CHAPTER 1 - ADMINISTRATION

CONTENTS

Subchapter 100 - ENGLISH LANGUAGE REQUIREMENT FOR FDA DOCUMENTS . . . . . Pg 2

Subchapter 110 - TRAVEL . . . . . Pg 2
111 - COMMON CARRIER . . . . . Pg 2
111.01 - Air
111.02 - Auto Rental
111.03 - Taxi
111.04 - Accident Insurance
111.05 - Gainsharing
112 - GOVERNMENT FURNISHED VEHICLES . . . . . Pg 3
112.01 - Interagency Motor Pool
112.02 - Accidents
112.03 - Liability
112.04 - Use Between Residence & Place of Employment
112.05 - Care & Custody of U.S. Vehicles
113 - PRIVATELY OWNED VEHICLE . . . . . Pg 4
113.01 - Accidents
114 - PER DIEM & SUBSISTENCE . . . . . Pg 5
114.01 - Per Diem Rates
114.02 - Hospitalized in Travel Status
115 - CHANGE OF OFFICIAL STATION . . . . . Pg 6
116 - ADVANCE OF FUNDS . . . . . Pg 6
117 - CLAIM FOR REIMBURSEMENT . . . . . Pg 6
118 - TELEPHONE COMMUNICATIONS . . . . . Pg 6
119 - ITINERARIES . . . . . Pg 7

Subchapter 120 - LEAVE . . . . . Pg 7
120.01 - Family and Medical Leave
120.02 - Organ Donation
120.03 - Voluntary Leave Transfer Program
120.04 - EASE
121 - ANNUAL LEAVE . . . . . Pg 7
122 - SICK LEAVE . . . . . Pg 8
123 - COMPENSATORY TIME OFF . . . . . Pg 8
124 - MILITARY LEAVE . . . . . Pg 8
125 - COURT LEAVE . . . . . Pg 9
126 - LEAVE WITHOUT PAY . . . . . Pg 9
127 - ABSENCE FOR MATERNITY REASONS . . . . . Pg 9
128 - VOTING AND REGISTRATION LEAVE . . . . . Pg 9
129 - COMMISSIONED CORPS LEAVE . . . . . Pg 9

Subchapter 130 - DISCLOSURE OF OFFICIAL INFORMATION . . . . . Pg 10
131 - SUBPOENA . . . . . Pg 10
132 - REQUESTS BY THE PUBLIC AND PLACE OF EMPLOYMENT . . . . . Pg 10
133 - SHARING NON-PUBLIC INFORMATION WITH OTHER GOVERNMENT OFFICIALS . . . . . Pg 11
134 - FREEDOM OF INFORMATION ACT . . . . . Pg 11
135 - INTERNAL FDA DOCUMENTS . . . . . Pg 11

Subchapter 140 - SAFETY . . . . . Pg 11
141 - PROTECTIVE EQUIPMENT . . . . . Pg 12
141.01 - Eye Protection
141.02 - Hearing Protection
141.03 - Protective Clothing
141.04 - Respiratory Protection
142 - AUTOMOBILE SAFETY . . . . . Pg 13
143 - SAMPLING . . . . . Pg 13
143.01 - Sample Fumigation and Preservation
143.02 - Electrical Hazards
143.03 - Physical Hazards
143.04 - Asphyxiation Hazards
143.05 - Radioactive Product Sampling
143.06 - Chemical Hazards
143.07 - Carbadox Sampling
144 - INSPECTIONS . . . . . Pg 15
144.01 - Man Lifts and Ladders
144.02 - Factory Inspection
145 - MICROBIOLOGICAL HAZARDS . . . . . Pg 16
145.01 - Animal Origin Products
145.02 - Viral and Other Biological Products
145.03 - Bacteriological Problems
145.04 - Hantavirus Associated Diseases
146 - REPORTING . . . . . Pg 18

Subchapter 160 - PUBLIC RELATIONS, ETHICS & CONDUCT . . . . . Pg 18
161 - MASS MEDIA (Press, Radio and TV) . . . . . Pg 18
162 - NON-GOVERNMENT MEETINGS . . . . . Pg 18
163 - RECRUITING . . . . . Pg 18
164 - COMMUNITY ACTIVITIES . . . . . Pg 19
165 - EQUIPMENT: CARE, CUSTODY, AND LOSS . . . Pg 19
165.02 - Maintenance of Equipment
165.03 - Lost or Stolen Equipment
166 - OFFICIAL CREDENTIALS, BADGE . . . . . Pg 19
168 - BUSINESS CARDS . . . . . Pg 20
169 - EMPLOYEE CONDUCT . . . . . Pg 20
169.01 - Professional Stature
169.02 - Outside Activity
169.03 - Financial Responsibility
169.04 - Gifts
169.05 - Attempted Bribery
169.06 - Health & Hygiene
169.07 - Sexual Harassment
169.09 - Disciplinary Action

Subchapter 170 - INTERDISTRICT ASSIGNMENTS . . . Pg 23

Subchapter 180 - FIELD ACCOMPLISHMENTS AND COMPLIANCE TRACKING SYSTEM . . . . . Pg 24

Subchapter 181 - OPERATIONAL AND ADMINISTRATIVE SYSTEMS FOR IMPORT SUPPORT . . . . . Pg 24

Subchapter 190 - REGULATORY NOTES . . . . . Pg 25
190 - OVERVIEW . . . . . Pg 25
191 - USES OF REGULATORY NOTES . . . . . Pg 25
192 - REQUIREMENTS FOR REGULATORY NOTES . Pg 25
193 - REGULATORY ENTRIES . . . . . Pg 25
194 - FORMAT FOR REGULATORY NOTES . . . . . Pg 25
195 - RETENTION OF REGULATORY NOTES . . . . . Pg 26

CHAPTER 1 - EXHIBITS . . . . . Pg 27
110-B ALLOWABLE EXPENSES CHART
110-D TRAVEL VOUCHER (SF-1012)

SUBCHAPTER 100 - 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 110 - TRAVEL

All official travel must be authorized and approved with a valid travel order (T.O.). Emergency travel can be approved and the travel order prepared and authorized after the fact. "After the fact" travel orders (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: http://intranet.fda.gov/ofm/default.htm.

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 Carlson-Wagonlit as the Agency-wide Travel Management Center. Carlson-Wagonlit operates from one central reservation center located in San Antonio, Texas. This reservation center has the capability to book airline tickets, hotel reservations, and car rentals via telephone, facsimile (fax), and through their on-line web reservation system. You are encouraged to use the "online" method when making reservations because of the flexibility associated with this service. 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: http://intranet.fda.gov/ofm/default.htm.

111 - 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 and 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:

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.

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 117 for mandatory statements required on a travel voucher.

111.01 - 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:

- Contract service is not available in time to accomplish the purpose of your travel
- Use of contract service would require you to incur unnecessary overnight lodging costs that would increase the total cost of the trip
- Contract service is outside normal working hours
- 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
- 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.

111.02 - 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 112.03 - 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.

111.03 - Taxi

Reimbursement 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.

111.04 - 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 111.02 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.

111.05 - 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: http://intranet.fda.gov/ofm/default.htm.

112 - 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.

112.01 - 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.

112.02 - Accidents

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

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, (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.

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 SF 91, Operator's Report of Motor Vehicle Accident. If there are witnesses, prepare SF-94, Statement of Witness. Submit these promptly with a narrative report of all circumstances. Report the actual damage done to all parties, vehicles or property involved.

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 own 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.

112.03 - 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.

112.04 - 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 indi-

cated 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.

112.05 - 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.
7. The use of tobacco products is prohibited in government-owned or commercial, leased vehicles

113 - 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 112.02 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.

113.01 - 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 112.03 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 Personal Property Management Section (HFA-225) Room 9-82, Parklawn Building, 5600 Fishers Lane, 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 112.03.

Reporting - Report vehicle accidents as instructed in IOM 112.02.

114 - 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. If your district permits entry of this information in a regulatory diary, be certain that administrative information can be readily distinguished from regulatory entries.

Administrative Notes - Your regulatory notes (See IOM 190) 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.

114.01 - Per Diem Rates

Consult your supervisor or administrative personnel for specific rates for specific locations or at the OFM website: http://intranet.fda.gov/ofm/travel/authorization/perdiem.htm . 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. See IOM Exhibit 110-D.

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.

1. 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.

114.02 - 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.

115 - CHANGE OF OFFICIAL STATION

The complexity of regulations pertaining to allowable expenses, per diem, advance trips to seek housing, etc. necessitate consultation with your supervisor or administrative personnel.

116 - 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. Make sure your T.O. 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. If you do not have a government travel card and are required to travel, please see your administrative officer about receiving a travel advance.

117 - CLAIMS FOR REIMBURSEMENT

Submit your claim for reimbursement after each trip unless instructed otherwise by your supervisor. Submit expenses for special travel orders promptly (within 5 days) after each trip. If local travel only, submit expenses on an SF 1164, "Claim for Reimbursement for Expenditures on Official Business." Claim expenses for all other travel on an SF 1012, "Travel Voucher." (See IOM Exhibit 110-D.)

Preparation of Claim on Travel Voucher - Clerical procedures vary from district to district, so consult your supervisor or administrative office for instructions. State all items in chronological order. Show your mode of transportation and if accompanied, the names of the other travelers. All vouchers are processed electronically using Travel Manager.

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 110-B for allowable expenses, receipts required, etc.

1. 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 110-B). 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 405.01(d) 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 IOM Exhibit 110-D and IOM 111 for receipts required for cash expenditures for transportation and IOM Exhibit 110-B.

118 - TELEPHONE COMMUNICATIONS

Commercial - Local, official telephone calls are reimbursable. When placing an official call from a non-govern-

ment 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 arrangement s 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.

119 - 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 120 - 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.

120.01 - Family and Medical Leave

Under the Family and Medical Leave Act of 1993 (FMLA), covered employees are entitled to a total of twelve administrative workweeks of leave without pay (LWOP) during any twelve month period for: birth and care of newborns, the care of a spouse, child, or parent - with a serious health condition, adoption or foster care, or a serious health condition.

You may substitute annual and/or sick leave, if appropriate, for unpaid leave under FMLA.

120.02 - Leave for Organ Donation

You are entitled to paid leave (excused absence) each calendar year (in addition to annual and sick leave) to serve as a bone marrow donor or organ donor. Consult your AO for the specific number of days of paid leave allowed for the different donation programs.

120.03 - Voluntary Leave Transfer Program

If affected by a medical or family medical emergency, you may make written application to become a leave recipient. The approval/disapproval of an application will be based on the determination that your absence from duty is, or is expected to be, at least 24 hours of unpaid leave.

120.04 - EASE

EASE (Enterprise Administrative Support Environment) is the agency's automated administrative system. Every employee can view their own official and operational data in the CORE module, update their location data, and view their timekeeping records in the ETA (EASE Time and Attendance) module, which includes leave balances and timecards.

To access the system, ORA headquarters employees should contact either Terri Ausfresser (301) 1827-1201 or Michele Berger (301) 827-1452 for an EASE password. Field employees should contact their Regional/District EASE Lead AO for assistance in determining their EASE Regional Automated Data Processing (ADP) Coordinator. A security statement must be completed and retained by the Information Systems Security Officer (ISSO) . The EASE Helpdesk can be reached at (301) 998-6777 for user support. Additional information about EASE is available on FDA's Intranet.

121 - ANNUAL LEAVE

Rate of Accrual

Length of Service	Hrs/Pay Period
Less than 3 years	4
3-14 years	6
15 or more years	8

Maximum Accumulation - Unused annual leave can accumulate up to 240 hours. (Under special circumstances some employees may have more than 240 hours) Annual leave in excess of 240 hours at the beginning of the first pay period of the new leave year is lost. If loss is due to administrative error, emergencies (exigencies) of public business, or sickness of the employee, and leave has been approved prior to the beginning of the third pay period before the end of the leave year, restoration may be requested.

Taking Annual Leave - As soon as you enter on duty you may use annual leave as accrued. Request annual leave from your supervisor by completing an SF 71- "Application for Leave," or other methods "he/she approves. "

Advanced Annual Leave - You may be granted all annual leave that will accrue up to the end of the last pay period of the leave year, except that annual leave may not be advanced to the following:

1. To a temporary employee beyond the date set for the expiration of his temporary appointment, or the end of the leave year, whichever is earlier.
2. To any employee if there is likelihood they will retire or be separated from the service before the date when they will have earned the leave.

122 - SICK LEAVE

Rate of Accrual - Each employee earns four hours of sick leave each pay period. There is no maximum limit on accumulation of sick leave. Sick Leave may be authorized for the following reasons:

1. Inability to work - Sick leave may be taken when you are unable to work because of sickness or injury. Consult your supervisor for leave options covering on-the-job injury. If in travel status, consult your supervisor.
2. Medical Treatment - for medical, dental, or optical examination or treatment.
3. Contagious Disease - (a) when a member of your family has a contagious disease and requires your care and attendance. A contagious disease is one ruled by health authorities having jurisdiction as subject to quarantine or requiring isolation of the patient; (b) when your presence on duty would jeopardize the health of others because of exposure to a contagious disease.
4. Adoption and adoption-related activities
5. Care for a family member with a serious health condition. Most employees may use a total of up to 12 administrative workweeks of sick leave each leave year to care for a family member with a serious health condition. The employee must, however, maintain a sick leave balance of 80 hours.
6. Care for a family member as a result of a physical or mental illness, injury, pregnancy, childbirth, or medical, dental, or optical examination or treatment. Under the Family Friendly Leave Act, FFLA, an employee is entitled to up to 40 hours of sick leave to care for a family member. An additional 64 hours of sick leave may be used if an employee's leave balance is over 80 hours. The 104 hours of sick leave available for family care counts toward the 12 administrative workweeks mentioned in number 5.
7. Bereavement - Make arrangements necessitated by the death of a family member or to attend a funeral of a family member.

Supporting Evidence - Any grant of sick leave in excess of three working days must be supported by a medical certificate or other evidence administratively acceptable. Advanced Sick Leave not to exceed thirty days may be advanced in cases of serious disability or ailments.

Advanced sick leave may be granted during a period of absence for maternity reasons when it is expected the employee will return to duty, and is supported by a medical certificate.

123 - COMPENSATORY TIME OFF

Compensatory (Comp) time off is absence from duty for the equivalent of approved overtime previously worked.

Employees must use compensatory leave by the end of the eighth pay period after the pay period in which it is earned. If not used by this time, it automatically reverts to pay as described in this section.

Employee Option - Employees whose rate of basic pay is less than the maximum step for the GS-10 grade may elect to take compensatory time off in lieu of pay for authorized overtime.

Supervisory Option - For employees whose rate of basic pay is in excess of the maximum for GS-10, Step Ten, the district has the option of requesting compensatory time off in lieu of pay for authorized overtime. However, if premium pay is authorized, the basic pay rate of GS-10, Step One, will be the maximum amount used for premium pay computation.

124 - MILITARY LEAVE

The reserve components of the Armed Forces are the U.S. Army and Air National Guards, the Army, Naval, Marine Corps, Coast Guard, and Air Reserves.

Each reservist of the Armed Forces or member of the National Guard is entitled to leave of absence from his/her duties without loss of pay, time, or efficiency rating for each day he/she is on active military duty. An eligible employee accrues fifteen days military leave (less for part-time employees) each fiscal year, and the military leave (not to exceed fifteen days) which is unused at the end of the prior fiscal year is carried forward for use in addition to the days which are credited at the beginning of a current fiscal year. This gives the full-time employee the potential of thirty days military leave during a fiscal year. Military leave is charged on a per hour basis. Employees will not be charged military leave for weekends and holidays that occur within the period of military leave.

The maximum amount of military leave that can be accrued and carried forward from fiscal year to fiscal year is fifteen days. It is the responsibility of the employee and their timekeeper to keep track of carried over military leave.

Military Aid to Enforce The Law - Each reservist or National Guardsman who is called to duty under certain conditions for the purpose of providing military aid to enforce the law is entitled to military leave up to twenty-two workdays (not including Saturday and Sunday) in a calendar year without loss of pay, time, or efficiency rating.

National Guard duty in cases of disaster such as floods, earthquakes, hurricanes, etc., is covered by this type military leave.

Certain activities are not eligible for military leave: (1) summer training for the Reserve Officers Training Corps, (2) temporary Coast Guard Reserve, (3) participation in parades by members of the State National Guard, (4) training with a State Guard or other state military organization

which is not a part of the National Guard, and (5) Civil Air Patrol.

Time taken on a work day to travel to the place where training is to begin must be either annual leave or leave without pay, unless military training orders encompass the period of travel time required.

Taking Military Leave - Present your military orders to your immediate supervisor as early as possible.

Military Furlough - Military leave of absence with pay is to be distinguished from military furlough when an employee is ordered to extended active duty for general service with the Armed Forces without civilian compensation. However, if you are recalled to extended active duty from a reserve unit, the first fifteen days of this duty can be credited to military leave with pay. Check with your supervisor regarding re-employment rights.

125 - COURT LEAVE

Authorized absence without charge to annual leave or loss of compensation is granted an employee for jury duty, or for attending court in a non-official capacity as a witness on behalf of the United States in a State or Federal Court. For leave purposes, municipal courts are considered state courts.

Jury Duty (Federal Court) - You will be granted leave without loss of pay or annual leave. You will receive no additional fee for jury duty.

Jury Duty (State Court) - You will be granted leave without loss of pay or annual leave. You must accept any fees you are paid and remit them to your district. You may exclude from that amount the portion paid which covers local mileage and meals. See your fiscal clerk.

Government Witness in Official Capacity - This is official duty status with no charge to leave.

Government Witness in Non-Official Capacity - You are paid your regular salary and carried on court leave.

Non-Government Witness - If you are not appearing on behalf of the government or in official capacity, you will be granted court leave to appear as a non-official witness on behalf of private parties if the Federal Government, the District of Columbia, or a state or local government is a party to the proceedings. You must turn in to your district any fees received. The only expense you are allowed to claim is mileage for use of a personally owned car.

If you are appearing as a non-official witness involving only private parties, you are required to take annual leave or leave without pay. You keep any fees received.

Upon completion of court leave, written evidence of court attendance must be submitted to your leave-approving official. See the Guide for Timekeeping and/or the Collective Bargaining Agreement, Article 19, Section 3A for more specifics.

126 - LEAVE WITHOUT PAY (LWOP)

LWOP is a temporary non-pay status and absence from duty, which may, at administrative discretion, be granted upon your request.

Under the Family Medical Leave Act (FMLA), taking LWOP is an entitlement. You are entitled to take job protected, unpaid leave for up to a total of 12 work weeks in any 12 month period.

Extended LWOP has been authorized in the past for:

1. Educational purposes, when the course of study or research is in line with a type of work being performed by the FDA.
2. Certain types of service with non-federal public or private enterprise.
3. Recovery from illness or disability that is not of a permanent or disqualifying nature, when continued employment or immediate return to employment would threaten impairment of employee's health or the health of other employees.

Absence Without Leave - Absence without leave is not to be confused with LWOP. Absence without leave is a non-pay status resulting from an Agency determination that it will not grant any type of leave (including LWOP) for a period of absence for which the employee did not obtain authorization.

127 - ABSENCE FOR MATERNITY REASONS

Absence for maternity reasons is a period of approved absence for incapacitation related to pregnancy and confinement. It is chargeable to sick leave or a combination, as appropriate, of sick leave, annual leave, compensatory time, credit hours, time off awards, and LWOP under FMLA. Voluntary Leave Transfer Program (VLTP) may also be an option.

It is your responsibility to advise your supervisor as soon as your pregnancy is known, so that steps can be taken to protect your health and personnel adjustments can be made.

The length of absence from work will be determined by the employee, her physician, and her supervisor on a case by case basis. Advanced leave for absences for maternity reasons is generally governed by the same policies and procedures as for other absences. See IOM 122.

128 - VOTING AND REGISTRATION LEAVE

When feasible, and without interfering seriously with operations, employees who desire to vote or register in any election or in referendums on a civic matter will be excused for a reasonable time for that purpose. When the polls are not open at least three hours either before or after an employee's regular hours of work, the employee will be excused for enough time to permit reporting for work three hours after the polls open or for leaving work three hours before the polls close, whichever requires lesser time off.

Example: If polls open at 6:30 AM and close at 6:30 PM, an employee who works 8:00 AM to 4:30 PM may be excused from 3:30 PM to 4:30 PM since this would be three hours before the polls close.

129 - COMMISSIONED CORPS LEAVE

The following information is provided for general guidance concerning the leave policy of the PHS Commissioned Corps.

This is a synopsis of the regulations covering this type of leave and does not cover all necessary information. Information concerning the complete Commissioned Corps leave policy can be obtained from the district copy of the "Commissioned Corps Personnel Manual" and/or "A Supervisors Guide to the Commissioned Personnel System".

Annual Leave - An officer earns thirty days of annual leave a year, at a rate of 2 1/2 days per month. Annual leave is accrued on a calendar year basis, and an officer may carry forward sixty days of unused annual leave from one calendar year to another. Leave in excess of sixty days not used by December 31 is forfeited.

Annual leave should be requested and approved in advance on a PHS-1345 form - "Request and Authority for Leave of Absence." If this is not possible, e.g. because of an emergency, an officer should immediately notify his official superior of the reason for the absence and complete the PHS-1345 upon return to duty.

Annual leave is granted in full days. Absence for less than a full workday is considered station leave. Non-workdays (e.g. Saturdays, Sundays, Holidays) at the beginning, or end, of a period of annual leave are not chargeable against an officer's leave account. However, non-workdays that fall within a period of leave are chargeable against an officer's annual leave account. This includes legal holidays. A consecutive period of absence from duty may not be authorized in two or more parts to avoid charging non-workdays falling within the period of annual leave.

An officer's annual leave record is maintained by his/her designated timekeeper as the official record.

Sick Leave - There is no accrual of, or charge for, sick leave. It is granted as needed for an officer's illness. Absence because of illness of a member of the family may not be charged to sick leave.

An officer unable to report for duty because of personal illness must notify his official superior. Upon return to duty, a PHS-1345 must be completed. This form is used to request and grant sick leave, in addition to annual leave. If an officer is on sick leave for more than three days, the officer must record in the "Remarks" section of the PHS-1345, either "the nature of the illness or disability" or "the need for medical services". The leave granting authority may, at its discretion, require a medical certificate signed by the officer's attending physician.

Sick leave requests are forwarded to the Chief, Medical Branch, Division of Commissioned Personnel, Room 4C-06, 5600 Fishers Lane, Rockville, MD 20857.

Station Leave - If an officer is absent from duty for a period of less than one workday or on non-workdays (e.g.; weekends, holidays, days which an officer is not scheduled for duty, see exceptions under Annual Leave, above), such absence is considered station leave and is not chargeable to annual leave.

If an officer desires to take station leave during regularly scheduled working hours, the absence must have advanced oral approval from the officer's official superior. An officer is automatically entitled to station leave during off-duty hours and on non-workdays, unless otherwise directed by the official superior. Therefore, station leave taken on non-workdays does not require the approval of the official superior. This is true, even if travel away from the vicinity of the duty station is contemplated, since there are no restrictions on an officer's travel while in leave status. An officer, however, is required to keep their official superior informed of their whereabouts when traveling away from the vicinity of the duty station.

Station leave may be granted for legitimate reasons, e.g., taking a family member to the doctor, personal business, etc. Normal practice is for station leave to be half day or less.

Additional information is available on the Division of Commissioned Personnel website.

SUBCHAPTER 130 - DISCLOSURE OF OFFICIAL INFORMATION

You are not to release or divulge any information obtained during FDA investigative or inspectional operations. 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 190. Procedures for release of Agency documents are established under the FOIA and the Privacy Act and are carried out by Agency and/or district information disclosure personnel e.g., FOI officers. If you are requested by anyone outside the Agency to release any of the aforementioned items or information, refer them to your district information disclosure personnel.

Material in FDA files not specifically exempted or not considered privileged under the laws enforced by the Agency shall be available to the public. See IOM 190 and 134.

131 - 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 and 20.2.

132 - REQUESTS BY THE PUBLIC, INCLUDING TRADE

Be guided by IOM 134 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 133).

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 408 and IOM 431.03 for cautions on collecting this type sample.

133 - 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 Regulatory Procedures Manual (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

134 - 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 trade secrets or names and titles of individuals against which no legal action is taken. Certain other material which the firm considers privileged information, and which FDA rules actually is privileged or confidential under the regulations, may also be exempted.

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 20, 21, 71.15, 171.1, 314.430, 431.70, 514.10, 514.11, 514.12 and others, all of which contain provisions regarding confidentiality in various FDA records and documents. See also, the RPM, subchapter 8, "Freedom of Information Act" and 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 informants. See IOM 518 for further guidance.

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 FDA'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 & Drug Administration, Freedom of Information Staff (HFI-35), 5600 Fishers Lane, Rockville, MD 20857.

135 - INTERNAL FDA DOCUMENTS

Do not quote to non-FDA personnel information which is identified "For Official Use Only", unless so instructed by your supervisor.

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 134 and IOM 1017.

SUBCHAPTER 140 - 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 510.01 – 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 141. It is ultimately your responsibility to ensure that you do not expose yourself to any hazard.

Disaster conditions present inherently dangerous situations. See IOM 940.

Operations in the radiological area also pose special dangers. See IOM 144.02. Obtain advice on protective measures from regional radiological health personnel.

141 - PROTECTIVE EQUIPMENT

141.01 - 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.

141.02 - 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.

141.03 - 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.

141.04 - 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 the following paragraph.

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. (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.

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.

- Do not enter any structure or conveyance or sample any product that is being treated with the fumigants Methyl Bromide or Phosphine.
- 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).
- 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 144.02 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 145.04 Hantavirus Associated Diseases

Note - Methyl Bromide and 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 143.04, Asphyxiation Hazards, and IOM 144.02, Factory Inspections, for additional cautions related to fumigants.

142 - AUTOMOBILE SAFETY

Automobile Condition - See IOM 165.

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 & 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 143.04 Asphyxiation Hazards.

143 - 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.)

143.01 - 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.

143.02 - 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. Do not use flash units in dusty areas because of the possibility of explosion hazard. See IOM 523 for additional information.

143.03 - 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 426.01

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 & needle were collected as part of your sample.

1. Railcars
   a. When sampling, make sure doors are propped open to avoid accidental closing if the car is bumped while you are in it.
   b. Display a warning flag or similar device to alert others you are in the car. If possible, have a railroad yardman present.
   c. When entering the car make sure the ladder is secure.
   d. On hot days, or after a car has been fumigated, it should be aired out prior to entering, preferably by opening both doors.
   e. Observe “No Smoking” in rail cars.
   f. Don’t crawl under railcars - go around them.
   g. Avoid any cables between the railroad tracks. These are often used to move cars on sidings. A cable snapping taut can kill or maim.
2, Grain Elevators
   a. Prior to use, make sure man lifts are operating properly.
   b. Make sure cross-rungs on ladders are safe.
   c. 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.
   d. Make sure walkways between bins are sturdy.
   e. Use caution when sampling from high bins or tanks. Wet or icy conditions may prevail, so check these conditions.
   f. 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.
3. Clothing
   a. 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.
   b. Do not carry notebooks, credentials, etc., in the outer pockets of your inspectional uniform because they could fall into the equipment.
   c. Steel mesh gloves should be worn when cutting portions from frozen products such as fish, etc.
4. Trucks - Make sure any truck you enter during sampling and/or inspection will remain stationary while you are in it.

143.04 - 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 144.02, 452.05, and 943 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.

143.05 - 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.

143.06 - 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 322 for further information and for the address and phone numbers of the ATSDR contacts.

143.07 - 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; (12) Notify the receiving laboratory of sample collection.

144 - 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.

144.01 - Man Lifts and Ladders

1. 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.
2. Before riding mechanical lifts, make sure safety equipment is installed and operating properly.
3. When riding power lifts, observe the following safety precautions: (a) Determine ahead of time what floors are serviced by the lift and at which floor you intend to get off; (b) Determine safety devices, and how they operate. Check lift for automatic cut off at the top or a safety stop cord; (c) Always face the belt when riding the lift; (d) Never carry excess equipment or items that protrude and could get caught between floors.
4. When using hand powered lifts, remember to: (a) Check the foot brake for proper operation; (b) Check if control rope is firmly fastened at the bottom; (c) If lift has a stop pin which must be removed prior to use or after use, determine how it is used and use it; (d) Check counterbalance of lift, and add or remove weights if necessary; (e) Never free-fall on the lift when descending; always keep descent in control by using the brake; (f) Use gloves to avoid rope burns or slivers from the hemp or metal pull ropes.
5. 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.
6. Some mills and elevators have makeshift ladders. Extreme care should be exercised when using these.

144.02 - 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.

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 & 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 143.04, 452.05 & 943 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.

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 problem to firm management.

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 overexposure 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 141. 29 CFR 1910.134 contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

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 & 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.

145 - 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.

145.01 - 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. Some 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.

145.02 - 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 ade-

quately protect the investigator. Contact the Center for Biologics Evaluation and Research (CBER), Division of Viral Products, HFM-445, for guidance.

Methods of transmission include: (1) Aerosols, which may be created by manufacturing operations (e.g., centrifugation, filling, etc.) or spills. Transmission may occur through inhalation; (2) Contact with contaminated objects, including equipment, animals, waste materials, reagents, file cabinets and doorknobs. Transmission can occur through ingestion, inhalation, or through broken skin.

Protective and preventive measures include:

1. Precautions listed in IOM 145.01 and 145.03
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 169.06.

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 (121oC/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.

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.

145.03 - 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 912).

145.04 - 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 & 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.

146 - REPORTING

Automobile Accidents - See IOM 112.02 - 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 160 - PUBLIC RELATIONS, ETHICS & CONDUCT

161 - MASS MEDIA (Press, Radio, and TV)

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 504.03 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.

162 - 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.

163 - RECRUITING

When assigned recruiting duties, your primary objective is to attract outstanding people to work for FDA. During recruiting discussions, explain the function and duties of the FDA, with emphasis on the relationship between the duties and the requirement for the highest standards of conduct and integrity.

Colleges - Your attitude in your contacts with the college placement officers, faculty members, and the students themselves will play an important part in the success of this program. Various booklets, prepared by FDA, set forth the objectives of the FDA college recruitment program. Obtain copies from your district for use in your recruitment activities.

Professional Societies - Since many experienced professional and scientific personnel are members of professional societies and organizations, this is another excellent recruitment source.

Do not overlook recruitment opportunities offered by such groups, e.g., in setting up displays and exhibits in connection with national or regional meetings or conventions. You are also encouraged to join and be active in professional organizations, including attendance at conventions and meetings.

Community Relations - Consumer information material has been prepared for use by FDA. In presenting such material to local business, civic, industrial, educational, and professional groups, the employment opportunities offered by the FDA may be discussed.

Publicity - Most consumer oriented publicity is handled by FDA's Consumer Affairs Officers, and you may be requested to assist at times. Radio and television stations are required to devote a certain percentage of broadcast time to public service programs, announcements, and other features. Therefore, most stations are eager to run spot announcements and/or feature stories about FDA employees who have made significant contributions to the Agency's program. These are also readily accepted and used by newspapers throughout the country. This is particularly so when the person featured is a local resident. Successful placement of physically or mentally handicapped persons, dedication of a new office building, awards ceremonies, etc., are other possibilities for development of news releases which could be used as recruitment tools. Be constantly alert, utilizing the recruitment potential of such situations as they present themselves, and alert your supervisor.

164 - COMMUNITY ACTIVITIES

All FDA employees are encouraged to take part in normal community, civic, charitable, or religious activities. See your supervisor if you have any questions about conflict of interest limitations.

165 - 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. See http://intranet.fda.gov/OIRM/manuals/smg/smg-htm/f2280_5.htm#Reporting.

165.02 - 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. 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.

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.

165.03 - 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.

166 - OFFICIAL CREDENTIALS, BADGE

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

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 21 CFR 5.35, is re-delegated to you. You are expected to use this authority wisely and judiciously. See IOM 501 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.

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.

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.

168 - 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.

169 - 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 briefly covered in the various subsections in this section. Study 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 & 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 intranet.

169.01 - 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.

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, mis-

management, 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).

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.

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 141 and IOM 519.

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; or (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; or (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; or (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.

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.

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.

169.02 - Outside Activity

Each FDA employee is encouraged to engage in outside activities which contribute to his technical or professional development, or advances the mission of FDA.

Standards Setting Activity - FDA encourages organizations to set standards of quality and safety, and to promote adherence to them. Since FDA considers such standards as supplemental to its own regulatory functions, its employees may, with limitations, be authorized to participate in such outside standards setting activities. These include such activities as: (1) development of standard performance requirements; (2) testing methodology; (3) manufacturing practices; (4) product standards; (5) scientific protocols; (6) compliance criteria; (7) ingredient specifications; (8) labeling; (9) other technical or policy criteria. For information and procedures to follow in obtaining approval for these activities see your district copy of the Staff Manual Guides, Guide Number 2125.1.

Outside Employment - Certain outside activities, paid or unpaid, unrelated to FDA's activities are permissible. Such employment must be approved. Outside jobs must not involve a real or apparent conflict of interest. They must not interfere with your efficiency, or require official time or use of official facilities or records. These limitations apply to all outside activities. In addition, you may not:

1. Engage in any work that identifies the DHHS or FDA with any commercialization of products.
2. Accept anything of value for helping a contractor in the procurement of a government contract.
3. Represent the Department in dealing with a matter in which you have a conflicting interest.
4. Be paid from outside sources for services in any matter "in which the United States has an interest."
5. Accept, from the outside, pay for the performance of your official duties.

Political Activity - As a Federal employee you may vote

as you please and express your opinion on political subjects. However you may not:

1. Use your official authority or influence for the purpose of affecting the results of an election.

2. Take an active part in political management of political campaigns. Consult your supervisor if there is any doubt in your mind regarding departmental regulations on activities prohibited by the Hatch Act.

Teaching, Speaking and Writing - The Standards of Ethical Conduct contain detailed information on teaching, writing and speaking. Please review them in detail if you are involved in outside activities of this nature. Employees may participate in these activities, however, advance approval is required and there are certain restrictions on accepting compensation for these activities.

Financial Interest - You may not have financial interests that conflict, or appear to conflict, with your responsibilities and duties as an FDA employee. You cannot engage, directly or indirectly, in financial transactions as a result of or primarily relying upon information obtained through your job. If you are required to file a Public or Confidential Financial Disclosure Report, you may not have substantial financial interest in industries regulated by FDA. See your supervisor if you have any reservation or question relative to financial interest or contact the Division of Management Programs, Ethics and Integrity Staff at 301-827-5511.

169.03 - Financial Responsibility

You are expected to conduct your financial affairs in accordance with accepted standards of ethical business practice, and to pay your just debts promptly.

169.04 - Gifts

Under Subpart C of the Standards of Ethical Conduct, guidance is provided on rules governing gifts between employees, including gifts to supervisors. On an occasional basis, such as a birthday or holiday, you may give an unsolicited gift valued at $10 or less to your supervisor. Also, you may give a gift to your supervisor to mark a special occasion such as his/her marriage, the birth of his/her child, and his/her retirement or transfer.

169.05 - 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.

169.06 - 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.

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.

169.07 - Sexual Harassment

Sexual Harassment is a violation of Sec. 703 of Title VII of the Civil Rights Act of 1964. Unwelcome sexual advances and other verbal or physical conduct constitute sexual harassment when:

1. Submission to such conduct is made, either explicitly or implicitly, a term or condition of an individual's employment,

2. Submission to, or rejection of, such conduct by an individual is used as the basis for employment decisions affecting such an individual, or

3. Such conduct has the purpose or effect of unreasonably interfering with an individual's work performance, or creating an intimidating, hostile, or offensive working environment.

In identifying sexual harassment, keep the following in mind: (1) the harasser's behavior must be unwelcome, (2) the gender of the harasser or the victim (whether opposite or same sex) does not lessen the legal relevance of a claim of sexual harassment, (3) even without suffering economic loss, (fired, demoted, denial of training) the mere fact the person is the recipient of unwelcome advances or working in a hostile environment makes the employee a victim of sexual harassment, (4) any person who is exposed to sexual harassment, regardless of whether he/she is the direct recipient, may be considered a victim.

FDA is responsible when an employee is sexually harassed, regardless of whether supervisors knew or should have known of the conduct.

Some actions a supervisor may take if sexual harassment complaints occur:

1. Conduct an inquiry of the sexual harassment allegation, and determine the facts.
2. Inform the alleged harasser(s) of the allegations.
3. Warn the alleged harasser(s) sexual harassment is a violation of Federal law and will not be tolerated.
4. Provide the alleged harasser(s) a copy of the FDA's sexual harassment policy and a copy of Sec. 703 of Title VII of the Civil Rights Act of 1964.

If the inquiry supports the victim's allegation(s) of sexual harassment, the supervisor should contact the Equal Employment Opportunity (EEO) office for guidance, and the Employee Relations Branch to determine if disciplinary action is warranted.

If a field employee is sexually harassed by a non-FDA employee during an inspection/investigation they should tell the individual to stop the harassing behavior, inform the individual's supervisor, and immediately notify their supervisor. If appropriate, the firm's management should be contacted by District management by phone, followed by correspondence informing them sexual harassment on the basis of sex is a violation Federal law. A copy of the FDA's sexual harassment policy should also be included. If the harassment continues contact FDA's EEO Office (HF-15) at 301-827-4848.

169.09 - Disciplinary Action

Penalties for violation of the statutes covering employee conduct are prescribed by law. They range from suspension or dismissal to fine and/or imprisonment. Some laws specify prohibitions but leave the penalty to administrative action. In any such violation, FDA will take such disciplinary action as best meets the objectives of deterring similar offenses and maintaining high standards of employee conduct and public confidence.

SUBCHAPTER 170 - INTERDISTRICT ASSIGNMENTS

See IOM 100 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.

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.

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.

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, HFC-160 (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, HFC-160.

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 180 - FIELD ACCOMPLISHMENTS AND COMPLIANCE TRACKING SYSTEM (FACTS)

The Field Accomplishments and Compliance Tracking System (FACTS) is FDA's automated system for field assignments, work results, firm information, consumer complaints, compliance actions, and time reporting. FACTS incorporates assignment management and work results for the following investigational activities: sample collections, establishment inspections, domestic investigations, and field examinations. FACTS also includes detailed information concerning analytical findings and compliance activities. All these data fields can be searched and viewed by any FACTS user.

FACTS has not changed the requirements for evidence development and documentation, identification of evidence or samples, submission procedures for records collected during inspections or investigations, timeframes for submission of potential regulatory actions, or many other activities you do. Be guided by outstanding policy and procedures in the IOM in these areas. Enter all information required by policy or procedure which may go beyond the "mandatory fields" to simply store information in FACTS. Consult the IOM, Compliance Program Guidance Manual (CPGM) or Assignment for required information. FACTS does not replace hardcopy narrative reporting for things such as inspections, investigations, consumer complaint follow-up and others.

FDA has not developed a "user's manual" for FACTS. Be guided by the information you received during your FACTS training, information and instructions contained in the Data Codes Manual (DCM) and the IOM. FACTS on-line HELP is your first source of information on the functioning of FACTS and how to enter data. If additional help is necessary, users contact the local FACTS Lead Users.

Each Supervisory Investigator (SCSO), Investigator (CSO) and Inspector (CSI) has a FACTS "electronic signature". This signature is used to electronically sign sample collection, inspectional, and investigational reports in FACTS. It also provides the same legal basis for regulatory activities as a handwritten signature on a paper document. FACTS is designed to limit the ability of individuals, other than the person recording the information, to make changes to stored information, in many, but not all, cases.

You are responsible for reporting your activities and time on all reportable operations. FACTS is designed to capture all the necessary data formerly kept in the Program Oriented Data (PODS) and Manpower Utilization Systems (MUS). You are responsible for reviewing and updating information in FACTS in the "MAINTAIN FIRM" data area. This is the same information previously kept in the Official Establishment Inventory (OEI) data system. These updates should be completed when you enter data into any FACTS record or record your time for the assignment.

Since most assignments will be requested and managed within FACTS, you should check your FACTS "Inbox" at least daily.

SUBCHAPTER 181 - OPERATIONAL AND ADMINISTRATIVE SYSTEM FOR IMPORT SUPPORT (OASIS)

The Operational and Administrative System for Import Support (OASIS), is a national database on imports, enforcement activities and findings. OASIS is designed to accomplish the following objectives:

- Make a risk assessment of incoming entry data to identify those which must be reviewed by FDA personnel and allow the others to enter commerce without further action
- Increase the productivity of investigations' personnel in the field though automated interfaces with the FDA Centers, Brokers/Filers, and the U.S. Customs Service (USCS)
- Integrate OASIS with other ORA systems to provide for seamless linkage of import and domestic functions
- Improve screening of imports by providing suggestions for actions likely to result in discovery of violations
- Provide faster turn-around for processing of importer's entries and faster and more consistent response to discovered violations and import alerts
- Provide national and district uniformity in processing of entries
- Assist compliance personnel in tracking the status of suspected violative products and information related to these products
- Provide the ability to track the performance of Private Laboratories who submit analytical work to FDA for imported products

- Automate the generation of the Notices of Action sent to firms regarding actions taken by FDA
- Provide redundant electronic notification of cargo hold/detain/release/refusal statuses to the filers via the USCS interface
- Maintain a base of information for generation of reports at the district, regional, and national level
- Adjust the regulatory strategy and screening of products based upon national database of trade patterns and sample/examination results
- Respond to congressional and management needs for information on the effectiveness of FDA programs

The system not only supports FDA field personnel in carrying-out their day-to-day activities, but also provides headquarters personnel and program staff within the FDA Centers with vital information on FDA compliance program guidance manuals and workforce accomplishments. By having national data on imports, enforcement activities and findings, FDA management is better able to spot emerging trends, identify emergency situations and alert all field personnel quickly, allocate resources more effectively, and effect greater uniformity in enforcement activities throughout the country.

Additional information about OASIS and guidance on its use can be found in IOM Chapter 6, Imports, and in the OASIS "Help" module.

SUBCHAPTER 190 - REGULATORY NOTES

190 - OVERVIEW

Regulatory notes are the record of your daily investigatory efforts. They record your observations relevant to violations and active cases. They are the vital link between your findings and your subsequent testimony in court. Because of the data, which regulatory notes contain, such as information pertaining to open investigatory files, trade secrets, and personal information protected under the Privacy Act, they are confidential. Regulatory notes are government property. The notes cannot be released to anyone outside the Agency, except with the express permission of your management, and after following FDA's procedures. (See IOM 130)

See IOM 114 for guidance on administrative notes.

191 - USES OF REGULATORY NOTES

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

192 - REQUIREMENTS FOR REGULATORY NOTES

See IOM 100 for English language requirement. Regulatory notes should be made at the time of the event they represent. Regulatory notes must be original recordings of an activity, and may be handwritten (in ink) or electronic. Do not erase, edit or rewrite original notes. Any corrections should be identified.

Regulatory notes in electronic format must be authenticated to ensure document integrity. If electronic notes are utilized, adhere to agency directives and procedures to safeguard and file electronic notes. Positive identification of regulatory notes in electronic format is imperative. Regulatory notes can be printed, and each page initialed (handwritten initials) and dated by the investigator. If this procedure is used, the original disk can be identified with the firm name, dates, and investigator's initials; placed in a FDA-525 envelope; and then sealed with an Official Seal, FDA-415a. NOTE: See IOM 522 -Exhibits, for guidance on the identification and storage of electronic data obtained from inspected firms, and used as exhibits for the EIR. Regulatory notes must be accurate, objective, factual, and free of personal feelings or conclusions.

193 - REGULATORY ENTRIES

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

Regulatory notes should contain the substance of all significant discussions with people contacted during the activity; e.g., discussions of individual responsibility. When entering a direct quote in a notebook, such as a statement against self-interest, it is important the exact words be used to preserve the original intent of the individual and subject. Every quote of significance appearing in the final report should be in your regulatory notes since they are part of the source documents, which will support any regulatory or administrative action.

Regulatory notes should not contain purely administrative information. See IOM 114 for guidance on administrative notes.

194 - FORMAT FOR REGULATORY NOTES

Your regulatory notes must always be kept in a bound notebook. The reason for this is the continuity and integrity provided by bound pages. Loose-leaf and spiral bindings allow easy removal of pages, an invitation to vigorous and heated cross-examination on the witness stand. Bound notebooks also prevent lost or misplaced pages.

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

Regulatory notes whether written or electronic are subject to audit at any time; must be available for review; and must, on demand, be surrendered to your supervisors or other authorized personnel. Regulatory notes should be identified with your name, telephone number, and address to facilitate their return if lost. Advancing technology may increase the preservation options available. District policy should be followed regarding the preservation of all regulatory notes.

195 - RETENTION OF REGULATORY NOTES

Regulatory notes are to be appropriately identified with your name and the bracketing dates they cover before they are turned over for storage. Follow your District's policy regarding the maintenance of regulatory notes.

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

If you leave FDA, or are transferred from your district, any regulatory notes in your possession must be identified and turned in to the district you are leaving. Districts are to retain regulatory notes as official records as outlined in the FDA Staff Manual Guide.

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

EXHIBIT 110-B
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	Statement on voucher if over $25.00
A. 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	
B. 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			

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount	Statement on voucher if over $25.00
4. Exchange of Currency a. ALLOWED (1) fees for cashing U.S. Government checks or drafts reimbursing traveler for travel expenses only incurred in foreign countries (2) commissions for conversion of currency in foreign countries (3) Costs of traveler's checks, money orders, certified checks purchased in connection with official travel. Costs may not exceed amount needed to cover reimbursable expenses. 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		
6. Not Allowed - Gratuities (tips) to Government employees				
C. 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).				
D. 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]	
E. POSTAGE Postage necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	xx	xx	xx[7]	
F. 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	
G. STEAMER CHAIRS, RUGS, CUSHIONS, ETC. For official steamship travel, expenses incident thereto at customary rates actually charged				
H. 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]	

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount	Statement on voucher if over $25.00
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.				
I. 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 111.3)		xx (Over $75)		
J. CHARGES for limousine service plus taxicab tip rates between airport and limousine pick-up or discharge point.		xx (over $75)		
K. 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.				
L. 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 118				
M. 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]	
N. SHIPMENTS (FREIGHT OR EXPRESS) – See IOM 454		xx	xx[12]	

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount	Statement on voucher if over $25.00
O. 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]	
P. LAUNDRY EXPENSES - Effective November 1, 1999 reimbursement of laundry expenses is allowed for travel 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. When a coin operated machine is used to launder clothing and a receipt can not be obtained, a statement must appear on the voucher to substantiate the claim.		xx		

FOOTNOTES:

1. Voucher must show weight of baggage when claim is the result of exceeding weight limitations 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.

TRAVEL VOUCHER

(Read Privacy Act Statement on the back)

1. DEPARTMENT OR ESTABLISHMENT BUREAU DIVISION OR OFFICE (1): FDA/SER/ATL/DO/IB

2. TYPE OF TRAVEL: [X] TEMPORARY DUTY [ ] PERMANENT CHANGE OF STATION

3. VOUCHER NO.

4. SCHEDULE NO.

5. a. NAME *(Last, first, middle initial)* (2): Rogers, Sidney H.

b. SOCIAL SECURITY NO. (6): 444-44-4444

6. PERIOD OF TRAVEL: a. FROM (8): 09/28/98 b. TO: 10/02/98

c. MAILING ADDRESS *(Include ZIP Code)* (3): 60 Eighth St. NE, Atlanta, GA 30309

d. OFFICE TELEPHONE NO. (7): 404-881-3151

7. TRAVEL AUTHORIZATION: a. NUMBER(S) (9): b. DATE(S) (10):

e. PRESENT DUTY STATION (4): Atlanta, GA

f. RESIDENCE *(City and State)* (5): Atlanta, GA

10. CHECK NO.

8. TRAVEL ADVANCE
- a. Outstanding (11): 0.00
- b. Amount to be applied: 0.00
- c. Amount due Government *(Attached [ ] Check [ ] Cash)*:
- d. Balance outstanding:

9. CASH PAYMENT RECEIPT
- a. DATE RECEIVED:
- b. AMOUNT RECEIVED: $
- c. PAYEE'S SIGNATURE:

11. PAID BY

12. GOVERNMENT TRANSPORTATION REQUESTS, OR TRANSPORTATION TICKETS, IF PURCHASED WITH CASH *(List by number below and attach passenger coupon; if cash is used show claim on reverse side)*

I hereby assign the United States any right I may have against any parties in connection with reimbursable transportation charges described below, purchased under cash payment procedures (FPMR 101-7). ▶ *Traveler's Initials*

AGENT'S VALUATION OF TICKET (a)	ISSUING CARRIER *(Initials)* (b)	MODE CLASS OF SERVICE AND ACCOMMODATIONS (c)	DATE ISSUED (d)	POINTS OF TRAVEL FROM (e)	POINTS OF TRAVEL TO (f)
A 0 612,080	154.50	EA	Y	09/23/98	ATL-Atlanta,	JAX-Jacksonv
(12)	(13)	(14)	(15)	(16)	

COMMENTS: (25)
Purpose of Travel (When Travel Manager is used to prepare travel voucher, the purpose of travel is not shown anywhere on the voucher. It is only documented on the travel order. The comments block can be used to state the purpose if necessary.) This travel voucher was created using Travel Manager 7.CB.

13. I certify that this voucher is true and correct to the best of my knowledge and belief, and that payment or credit has not been received by me. When applicable, per diem claimed is based on the average cost of lodging incurred during the period covered by this voucher.

TRAVELER SIGN HERE ▶ Sidney H. Rogers (17) DATE (18) AMOUNT CLAIMED ▶ (19) 603.85

NOTE: Falsification of an item in an expense account worth a forfeiture of claim (28 U.S.C. 2514) and may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both (18 U.S.C. 287, id. 1001).

14. This voucher is approved. Long distance phone calls, if any, are verified as necessary in the interest of the Government. *(NOTE: If long distance telephone calls are included, the approving official must have been authorized in writing by the head of the department or agency to so certify (31 U.S.C. 638a).)*

APPROVING OFFICIAL SIGN HERE ▶ (20) DATE

17. FOR FINANCE OFFICE USE ONLY COMPUTATION

a. DIFFERENCES, IF ANY *(Explain and show amount)*: (22) $

15. LAST PRECEDING VOUCHER PAID UNDER SAME TRAVEL AUTHORIZATION
- a. VOUCHER NO
- b. D.O. SYMBOL
- c. MONTH & YEAR

b. TOTAL VERIFIED CORRECT FOR CHARGE TO APPROPRIATION *Certifier's initials:* $

16. THIS VOUCHER IS CERTIFIED CORRECT AND PROPER FOR PAYMENT

AUTHORIZED CERTIFYING OFFICIAL, SIGN HERE ▶ (21) DATE

c. APPLIED TO TRAVEL ADVANCE *(Appropriation symbol)*: $

d. NET TO TRAVELER ▶ $

18. ACCOUNTING CLASSIFICATION

1012-16 NSN 7540-00-634-4180 STANDARD FORM 1012 (REV. 10-77)

SCHEDULE OF EXPENSES AND AMOUNTS CLAIMED

INSTRUCTIONS TO TRAVELER *(Unused items are self explanatory)*

Col. (c) If the voucher includes per diem allowances for members of employee's immediate family, show members' names, ages, and relationships to employee and marital status of children (unless information is shown on the travel authorization.)

Complete only for actual expense travel

Col. (d) thru (g) Show amount incurred for each meal, including tax and tips, and daily total meal cost.

(h) Show expenses such as: laundry, cleaning and pressing of clothes, tips to bellboys, porters, etc. (other than for meals).

(i) Complete for per diem and actual expense travel.

(j) Show total subsistence expense incurred for actual expense travel.

(m) Show per diem amount, limited to maximum rate, or travel on actual expense, show the lesser of the amount from col. (j) or maximum rate.

(n) Show expenses, such as: taxi/limousine fares, air fare (if purchased with cash), local or long distance telephone calls for Government business, car rental, relocation other than subsistence, etc.

(26)

Complete this information if this is a continuation sheet. PAGE 2 OF PAGES

TRAVEL AUTHORIZATION NO. (9) & (10)

TRAVELER'S LAST NAME: Rogers

DATE 19 98 (23) (a)	(24) (Hour and a/p/m) (b)	DESCRIPTION (Departure/arrival city, per diem computation, or other explanation of expenses) (c) 25	ITEMIZED SUBSISTENCE EXPENSES: MEALS BREAK-FAST (d)	LUNCH (e)	DINNER (f)	TOTAL (g)	MISCELLANEOUS SUBSISTENCE (h)	LODGING (i)	TOTAL SUBSISTENCE EXPENSE (j)	MILEAGE RATE (27) NO. OF MILES (k)	AMOUNT CLAIMED (28): MILEAGE (l)	SUBSISTENCE (m)	OTHER (n)
09/28		D-:RES: Atlanta,GA											
09/28		:			Air fare								154.50
09/28		A-:JACKSONVILLE,FL				22.50		73.00	95.50			95.50	
09/28		:			Taxi residence to o								6.90
09/29		Taxi-airport to hotel											2.30
09/29		Subsistence				30.00		73.00	103.00			103.00	
09/30		:			Official Business -								2.30
09/30		Subsistence				30.00		73.00	103.00			103.00	
10/01		Subsistence				30.00		73.00	103.00			103.00	
10/02		D-:JACKSONVILLE,FL											
10/02		:			Taxi-airport to res								6.90
10/02		:			Taxi-hotel to airpo								3.45
10/02		A:RES: Atlanta,GA											
10/02		Subsistence				22.50			22.50			22.50	

If additional space is required, continue on another 1012-A BACK, leaving the front blank.

	MILEAGE (l)	SUBSISTENCE (m)	OTHER (n)
SUBTOTALS ▶	0.00	427.00	176.35
TOTALS ▶	0.00	427.00	176.35

Enter grand total of columns (l), (m) and (n), below and in item 13 on the front of this form

(29) TOTAL AMOUNT CLAIMED ▶ 603.35

In compliance with the Privacy Act of 1974, the following information is provided: Solicitation of the information on this form is authorized by 5 U.S.C. Chap. 57 as implemented by the Federal Travel Regulations (FPMR 101-7), E.O. 11609 of July 22, 1971, E.O. 11012 of March 27, 1962, E.O. 9397 of November 22, 1943, and 26 U.S.C. 6011(b) and 6109. The primary purpose of the requested information is to determine payment or reimbursement to eligible individuals for allowable travel and/or relocation expenses incurred under appropriate administrative authorization and to record and maintain costs of such reimbursements to the Government. The information will be used by officers and employees who have a need for the information in the performance of their official duties. The information may be disclosed to criminal or regulatory investigations or prosecutions, or when pursuant to a requirement by this agency in connection with the hiring or firing of an employee, the issuance of a security clearance, or investigations of the performance of official duty while in Government service. Your Social Security Account Number (SSN) is solicited under the authority of the Internal Revenue Code (26 U.S.C. 6011(b) and 6109) and E.O. 9397, November 22, 1943, for use as a tax payer and/or employee identification number disclosure is MANDATORY on vouchers claiming travel and/or relocation allowance expense reimbursement which is, or may be, taxable income. Disclosure of you SSN and other requested information is voluntary in all other instances; however, failure to provide the information (other than SSN) required to support the claim may result in delay or loss of reimbursement.

STANDARD FORM 1012 BACK (10-77)

EXHIBIT 110-D
TRAVEL VOUCHER (SF-1012) PREPARATION INSTRUCTIONS

The numbers below correspond to the circled numbers on IOM Exhibit 110-D. Check with your supervisor for any additional requirements by your district. Travel vouchers should be legible and must be completed in ink.

1. Location: Insert the name of the Department, Agency, & Center/Office or Field District Office.
2. Payee's Name: Enter traveler's name exactly as it appears on Travel Order. (Commissioned Officers, also show rank.)
3. Mailing Address: Show address to which payment would be mailed if applicable.
4. Present Duty Station: Enter your official duty station such as District. In case travel is to new station as on transfer, enter new station.
5. Residence: Enter your permanent residence.
6. Social Security Number: Insert your number.
7. Office Telephone No.: Enter number at which you can be reached.
8. Period of Travel: Enter first and last dates of expenses covered by voucher.
9. Authority No.: Enter Travel Order number from your travel order or obtain DO number from supervisor.
10. Authority Date: Enter date of TO. Obtain from your fiscal clerk for travel under district TO.
11. Travel Advance: Claim government-issued cash advances here. Don't claim federal credit card ATM withdrawals here.
12. Agent's Valuation of Ticket: Enter the total amount of travel and/or accommodation as shown on the TR.
13. Initials of Carrier Issuing Ticket: Show the initials of the carrier who issued the ticket.
14. Mode, Class of Service & Accommodation: Specify the type of transportation, i.e., rail air, bus; also type of accommodation used.
15. Date issued: Insert the date the ticket was issued.
16. Points of Travel: Enter point of origin and destination. If round trip, specify "& return".
17. Payee: Sign your name.
18. Date: Enter date you sign the voucher.
19. Amount Claimed: Enter the total amount of expenses for which gross reimbursement is claimed.
20. Approved: Your supervisor or other administrative official signs here to indicate administrative approval. If any expenses claimed require specific approval, e.g., taxi fares in excess of maximum or goods or services not specified on TO, the approval must be made by an official designated to authorize travel.
21. Last Preceding Voucher: If you submitted a previous voucher under the same TO, enter date submitted.
22. Accounting Classification: Your DO Fiscal Clerk normally enters this.

REVERSE SIDE OF VOUCHER

23. Date: Show date on which item of expense was incurred.
24. Time: Show date of departure from, and arrival at, official station or other place where official travel begins and ends. Other places visited while in travel status should be shown, but time of arrival is not necessary unless required by your district.
25. Description: State the general purpose of trip. (Note: Travel Manager computerized authorization/voucher program does not allow for placement of purpose on the reverse side of the voucher. If needed, the purpose can be placed in the comment section which prints on the front of the voucher.)

    Itemize chronologically all expenses for the period covered by voucher including per diem and lodging.
    Where a constructive cost is required, such as when your personal car is used in lieu of taxi or common carrier, provide specific flight or carrier schedules, times, and names of carriers. When allowable expenses are not to exceed constructive cost by common carrier, show the lesser of the actual cost or constructive cost in the "Amount Claimed" column.

a. 24 Hours or Less;
   No M&IE shall be allowed for domestic travel when the travel period is 12 hours or less in the same calendar day, or the employees workday plus 2 hours for employees who work a so-called non-standard workday.
   When the travel period (entire trip) for which per diem has been authorized is more than 12 hours, but does not exceed 24 hours, the per diem allowance for the trip will be ¾ of the applicable M&IE allowance for the temporary duty assignment location.

b. Over 24 Hours:
   The M&IE Allowance is ¾ of the daily rate on first and last date of travel when overnight travel is involved and the full daily rate for each intervening day.

26. Instructions to Traveler: Self-explanatory.
27. Mileage Rate: Show rate per mile as authorized in the TO and the net mileage claimed. Any significant difference between mileage claimed and the Standard Highway Mileage should be explained.
28. Amount Claimed: Enter the amounts claimed opposite the specific description of items explained under "Description".
29. Grand Total: Enter the grand total to be carried forward to the face of the voucher. (Item 20)

NOTE:

1. When reclaiming a portion of a previous voucher which was suspended, identify fully and attach a copy of the suspension notice.
2. Lodging receipts are required. Submit Hotel Receipt with voucher.