot space on ladder rungs.

Some mills and elevators have makeshift ladders. Extreme care should be exercised when using these.

1.5.4.2 - Factory Inspection

Inspections of retorts require extra safety precautions. Be alert for live steam and other potentially dangerous heat sources. Do not enter a retort if your safety cannot be assured. When it is necessary to enter a retort, inform plant management. If firm has safety interlock switches, make sure they are engaged and locked. Have a second investigator or plant management stand outside the retort to assure nothing will happen.

1.5.4.2.1 - THERMAL

When inspecting freezers, make sure doors cannot accidentally snap shut and lock you inside. Be alert to ammonia leaks while inspecting freezing and refrigerating operations. Note: ammonia under normal operating conditions retains its chemical stability and will not burn or support combustion. An ammonia leak in a freezer can cause explosions if proper air/ammonia mixtures are reached. It can be toxic if inhaled, and can cause eye and throat irritation. If an ammonia leak is discovered during an inspection, leave the area immediately and notify management of the leak. Warning: If an ammonia-contaminated area must be entered, a full-face mask or self-contained oxygen mask or a gas absorbing canister mask must be worn. Protective clothing is also necessary, if the ammonia concentration is high. If you are unable to obtain the use of the mask and protective clothing, then do not enter the area.

Use care when entering areas where large amounts of dry ice are used or stored. Be sure the area is adequately ventilated prior to entering. See IOM 1.5.3.4, 4.5.3.5 and 8.5.3 for additional cautions concerning use of dry ice.

When visiting facilities handling drug products, check with management to determine if any of the articles produced require special handling or protective equipment, such as respirators.

1.5.4.2.2 - CHEMICAL

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

Ethylene Oxide (EO) - EO is a colorless gas or volatile liquid with a characteristic ether-like odor above 500 ppm. Unmonitored and inadequate ventilation will allow EO

buildup of extremely high concentrations, especially in facilities utilizing malfunctioning or leaking equipment. Door gaskets, valves, and threaded fittings are typical areas where leaks have been observed. Additionally, exhaust vents from the sterilizer and the sterilizer room should not be located near air conditioning intake vents, or vented directly into work areas. If the odor of EO is detected, ventilation and containment are inadequate. Leave the area and report the situation to your supervisor for further inspectional guidance. Special EO monitoring equipment is available upon request from DFI for investigators" safety monitoring of inspectional site.

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

1.5.4.2.3 - IONIZING RADIATION

Each investigator who visits a manufacturer of radioactive products or tests ionizing radiation emitting products (e.g., diagnostic x-ray tests) must wear a Thermoluminescent Dosimeter (TLD) to estimate external exposure. These are available in each district; personal alarm dosimeters are also available. These can alert the investigator to high exposure areas during visits to manufacturing firms. Make an estimate of the time spent in areas where radiation is present, and estimate exposure during this time from your personal dosimeter. The estimate can be compared to the results from the TLD badges, which would be processed by Winchester Engineering and Analytical Center (WEAC). Contact WEAC for additional information concerning TLD badges.

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

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

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

1.5.5 - MICROBIOLOGICAL HAZARDS

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

1.5.5.1 - Animal Origin Products

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

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

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

1.5.5.2 - Viral and Other Biological Products

Take proper precautions to protect yourself. If necessary, consult your supervisor and/or district microbiological personnel. NOTE: Inspection of vaccine manufacturers may require inoculation in advance of the inspection to adequately protect the investigator. Contact the Center for Biologics Evaluation and Research (CBER), Division of Viral Products, HFM-445, for guidance.

Methods of transmission include aerosols, which may be created by manufacturing operations (e.g., centrifugation, filling, etc.) or spills. Transmission may occur through inhalation; contact with contaminated objects, including

equipment, animals, waste materials, reagents, file cabinets and doorknobs. Transmission can occur through ingestion, inhalation, or through broken skin.

1.5.5.2.1 - PROTECTIVE AND PREVENTIVE MEASURES

Protective and preventive measures include:

1. Precautions listed in IOM 1.5.5.1 and 1.5.5.3
2. Do not touch. This means equipment, materials, reagents, animals, etc.
3. Wear protective clothing. Evaluate the needs for gowns, caps, masks, gloves, and shoe coverings, and wear them where necessary. Protective clothing worn in a work area where a virus or spore bearing microorganism is handled must not be worn into a work area for another product. Leave all used protective clothing at the firm for proper disposal.
4. Wash hands thoroughly after leaving each work area.
5. Determine if the firm has established safety precautions and procedures, and follow them if adequate.
6. If the firm is processing viruses or other potentially infectious biological agents during the inspection, determine if it is advisable to enter the work areas. Chances of infection through aerosols are reduced when there is no active processing.
7. Females of childbearing age are advised not to inspect areas where the Rubella virus is actively processed unless immunity has been established. Infection during pregnancy may result in congenital abnormalities.
8. Vaccines are available for your protection against some organisms (e.g., Rubella). For information on inoculations and physical examinations, refer to IOM 1.5.1.5.

1.5.5.2.2 - VIRAL HEPATITIS AND HUMAN IMMUNODEFICIENCY VIRUS

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

Keep in mind the following warnings:

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

1.5.5.2.3 - PRECAUTIONS FOR NON-CLINICAL LABORATORY INSPECTIONS

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

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

1.5.5.3 - Bacteriological Problems

Take proper precautions to protect yourself. If necessary consult with your supervisor and/or district microbiological personnel. Possible routes of Salmonellosis include dust inhalation in dried milk and dried yeast plants. Thyroid processing plants may also be a source of this problem.

In no case should you taste any item implicated or suspect of causing injuries or illnesses (e.g., consumer complaint samples, etc.). Handle these with extra care since even minute portions of certain items may cause serious illness or even death (See IOM 8.3.3).

1.5.5.4 - Hantavirus Associated Diseases

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

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

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

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

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

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

Anyone who develops a febrile or respiratory illness within 45 days of the last potential exposure should immediately seek medical attention. Inform the attending physician of the potential occupational risk of Hantavirus infection.

1.5.6 - WIRELESS DEVICES

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

1. If you carry a blackberry, cell phone, or other wireless device, always enquire about a firm's policy with regard to their operation within the establishment as they may pose a safety hazard.
2. The General Services Administration's FMR Bulletin B-2 discourages the use of hand held wireless phones while operating Government owned and commercially leased and rented vehicles.
3. FDA policy [Staff Manual Guide 2173.1] discourages the use of hand held wireless phones or other wireless devices while operating government, commercially leased/rented vehicles. Drivers who use cell phones within their scope of work are required to use hands-free cell phones and other hands-free devices.

1.5.7 - REPORTING

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

Injuries - If you are injured during the performance of official duties, report immediately to your supervisor. If medical aid is required, obtain it as soon as possible. Check with your supervisor on what accident report forms are required and procedures to be followed.

Note: Supervisors must refer to Chapter IV - Guide 8, Compensation for Injury, of the DHHS Personnel Guides for Supervisors concerning procedures to follow and forms to be filled out whenever an employee is injured.

SUBCHAPTER 1.6 - PUBLIC RELATIONS, ETHICS & CONDUCT

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

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

Over the past few years, the inspectional and investigational activities of the FDA have received extensive coverage in the electronic and print media. Regional and District Directors are the spokespersons for FDA in their respective areas. However, investigators and inspectors are occasionally requested by the media to comment or provide information on their individual inspectional activities. Such requests include being interviewed and filmed during inspections, investigations and sample collections. If media representatives contact you, be courteous and helpful, but refer all requests for information, interviews and personal appearances to your supervisor. You may be permitted to appear on camera or be interviewed, but authorization must be gained in advance. Otherwise, your Regional or District office will handle the inquiry, or refer it

to the Assistant Commissioner for Public Affairs (HFI-1) at headquarters.

Do not solicit media interviews or on-camera appearances. In those instances where media request you be interviewed or filmed, the request should be tactfully declined and referred to the district office, your immediate supervisor and/or District Director. There may be occasions when management of a firm you are inspecting invites representatives from the news media to observe the inspectional process. Please see IOM 5.1.4.3 for instructions on how to appropriately handle such events.

FDA publications, press releases and talk papers on a wide variety of subjects are available in your district, and are helpful in answering media and public inquiries. In addition, you should refer them to FDA's Internet Web site. Talk papers, press releases, FDA publications, federal register announcements, etc. are on-line at this Web site.

1.6.1.1 - Non-Government Meetings

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

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

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

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

1.6.2 - EQUIPMENT CARE, CUSTODY, AND LOSS

Care and custody

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

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

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

1.6.2.1 - Maintenance of Equipment

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

1.6.2.1.1 - REPAIRS

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

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

1.6.2.1.2 - EQUIPMENT CALIBRATION

You are responsible to assure equipment assigned to you is calibrated for accuracy. This includes thermometers, pyrometers, balances, scales, stopwatches, etc. Keep a record of the calibration with each item requiring calibration. Calibration of certain inspectional equipment can be done by your District laboratory.

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

1.6.2.2 - Lost or Stolen Equipment

As soon as you discover any government property assigned to you or in your custody is missing, report it verbally to your supervisor. Normally, you must submit a form GSA-3155, "Offense/Incident Report". Your district should have these in stock. This form must be supplemented by a memorandum detailing the circumstances surrounding the loss, including the

comprehensive steps you took to recover the items. The procedure is outlined in the Staff Manual Guide FDA 2280.5.

Follow your district procedures for any additional requirements.

1.6.3 - OFFICIAL CREDENTIALS, BADGE

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

1.6.3.1 - Delegated Authority

When you are issued the FDA official forms FDA-200 A&B, certain parts of the Commissioner's enforcement authority, as specified in Staff Manual Guide 1410.32, is re-delegated to you. You are expected to use this authority wisely and judiciously. See IOM 5.1.1.2 on cautions against Xeroxing or photocopying your credentials.

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

1.6.3.2 - Qualifications for Credentials

FDA employees engaged in general inspectional and investigational operations are issued FDA-200 A&B credentials. By virtue of their position, these employees are recognized as qualified to perform the duties assigned.

FDA Official Credentials confer extensive inspectional authority on you. Exercise the utmost care of your badge and credentials. Carry them in a manner that will assure positive protection against loss. For example, do not carry them in the upper pockets of your clothing where they may fall out if you bend over. You may not only lose your credentials and badge, but they may, during inspections, fall into vats or machinery resulting in embarrassment and possible financial loss to you as well. Also, carrying your credentials and badge in the glove compartment of your car or leaving them in the pocket of an unattended coat or jacket are invitations to loss or theft.

1.6.3.3 - Lost or Stolen Credentials, Badge

The procedure for reporting loss or theft of credentials and/or badge is in the Supervisory Staff Manual Guide, SMG 2280.3. Notify your supervisor immediately, and submit a written report of the loss or theft to him. If instructed, report the loss or theft to local law enforcement authorities and request the police report identification number. Also ask that the number of the lost credentials/badge be entered into the National Crime Information Center (NCIC). Include this information in your report.

1.6.4 - BUSINESS CARDS

In June 1999, the FDA determined it is proper to use general appropriation funds to purchase business cards for employees whose interactions with outside organizations further the agency's mission. Due to certain restrictions pertaining to the purchase of business cards, employees should consult with local management prior to purchasing such items, to ensure adherence to agency policy and procedures.

1.6.5 - EMPLOYEE CONDUCT

As a government employee of the FDA, as few limits as possible are placed on your interests and activities. Nonetheless, certain limitations are necessary to protect the interest of the government. These constraints are covered the Standards of Ethical Conduct for Employees of the Executive Branch, and consult with your supervisor if you have any questions or concerns in this regard. The Standards of Ethical Conduct for Employees of the Executive Branch can be found on FDA's intranet under the Office of Human Resources and Management Services' (OHRMS) ethics laws.

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

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

The Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635) gives concise details on what is expected, insofar as conduct is concerned. In addition, certain subparts, and Appendix A to Part 73 of the HHS Standards of Conduct, remain in effect. Additional information is also available on FDA's internet at www.fda.gov/opacom/ethics/.

1.6.5.1 - Professional Stature

You are the eyes and ears of FDA, and to most of the public you are their only contact with FDA. Your actions may be the basis upon which they judge the entire FDA. The public expects exemplary behavior and conduct from the government employee. This responsibility applies to both on the job and off the job activities. As you inspect or

appraise individuals, you are, in turn, being evaluated. Both the industries FDA regulates and the public-at-large are keenly aware of, and are quick to report, what they consider improper actions by government employees.

When you issue an FDA 483, the firm is provided with information as to how to contact the District Office with such reports and information on the Small Business Enforcement Fairness Act of 1996 (SBREFA), which provides regulated industry a means for addressing industry concerns about government agency enforcement activities. See IOM 5.2.3.1.1. You may receive complaints or other questions from the regulated industry during routine field operations, such as sample collections, investigations, import entry reviews and establishment inspections where an FDA 483 was not issued. In these circumstances, provide the firm the "Information for FDA - Regulated Industry" Website "www.fda.gov/oc/industry." Explain there are Small Business links on the webpage and the FDA Ombudsman link is located under the Contact FDA heading and they may also call the District Office. Document this discussion in your regulatory notes and include it in your Establishment Inspection Report (EIR) in the Discussion with Management section, your Memorandum of Investigation, or the remarks section of your collection report.

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

1.6.5.1.1 - INTEGRITY

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

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

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

The Office of Internal Affairs (OIA), Office of the Commissioner (OC), is responsible for obtaining factual information for the FDA on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by Agency personnel. If you uncover or suspect any such problems, report them to your supervisor. The District/Region will contact OIA. 21 CFR 19.21(b) requires the facts be forwarded to OIA, HF-9, in writing. OIA will maintain the anonymity of your complaint, if you so desire.

Under the Federal Managers" Financial Integrity Act, it is your duty to report any serious problems of waste, mismanagement, fraud or misuse of Government funds by any personnel from other agencies or government contractors. These problems should be reported to your supervisor, who will, in-turn, notify the Division of Management Programs (HFA-320).

1.6.5.1.2 - ATTITUDE

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

1.6.5.1.3 - ATTIRE

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

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

1.6.5.1.4 - EMPLOYEE PROHIBITIONS - GIFTS, LUNCHEONS, AND SNACKS

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

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

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

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

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

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

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

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

1.6.5.1.5 - ORA POLICY

ORA's policy requires you do not use or consume a firm's products at any of the firm's facilities. This can be interpreted as acceptance a product is satisfactory and could embarrass the Agency, particularly in the event of a subsequent regulatory action against the firm.

1.6.5.1.6 - PROFESSIONAL PERSONNEL CONTACTS

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

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

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

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

1.6.5.2 - Attempted Bribery

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

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

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

SUBCHAPTER 1.7 - INTERDISTRICT ASSIGNMENTS

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

1.7.1 - ISSUANCE AUTHORITY

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

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

Assignments involving three or more districts, or requiring more than three working days to complete, shall be

approved by the branch director or appropriate manager of the issuing district. Multiple district assignments need to be closely monitored by the issuing district to avoid unnecessary duplication of work.

1.7.2 - PROCEDURES

Each assignment shall contain the following details:

1. Description of the problem and nature of the assignment, i.e., sample collection, records collection, inspection, etc.
2. Full name, address and the FDA Establishment Identifier (FEI) number of the responsible firm. You may also provide the central file number (CFN) if known or available.
3. Program Assignment Code (PAC).
4. Product code and full description of product including lot number(s) and code(s).
5. Home district code.
6. Full name and address of the firm (or firms) and individual(s) to contact to accomplish the assignment.
7. Priority and requested completion date.
8. Name, telephone number and mailing symbol of the contact person who can answer questions concerning the assignment and the person who should be notified of results.
9. Where to send samples, records, reports, etc.

1.7.3 - ASSIGNMENTS AND REPORTING

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

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

Copies of assignments which involve emergencies, danger to health situations or highly publicized investigations shall be sent via e-mail or Federal Express (FedEx) to the Emergency Operations Center, HFA-615 (301-443-1240). Completion and referrals - A copy of the Establishment Inspection Report (EIR), C/R, memorandum, etc., showing results should be sent to the person specified in the assignment, along with a copy of the assignment. When an assignment is completed, make sure the appropriate FACTS fields are updated/entered as necessary. Copies of responses to assignments that involve emergencies, danger to health situations, or highly publicized investigations shall also be sent to Emergency Operations Center, HFA-615.

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

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

SUBCHAPTER 1.8 - ORGANIZATION OVERVIEW

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

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

1. http://www.fda.gov/oc/ with organizational charts at: http://www.fda.gov/oc/orgcharts/orgchart.html
2. Center for Biologics Evaluation and Research: with organizational charts at: http://www.fda.gov/cber/inside/org.htm
3. Center for Drug Evaluation and Research: http://www.fda.gov/cder/office.htm with organizational charts at: http://www.fda.gov/cder/cderorg.htm
4. Center for Devices and Radiological Health: http://www.fda.gov/cdrh/organiz.html with organizational charts at: http://www.fda.gov/cdrh/organiz.html
5. Center for Veterinary Medicine: http://www.fda.gov/cvm/aboutcvm.html with organizational charts at: http://www.fda.gov/cvm/Documents/cvm1.pdf
6. Center for Food Safety and Applied Nutrition: http://www.cfsan.fda.gov/~lrd/cfsan4.html with organizational charts at: http://www.fda.gov/oc/orgcharts/CFSAN.pdf
7. Office of Regulatory Affairs: http://www.fda.gov/ora/hier/ora_overview.html with organizational charts at: http://www.fda.gov/oc/orgcharts/ora.html

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

There are approximately 9300 FDA employees.

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

FDA is responsible for ensuring:

Foods are safe, wholesome, and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.

Regulated products are honestly, accurately, and informatively represented.

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

1.8.1 - FDA PRINCIPLES

We strive to:

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

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

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

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

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

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

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

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

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

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

SUBCHAPTER 1.9 - OFFICE OF REGULATORY AFFAIRS

1.9.1 - ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS

The Acting Associate Commissioner for Regulatory Affairs (ACRA) is Michael A. Chappell, and the Deputy Associate Commissioner for Compliance Policy is Steven M. Solomon, DVM, MPH. The Deputy Associate Commissioner for Field Operations is Michael A. Chappell

ORA is under the leadership of an Associate Commissioner known as the ACRA. This office is responsible for the activities and operations of the field headquarters staff and the field staff of FDA. The Headquarters Office Directors and the Regional Food and Drug Directors (RFDD's) report to this office.

This office advises and assists the Commissioner and other key officials on regulations and compliance oriented matters which have an impact on policy development and execution and long-range program goals.

As of November 2008, there were over 3500 employees in the ORA field organization including ORA headquarters. For ORA contact information, see the ORA Field Contacts Directory at the end of this manual.

Immediate office of ORA:
Special Assistant to ACRA - Amy Waltrip
Regulatory Counsels - Carolyn Becker and Anne Kirchner
Senior Advisor for Risk Analysis – Kara Morgan
QMS – Brenda Holman
Senior Advisor for Science – John Marzilli
ORA Executive Operations - Charlotte Christin

1.9.2 - ORA HEADQUARTERS ORGANIZATION

ORA consists of four individual offices which operate independently of each other. However, their functions are related and they support each other. A description of the function of each office is outlined below.

1.9.2.1 - Office of Resource Management (ORM) (HFC-10), James M. Strachan, Director

The Deputy Director of ORM is Michael W. Roosevelt.

ORM is basically responsible for the planning, management, and evaluation of the operations of the field offices. It is also responsible for the computer systems which handle the information generated by the field offices.

The Division of Management Operations in ORM controls the budget for the field's day to day operations. ORM allocates funds as determined by actual needs of the field and headquarters units.

1. The training of personnel stationed in the field is also coordinated by The Division of Human Resource Development in ORM. ORM has the following divisions:
2. Division of Management Operations (HFC-20) Director - Richard Garwood
   a. Management Operations and Analysis Group Michele M. Berger, Supervisor
   b. Financial and Program Analysis Group, Andrea Oliver, Director
   c. Facilities Management Group, Randy Higgins, Supervisor
3. Division of Planning, Evaluation and Management (HFC-40), John A. Lechus, Director
   a. Program Planning and Workforce Mgmt. Branch, Carrie Mampilly, Supervisor
   b. Program Evaluation Branch Lynnette I. Riggio, Supervisor

4. Division of Human Resource Development (HFC-60), Gary German, Director
   Vacant, Deputy Director
5. Commissioned Corps Liaison, Diann Shaffer
6. FDA History Office (HFC-24): John Swann, and Suzanne White Junod, Historians.

1.9.2.2 - Office of Regional Operations (ORO) (HFC-100) David K. Elder, Director

The Director of ORO is David K. Elder. The Deputy Director is vacant. Special Assistant to the Director is Kara Lynch. International Affairs Program Manager is vacant.

ORO coordinates and manages all Agency field operations, Team Biologics Core Team, and the Prior Notice Center on behalf of the ACRA; develops issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within the Agency through which headquarters offices obtain field support services.

It evaluates the overall management and capabilities of the Agency's field organization; initiates action to improve the management of field activities. Coordinates nationwide health fraud activities between the field, states, and Headquarters organizations. Coordinates field public affairs and information programs; distributes timely information to the field; coordinates activities with Agency counterpart organizations. Serves as the Agency focal point in developing and maintaining international regulatory policy and activities to assure the safety, efficacy, and wholesomeness of regulated imported products. Coordinates Agency procedures with Headquarters and field offices and is the primary contact with the U.S. Customs Service and others among those offices. Develops and/or recommends to the ACRA policy, program, and plans for applied research relating to Agency enforcement problems; coordinates such research efforts with appropriate agency components. Directs and coordinates the Agency's emergency preparedness and civil defense programs. Provides other Agency components with laboratory support in highly specialized areas.

ORO has the following components:

1.9.2.2.1 - DIVISION OF FIELD INVESTIGATIONS (HFC-130)

Michael C. Rogers, Director 301-827-5653
Patricia Alcock, Deputy Director 301-827-5653

DFI provides coordination, direction, assistance, and management for the field's domestic and foreign investigative activities. It serves as the Agency focal point for Headquarters/field relationships on investigational and inspection problems, and programs and operations. It develops and reviews investigative and inspectional procedures, training programs, and prepares and issues investigative and inspectional guidance manuals. The division provides the field investigative and engineering technical assistance and guidance for foreign inspections.

DFI has two branches: Domestic Operations Branch and International Operations Branch. The Division's deputy director manages ORA's National Experts.

Gerald D. Bromley, Jr. is the Director of the Domestic Operations Branch, and Rebecca Ramos Hackett is the Director of the International Operations Branch. They may be reached at 301-827-5653.

The following personnel within the Domestic Operations Branch are available to help you in various program related activities and may be reached at DFI's main number 301-827-5653 or at the numbers below:

James Dunnie	Human Drugs, Veterinary Drugs	301-827-5652
Norman Fogg	Foods	301-827-5645
Vacant	Medical Devices	
Gail Katz	Biologics	301-827-3357
Ruark Lanham	Bioresearch Monitoring, Good Laboratory Practices (GLPs)	301-827-6691
Barbara Marcelletti	Foods, Seafood HACCP	301-827-5635
Vacant	Bioresearch Monitoring, Clinical	
Vacant	Biologics, Microbiology	

Personnel responsible for foreign inspections and trip planning in the International Operations Branch:

Linda Adams	Drugs	301-827-5648
Olaide Akimade	Drugs	301-827-3902
Oumou Barry	Biologics	301-827-3904
Deborah Blanks	Foods	301-827-0943
Barbara Blosser	Drugs	913-752-2466
Dyrene Braswell	Program Assistant	301-827-5659
Luis A. Carrion	Foods	787-474-9520
Lawrence Carter	Drugs	301-827-3903
Doreen Chin Quee	Devices	301-827-5632
Denaja Crutchfield	Assistant	301-827-6884
Olga Duran	Drugs	301-827-5644
Patricia Griffin	Devices	301-827-5668
Attila Kadar	Bimo	301-827-5647
Tania Mercado	Bimo	301-827-5637
Heriberto Negron-Rivera	Drugs	301-827-3901
Irma Rivera	Drugs	301-827-5665
Minerva Rogers	Devices	301-827-5633
Naveen Walker	Foods	301-827-0167
Joyce Watson	Biologics	301-827-5664
Marisa White	Bimo	301-827-5629

The National Experts, stationed at a District office or resident post, are assigned to DFI.

Thomas Arista	DAL-DO Biotechnology	214-253-4920
Regina T. Brown	NWJ-DO Drugs	732-940-8946 x14
Mary T. Carden,	NYK/BUF Biologics	716-541-0352
Debra Devlieger	SEA-DO Food/LACF	206-842-0251
Sharon K. Thoma	MIN-DO Drugs	612-758-7159
Brian Hendrickson	DET-DO Food/LACF	317-226-6500 x104
Joan Loreng	PHI-DO Biologics	215-717-3724
Dr. Gerald McGirl	SAN-DO BIMO	510-337-6850

Rebeca Rodriguez	SJN-DO Drugs	787-474-9556
Robert D. Tollefsen	SEA-DO Computer	425-483-4923
David B. Wieneke	MIN-DO Food, Aseptic Processing, Dairy	612-758-7177
Kimberly Lewandowski-Walker	MIN-DO Devices	414-771-7167 x23
Norman Wong	SEA-DO Devices	206-483-4935
Ingrid Zambrana	ATL-DO Food Outbreak and Food Defense	404-253-1284

1.9.2.2.2 - DIVISION OF FIELD SCIENCE (DFS) (HFC-140)

Carl Sciacchitano, Director
Thomas Savage, Deputy Director
301-827-1232

DFS provides a focal point for all aspects of ORA Field Laboratories and serves as the Headquarters' scientific and technical staff. It manages FDA's overall field scientific resources to assure their coordinated, efficient, and effective use; provides coordination between field and center scientific programs, and develops and manages the Science Advisor Program and Department of Defense Shelf life Extension Program.

DFS manages field research programs and the applicability of new, complex, scientific instruments for field analyses and provides scientific and analytical expertise related to laboratory automation, analysis, process control and acquisition of automated data laboratory instruments. DFS manages the scientific aspects of the FACTS. The Division participates in the determination of long and short-range field scientific facility needs and in the formulation, delivery, and evaluation of training and career development plans for field scientists. Program contacts in DFS are:

1. Larry D' Hoostelaere, CBER/CDRH programs contact; Mad Cow and TSE issues
2. Marsha Hayden, CFSAN programs contact
3. Don Lech, CDER programs contact
4. George Salem, CVM programs contact

They can all be reached at 301-827-7605/6

1.9.2.2.3 - DIVISION OF FEDERAL-STATE RELATIONS (DFSR) (HFC-150)

Richard H. Barnes, Director 301-827-6906
Preetham R. Sudhaker, Staff Manager, Contracts and Grants Staff
Catherine M. McDermott, Staff Manager, Public Affairs and Information Staff

DFSR interacts with counterpart State and local officials to promote cohesive and uniform policies and activities in food and drug related matters. It also serves at the focal point for cooperating officials from state agencies that need information, coordination or services from headquarter units. DFSR coordinates efforts between FDA and state and local counterparts. DFSR also provides information to and receives information from state, territorial, and local agencies. Work is completed by cooperating directly with state and local government officials and industry and indirectly through FDA field offices and national regional and state associations.

DFSR manages a contract/grant program with the states benefiting them with technical training, familiarity with federal requirements and more uniform enforcement of consumer laws through cooperation and coordination with FDA. Contracts involve food safety, tissue residues, radiological health, and medicated feeds which allows FDA to enlarge coverage of the Official Establishment Inventory (OEI) and also to redirect resources to other problems. Grants include areas in Food Safety and Food Defense, Health Fraud and small conference issues. Cooperative agreements include areas in FERN and BSE.

DFSR coordinates work between FDA and State and local agencies through Voluntary Work Agreements such as partnership agreements, memoranda of understanding (MOU's) and coordinated operations plan for emergencies (COPE).

DFSR serves as Liaison for Cooperative Programs between headquarters, CFSAN and FDA field staff. Cooperative Programs include the retail food program, milk safety and shellfish sanitation program areas which CFSAN leads the daily responsibility for providing assistance to FDA regional specialists who in turn interact with state specialists. DFSR also provides policy and technical information on medicated feeds and drugs to state control officials.

DFSR is responsible for the commissioning of State officials and oversees the national program which provides authority to state and local officials to conduct investigations and collect samples to enforce the Federal Food Drug and Cosmetic Act. Also included is the sharing of a wide range of Agency documents as well as responding to state and local requests for information on Agency policy or position. DFSR coordinates the activities of FDA Field Public Affairs Specialists (PAS), the first line contact for consumers, health professionals, academia and the media on current and emerging FDA issues. DFSR is responsible for monitoring and maintaining the Public Affairs Reporting System (PAIRS). DFSR is responsible for the State Advisory Fax/Email System (SAFES), a communication system, which allows FDA to send out information including fax and e-mail emergency/priority messages to specific program groups, e.g. State Boards of Pharmacy, State Health Commissioners, State Food Program Directors, and others 24 hours/day.

1.9.2.2.4 - DIVISION OF IMPORT OPERATIONS POLICY (DIOP) (HFC-170)

Domenic J. Veneziano, Director 301-443-6553
Deputy Director, Vacant

This division provides direction, assistance, management and oversight of field import operations. It serves as Agency focal point for contact with U.S. Customs and

other Federal Agencies regarding import activities. Develops and reviews agency import policies, procedures, programs, etc. and is responsible for issuing import informational directives (Import Alerts, Bulletins, etc.) and RPM, Chapter 9. DIOP is responsible for the maintenance of the Operational and Administrative System for Import Support (OASIS), including the coordination with program Centers to establish automated screening criteria.

Contact points within DIOP are:
1. Systems Branch (HFC-171)
   Steven Kendall, Director 301-594-1162
2. Operations and Policy Branch (HFC-172)
   John E. Verbeten, Director 301-594-3845

1.9.2.2.4.1 - Prior Notice Center (PNC) (HFC-180)

Laura J. Draski, Director 301-621-7809
Anthony C. Taube, Deputy Director 866-521-2297

The PNC was established as a result of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA), specifically related to the prior notice requirements of the BTA. The PNC provides a focal point to the FDA field on all aspects of Prior Notice with expertise in researching import shipments and their related firms. The PNC operates 24 hours a day, 7 days a week within Customs & Border Protection's National Targeting Center to receive, review and provide the appropriate response to information submitted in advance of FDA regulated food products, including animal feed, imported or offered for import into the United States. The purpose of prior notice is to enable FDA to target for exam the highest risk imported foods at the time of arrival, in order to maximize food safety and security in the United States and to prevent products that may be intentionally contaminated and/or may pose a potential significant health risk due to terrorism or other health related emergency from entering into U.S. Commerce.

Contact Points within Prior Notice Center are:
Nabil Anis, Watch Commander
D. Yvette Arline, Watch Commander
Greta Budweg, Watch Commander
Kelli Giannattasio, Watch Commander
Janice Gordon, Watch Commander
Jamie Hughes, Watch Commander
Lonna Potter, Watch Commander
Angel Suarez, Watch Commander
Marilyn White, Watch Commander

All of the above can be reached at 866-521-2297

1.9.2.3 - Office of Enforcement (OE)(HFC-200) Vacant, Director

The Director of OE is vacant and the Deputy Director is Alyson L. Saben.

OE advises and assists the ACRA and other key officials on regulations and compliance policy matters which impact on policy development, implementation and long range goals. OE also coordinates, interprets, and evaluates the FDA's overall compliance efforts and, as necessary, establishes compliance policy and recommends policy to the ACRA.

OE also acts as liaison with other federal agencies on compliance matters, evaluates proposed legal actions, coordinates actions with the Office of Regional Operations (ORO) and the Office of Chief Counsel (OCC) and handles appeals of proposed compliance actions which are disapproved by the centers or OCC.

This office coordinates agency bioresearch monitoring activities and serves as Agency focal point for the Federal Medical Products Quality Assurance Program (GWQAP).

OE consists of the following elements:
1. Division of Compliance Management and Operations (DCMO) and Recall Staff (HFC-210) Vacant, Director
2. Division of Compliance Policy (DCP)(HFC-230) Douglas W. Stearn, Director
3. Division of Compliance Information and Quality Assurance (DCIQA) Staff (HFC-240) Katherine A. Hollinger, Director

1.9.2.4 - Office of Criminal Investigations (OCI) (HFC-300) Terrell L. Vermillion, Director

This office advises and assists the ACRA and other key officials on regulations and criminal violations involving regulated activities and products.

OCI directs and conducts criminal investigative activities in coordination with FDA headquarters units and with other Federal, state and local law enforcement agencies. OCI is instrumental in implementing FDA criminal investigation policy, training, and coordination. OCI interfaces directly with Federal and local prosecutorial offices and participates in grand jury proceedings and judicial actions as required.

OCI has 170 employees in headquarters and the field.

1.9.3 - ORA FIELD ORGANIZATION

The ORA field organization is divided into regional offices. The Regional Offices are under the control of Regional Food and Drug Directors (RFDD's) who report to the ACRA. There are currently five regional offices which are located as follows:

Northeast	New York, NY
Central	Philadelphia, PA
Southeast	Atlanta, GA
Southwest	Dallas, TX
Pacific	San Francisco, CA

Each regional office directs 2 to 7 district offices.

There are currently 20 district offices located in major cities around the country. Each district office (DO) is usually comprised of four branches or units as follows:

1. Administrative Branch
2. Compliance Branch
3. Investigations Branch - some DOs may have 2 investigations sections, one for domestic products and one for imported products.

Laboratory Branch - not all DOs have laboratories

SUBCHAPTER 1.10 - REFERENCES

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

1.10.1 - LAW, REGULATION AND GUIDANCE

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA Modernization Act of 1997, (FDAMA), the International Conference on Harmonization (ICH), the Mutual Recognition Agreement (MRA), national emergencies and initiatives, and other forces continue to impact FDA inspectional operations as changes in law, regulation, guidance and internal procedures issue. As ICH members (Japan, U.S. and European Union) reach consensus agreements, ICH guidelines are adopted by all three governments. In the United States, they may replace outstanding FDA guidance in the medical device, human and animal drug areas. Unless exempted, the Bioterrorism Act and implementing regulations require most domestic food facilities and foreign food facilities who export to the U.S. to register as of December 12, 2003; FDA began accepting registrations on October 16, 2003. The Bioterrorism Act requires that FDA receive prior notice of food imported into the United States, beginning on December 12, 2003. The 2002 MDUFMA authorizes FDA to charge user fees for medical device premarket review; it allows third party medical device inspections, sets out new regulatory requirements for single-use devices, and directs FDA to establish the Office of Combination Products. FDA drug GMP initiative and Process Analytical Technology (PAT) efforts are underway.

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

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

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

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

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

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

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

Guidance documents for industry do not establish legally enforceable rights or responsibilities and are not legally binding on the public or the agency. Rather, they explain how the agency believes the statutes and regulations apply to certain regulated activities. For a more detailed explanation of the background to the development, issuance and use of guidance documents see the preamble to the February 27, 1997 Federal Register Volume 62 Number 39. To access 21 CFR 10.115 Good Guidance Practices, see http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfrv1_01.html . Also see http://www.fda.gov/cdrh/ohip/guidance/1323.pdf to access the CDRH Manual for the Good Guidance Practices (GGP) Regulation - Final Guidance for FDA Staff (2/01). For a comprehensive list of FDA current guidance documents, see http://www.fda.gov/opacom/morechoices/industry/guidedc.htm.

The Federal Register is the official daily publication for rules, proposed rules, and Notices of federal agencies and organizations as well as Executive Orders and other Presidential documents. The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive Departments and agencies of the Federal Government. Most regulations enforced by FDA are located in Title 21 of the CFR. For a listing of all titles in the U.S Code, see http://www4.law.cornell.edu/uscode/#TITLES.

1.10.2 - SOURCES OF INFORMATION

1.10.2.1 - Investigator Training and Certification

ORA's Investigator certification program provides a focused training plan for the ongoing professional development of agency investigators. The program is designed to address the specific needs of agency District Offices by providing a structured mechanism for investigators to maintain the required levels of competency.

Performance certification promotes uniformity in investigator training and experience. The program is designed to promote the efficient use of (ORA) training resources. Investigators who complete the program will be formally recognized as meeting the competencies required at the specific certification level achieved.

Additional information on ORA's Investigator Certification program, including procedure documents and forms for certification in specific commodity areas, is available on ORA U on DHRD's intranet site.

In addition to managing the investigator certification program through ORAU, the Division of Human Resource Development (DHRD) (HFC-60) manages and coordinates with Regions and Districts, the ORA staff's overall ongoing professional development training through in person and web-based courses, broadcasts, and video conferences. For more information on available training on the ORA U, see DHRD's intranet site.

1.10.2.2 - Contacting FDA Employees

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

CFSAN - See http://www.cfsan.fda.gov/~dms/srchbfd.html.

CBER - See http://www.fda.gov/cber/inside/org.htm

CDRH - See http://www.fda.gov/cdrh/organiz-info.html. For a list of resource staff by topic of specialization in the Division of Small Manufacturers, Consumer and International Affairs, see http://www.fda.gov/cdrh/dsma/dsmastaf.html#DSMICA_Staff

CVM - See http://www.fda.gov/cvm/cvmlist.html

CDER - See http://www.fda.gov/cder/directories/reference_guide.htm. For a list of resource staff by topic of specialization, in the CDER Division of Manufacturing and Product Quality, (HFD-320) see http://www.fda.gov/cder/dmpq/subjcontacts.htm.

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

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

1.10.2.3 - Internet and Intranet

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

Two features will facilitate your navigation of the FDA website, For the FDA "Website Index", see www.fda.gov/opacom/hpchoice.html. To access the FDA "Website Map", see www.fda.gov/sitemap.html.

Subscribe to various FDA e-mail lists for updates on web postings. See www.fda.gov/emaillist.html.

FDA libraries are accessible on the FDA intranet site.

1.10.2.4 - FDA on Disk

The FDA Gold Disk is an electronic source of regulatory references maintained on CD-ROM by the Office of Enforcement, Division of Compliance Information and Quality Assurance (HFC-240) Scott Lewis 781-596-7748. To order a Gold Disk, contact San Francisco District, Gwen Wong, 510-337-6890. FDA personnel who do not have access to an FDA network server can use the Gold Disk in an off-line mode. It may also be available on your local district server. Check with your computer support personnel. The FDA gold disk is a convenient source of FDA regulatory references in electronic format when Internet access is not available. It contains, for example, the Federal Food Drug and Cosmetic Act, Title 21 CFR, Compliance Policy Guides, Enforcement Reports, Talk Papers, Import Alerts, Investigations Operations Manual,

Regulatory Procedures Manual, selected Compliance Programs, the Food Code, and listings of approved drug products. The Gold Disk is not releasable under FOI and is not available to the public. It is for FDA use only. The subset of the Gold Disk available to state and local agencies (but not releasable under FOI) is the Eureka Disk. To order this, contact Christina Segura-Ramos in the ORA Division of Federal-State Relations (DFSR) at 301-827-2901.

1.10.2.5 - Electronic-Fax Information Systems

The FDA Medical Devices fax information system issues documents twenty-four hours a day, seven days a week on request to 800-899-0381. Follow the directions by the automated attendant to receive a faxed list of references and their order numbers. Next, request specific documents by number as indicated on the index.

Biologics, Human/Animal Drugs and Foods do not have fax information systems.

1.10.2.6 - FDA/ORA Manuals and Reports

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

1. Compliance Policy Guides (CPGs): A limited number of 2000 paper manuals available by contacting OE/DCP at 240-632-6860;
2. Compliance Program Guidance Manual (CPGM): No paper manuals;
3. Data Codes Manual: No paper manuals; for electronic lists of program assignment codes and establishment type codes contact ORM/Division of Program Evaluation and Management
4. Enforcement Reports: No paper reports;
5. Field Management Directives (FMDs) - No paper manual;
6. Guide to International Inspections and Travel - For paper manuals contact ORA/DFI 301-827-5653;
7. Inspection Technical Guides - No paper manuals;
8. International Cooperative Agreements Manual - No paper manuals;
9. Investigations Operations Manual (IOM) - Current edition paper manuals available by contacting ORA/ORO/Division of Field Investigations at (301) 827-5653.
10. Laboratory Procedures Manual (LPM) - No paper manuals;
11. Laboratory Information Bulletins (LIB) - No paper copies;
12. Regulatory Procedures Manual (RPM) - No paper copies;
13. Recalls and Safety Alerts - No paper copies;
14. Staff Manual Guide: No paper manuals;
15. State and Federal Cooperative Agreements: No paper copies.

1.10.2.7 - Forms and other Publications

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

Order paper copies of FDA forms from the USDA Consolidated Forms and Publications Distribution Center, Beltsville Service Center at 6351 Ammendale Road in Beltsville, MD 20705. Phone or fax orders will not be accepted. Forms may be ordered electronically. To obtain a customer number necessary to order forms electronically, or for other questions concerning FDA forms, contact:

FDA/Office of the Commissioner/Office of Management/ Office of Management and Programs/Division of Management Systems/Paperwork Reduction and Records Branch
Elizabeth Sands, Forms Management Officer, (HFA-250)
5600 Fishers Lane, Room 6A-22
Rockville, MD 20857
301-827-1480
FAX 301-594-0060
Or e-mail to Elizabeth.Sands@fda.hhs.gov
or Formsmanager@oc.fda.gov.

The Department of Health and Human Services (DHHS) Program Support Center, 16071 Industrial Drive, Gaithersburg, MD 20877 also maintains a limited selection of FDA forms and publications. To search their catalog, see https://propshop.psc.gov/shopping/formspubs.asp#/. For questions, contact Danny Saum at PSC at 301-443-7634.

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

1.10.2.8 - Regulatory References and the General Public

The general public must make a request under the Freedom of Information Act (FOIA) in order to obtain certain FDA documents requiring redaction. See IOM 1.4.4 (Freedom of Information Act) and IOM 1.4.5 (internal Documents) for additional information on FOIA. For instructions to the public on how to file an FOIA request, see www.fda.gov/foi/foia2.htm.

Many FDA documents are available to the public without an FOIA request. To obtain forms, direct the public to the FDA Public Use Forms web page. The public can purchase paper editions of various agency manuals, such as the Food Code and Compliance Program Manuals if ordered by NTIS item number from the National Technical Information Service (NTIS). Instruct the person seeking a publication to first locate the NTIS item number by calling the NTIS sales department at 800-553-6847. The next step is to enter the NTIS item number in the search box at the NTIS website at www.ntis.gov, and follow directions on ordering the publication. For additional information on NTIS publications, direct the public to contact:

National Technical Information Service
Technology Administration
U.S. Department of Commerce
Springfield, VA 22161
Order Desk: 703-605-6585
Fax: 703-605-6900

The public may also obtain federal publications from the U.S. Government Bookstore on-line or on site. See http://bookstore.gpo.gov/locations/index.html for locations of on-site U.S. government bookstores.

The public may also obtain FDA documents from the CDRH automated FAX information service listed in section 1.10.2.5 of Subchapter 1.10.2. FDA references are also available to the public in electronic format from the FDA website. From the FDA homepage, link to special information for consumers, industry, health professionals, patients, state and local officials. For example, direct industry to the FDA industry web page.

Those regulated by FDA may contact their ORA Regional Small Business Representative (SBR) for an explanation of how FDA requirements apply to specific circumstances.

SBRs also locate relevant references, make referrals, conduct or participate in workshops and conferences, or make non-regulatory audits on request. See http://www.fda.gov/ora/fed_state/Small_Business/regional.htm for a list of SBRs and the regions they serve.

Direct industry inquiries in accordance with District policy either to appropriate District personnel, to the ORA Small Business Representative for your region, to an FDA industry assistance office or the Center Ombudsman, or to the Office of the Commissioner. In CDRH, the Division of Manufacturers, International and Consumer Affairs (DSMICA) staff specializes in industry assistance. For FDA drug manufacturing queries, a list of resource staff in the CDER Division of Manufacturing and Product Quality, (HFD-320) identifies each staff member by area of knowledge. Refer questions about post approval changes to the CDER post approval changes e-mail box at pac314_70@cder.fda.gov. Refer questions about good clinical practice requirements to the FDA's GCP staff.

Refer consumer inquiries to the appropriate District Public Affairs Specialist.

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

1.10.2.9 - Acronyms

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

1. CDER Acronym list compiled by the CDER Division of Biometrics III
2. CVM Related Acronyms and Abbreviations
3. CFSAN Abbreviations and Acronyms from the CFSAN Risk Analysis Working Group Report "Initiation and Conduct of All Major Risk Assessments within a Risk Analysis Framework" (3/02)
4. Draft Listeria monocytogenes Risk Assessment report: Abbreviations and Acronyms
5. ORA Glossary of Computerized System and Software Development Terminology
6. Fiscal Year 2001 Performance Plan, FY 2000 Final Performance Plan, and FY 1999 Performance Report Glossary of Acronyms
7. Fiscal Year 2004 Annual Performance Plan, FY2003 Revised Performance Plan, FY 2002 Annual Performance Plan see Appendix F Glossary of Acronyms at http://www.fda.gov/ope/fy04plan/2004pp-mainpage.html.

1.10.3 - SPECIAL REGULATORY BY PRODUCT CATEGORY

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

EXHIBIT 1-1
ALLOWABLE EXPENSES CHART

Below is a table of allowable expense items and the requirements that must be met to assure reimbursement. Unless "xx" appears in one or more of the columns at the right, there are no special requirements for reimbursement.

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount
BAGGAGE 1. Weight allowance on baggage transported free of charge by common carrier on ticket: a. Rail. Up to 150 lbs. (domestic) b. Air. Varies. Up to 70 lbs. per each of 2 bags within the continental U.S. on major trunk or regional carriers. c. Steamship. No specific limitation on baggage carried in traveler's stateroom. There is no additional allowance for free transportation of baggage for infants.			
2. Excess Baggage Charges for government property Note: Where air coach or air tourist accommodations are used, transportation of baggage up to the weight carried free on first-class service is allowed	xx	xx	xx[1]
3. Service Charge for checking baggage by checking agent where such charges for checking baggage in baggage rooms, or station or air terminal		xx	xx
4. Storage Charges (e.g., when traveler stores baggage or equipment not needed during a portion of his trip		xx	xx[2]
5. Transfer Charges - when necessary for official travel (e.g., when changing between stations where free transportation is not issued by common carrier.) CAUTION: Where the traveler's plans are changed he shall make sure that baggage that has been checked beyond the point where he leaves the train is stopped or transferred. If baggage cannot be intercepted or transferred and is carried to original destination on unused portion of ticket, the traveler shall give full explanation of facts when submitting unused portion of ticket. Failure to do so will result in any excess cost being charged to traveler.		xx	xx
FEES OR TIPS 1. Parking Fees - charges for parking automobiles	xx	xx (over $75)	
2. Porter - allowable only at transportation terminals for handling Government property carried by travelers. Porter fees for personal property, brief cases, etc. are not allowed.			xx[3]
3. Registration a. for attendance at local non-government sponsored meetings b. other	HHS-99		
4. Exchange of Currency a. Allowed i. fees for cashing U.S. Government checks or drafts reimbursing traveler for travel expenses only incurred in foreign countries ii. commissions for conversion of currency in foreign countries iii. Costs of travelers checks, money orders, certified checks purchased in connection with official travel. Costs may not exceed amount needed to cover reimbursable expenses. b. Not allowed: exchange fees for cashing checks or drafts issued in payment of salary.	xx xx xx	xx xx[4]	
5. For Foreign Travel - Passports, visa fees, costs of photographs for passports and visas, costs of certificates of birth, health, identity, and of affidavits, and charges for inoculations not obtainable through a Federal dispensary	xx	xx	

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount
6. Not Allowed - Gratuities (tips) to Government employees			
HIRE OF ROOM 1. Allowed: When necessary to engage a room in a hotel or other place to transact official business	xx	xx	xx[6]
2. Not allowed: Hotel accommodations for personal use (cost included in subsistence allowance).			
PERSONAL SERVICES 1. Stenographic and typing services, guides, interpreters, drivers of vehicles, etc.	xx	xx	xx[5]
2. Rental of typewriter	xx	xx	xx[5]
POSTAGE Postage necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	xx	xx	xx[7]
POST OFFICE BOX RENTAL Where necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	xx	xx	xx
STEAMER CHAIRS, RUGS, CUSHIONS, ETC. For official steamship travel, expenses incident thereto at customary rates actually charged			
STREETCARS AND BUSES WHILE IN TRAVEL STATUS 1. Allowed: Public transportation fares; a. from (or to) common carrier, or other terminals, to (or from) place of abode or place of business b. between place of abode and place of business, or between places of business	xx	xx (over $75)	xx[9]
2. Not allowed: Public transportation fares between places where meals are taken, and places of business or places of lodging, except where nature and location of work at temporary duty station is such that suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.			
TAXICABS WHEN USED LOCALLY WHILE IN TRAVEL STATUS 1. Use allowed: a. from (or to) common carrier or other terminal to (or from) place of abode or place of business. b. between place of abode and place of business, or between places of business, where cheaper mode of transportation is not available, or is impracticable to use.	xx	xx (over $75) xx (over $75)	xx[9]
2. Use not allowed: between places where meals are taken, and places of business, except where nature and locations of suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.	xx	xx (over $75)	xx[9]
3. Fares and Tips (refer to IOM 1.2.1.3)			
CHARGES for limousine service plus taxicab tip rates between airport and limousine pick-up or discharge point.		xx (over $75)	
TELEGRAMS AND CABLEGRAMS 1. Allowed: Charges for telegrams, cablegrams, and radiograms on official business. (Note: traveler shall use government facilities where available. Where not available official messages may be sent collect via commercial facilities.		xx	xx[10]
2. Not allowed: messages of a personal nature, including request for leave, information about salary check, expense voucher, hotel reservation, etc.; except that a request for hotel reservation incident to official business provided reference is made to official conference or official business involved is allowable.			

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount
TELEPHONE CALLS 1. Allowed: charges for local and long distance calls when made on official business		xx[10] & xx[11]	
2. Personal calls - see IOM 1.2.8			
RECORDS Charges for copies of records furnished by State officials, such as Clerks of Courts, etc., when necessary for performance of official business		xx	xx[5]
SHIPMENTS (FREIGHT OR EXPRESS) - see IOM 4.5.5		xx	xx[12]
EMERGENCY OR OTHER MISCELLANEOUS EXPENSES 1. Cash used in lieu of transportation request for passenger transportation and accommodations. 2. Purchase of emergency supplies. 3. Any other miscellaneous expenditures incurred by traveler in performance of official business, such as samples of drugs, cosmetics, etc. purchased by FDA inspectors and investigators.	xx xx	xx xx	xx[5]
LAUNDRY EXPENSES Effective November 1, 1999 reimbursement of laundry expenses is allowed within the continental U.S. (CONUS)[13] when the traveler is in travel status for four or more consecutive nights and provides a receipt for all official laundry expenses. Reimbursement will be limited to actual expenses not to exceed an amount equal to $5 times the number of consecutive nights on the trip for the first 30 days at a temporary duty travel location; $3 times the number of consecutive nights on the trip for days 31 through 90 and $2 times the number of consecutive nights on the trip beyond 90 days.		xx	

FOOTNOTES:

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