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1.1 – Administration Notes

The FDA is a part of the Department of Health and Human Services (HHS). An appointed Commissioner who serves at the discretion of the President heads the agency. The FDA is a team of dedicated professionals working to protect and promote the health of the American people. The FDA's complete organization structures are available on FDA's Intranet website.

The Office of Inspections and Investigations (OII) is responsible for the operational activities of FDA through the work of its headquarters and field staff across the continental United States and Puerto Rico. OII inspects regulated products and manufacturers, conducts sample analyses of regulated products, and reviews imported products offered for entry into the United States. Resources for OII employees can be found on the OII Site.

Accessible to all FDA employees, the InsideFDA and OII intranet websites contain information about organizational structures for FDA/OII The OII Organizational chart provides an overview of current OII organization; information about specific offices within OII can be found on the employee resources page on the OII main SharePoint site. The FDA intranet site also contains the Employee Resources Hub that provides FDA employees with information such as new employee orientation, employment programs, human resources, facility services, trending topics, occupational safety and health services, and employee trainings. The Administrative Topic Hub covers resources for topics pertaining to acquisitions and grants, budget and finance, Continuity of Operation Plans (COOPs) and emergency planning, financial services, forms and office templates, furlough guidance, security, workforce management, and travel services.

1.2 – OII Travel

All official travel must be authorized and approved with a valid travel authorization (TA) using FDA's Electronic Government Travel Service, ConcurGov. Typically, the travel authorization should be submitted at least 5 days in advance for review and approval. Travel itineraries listing where and how you can be reached should be provided to your supervisor since situations arise which necessitate contacting you while in travel status.

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

Additional information can be obtained by contacting your Administrative Staff or visiting OFM's – Division of Travel Services (DTS) site.

The Fiscal Management Manual site provides policy, process, procedure, training, and additional materials for the FDA financial community.

Emergency travel can be approved, and the travel order prepared and authorized after the fact. "After the fact" TAs should be utilized on a very limited basis. The preparer should ensure that a detailed justification/explanation is provided and uploaded as an attachment in the TA to facilitate processing.

The Federal Travel Regulation (FTR) contained in 41 CFR 301, the Department of Health and Human Services (DHHS) Travel Manual, the FDA supplements to the DHHS 2012 Travel Manual govern official travel. Become familiar with these documents.

The HHS Travel Policy Manual is intended for use by HHS Employees, invitational travelers, consultants, and others authorized to travel on behalf of the Department. Please note that the words “employee” and “traveler” are the same for the purpose of this policy and in alignment with the FTR definition of “employee.”

The current HHS Travel Policy Manual provides users with the complete source of the Department’s management policies and procedures regarding travel and transportation procedures. Topics addressed in the Manual include, but are not limited to, Temporary Duty (TDY) Travel, Relocation Allowances, Interagency Personnel Agreements (IPAs) Travel and Transportation Expenses connected with the death of certain employees, and Acceptance of Payments of Travel Expenses from Non-Federal Sources (Sponsored Travel). All material contained in the Investigations Operations Manual (IOM) must be used in conjunction with, and subject to, federal travel regulations.

Job aids and SOPs are provided to guide users in how to prepare for travel with FDA. Additional travel information can be obtained from the Travel Information for OII Employees Site , as well as the Office of Financial Management (OFM) Intranet home page.

1.2.1 - Government Contractor-Issued Travel Charge Card

The Government Travel Charge Card Program (GTCC) provides travelers with a safe, effective, convenient, and commercially available method to pay for expenses associated with official travel. Refer to the FDA Staff Manual Guide (SMG) 2343.1 for additional information on policy governing the Agency-wide Travel Card Program and the procedures employees must follow for use of the card while on official travel.

Your Government Travel Card is a tool that assists you in the performance of your duties. The way you use the travel card will reflect directly upon you as an employee and as an individual. With the privilege of a government travel card also come the responsibilities for its proper use. Use of the card does not relieve you of the responsibility to employ prudent travel practices and to observe rules and regulations governing travel for FDA, and as set forth in the FTR.

Travel charge cards are issued to employees to pay for all official travel and travel-related expenses. You must use the card only for authorized expenses incurred in connection with official travel orders, for example, lodging, transportation, baggage fees, parking, and meals, unless you have been granted an exemption. Exceptions can include 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. For more information on authorized exemptions, see the HHS Travel Manual, Chapter 9-00-10 C and D or go to the HHS Office of Finance web site for additional information on policy governing the Department-wide Travel Card Program and the procedures employees must follow for use of the card while performing official travel.

Personal use of the travel card or using the travel card to pay for someone else's travel expenses is prohibited. The use of the travel card for non-official expenses may result in disciplinary actions. Do not charge office supplies, training, conference registration fees, photocopies, postal services, or equipment on the travel card. Instead, use the purchase card or other acquisition vehicles to procure non-travel related services and products.

The only exception for use of the card not in connection with official travel applies to ATM withdrawals for purchase of samples. (See IOM 4.2.8.3.)

Payments will include direct payment to the credit card company for expenses charged to the individual's official government travel credit card. Typically, the M&IE portion of per diem is reimbursed to the personal bank account, not the travel card. The HHS Travel Policy Manual states that the Government Issued travel card must be used for all travel related expenses including Per Diem and including M&IE. Concur defaults to reimbursing M&IE to the personal bank account. However, this can be changed during the TA and/or voucher creation stage to have the M&IE reimbursed to the Travel Card.

ATM cash advance is to be used only to cover anticipated out-of-pocket incidental travel expenses which generally cannot be charged directly to the card. Excessive ATM cash advances not commensurate with travel are Travel Card misuse. Therefore, direct charge of the Travel Card must be utilized in lieu of ATM Cash whenever and wherever possible for approved, travel related expenses. You will use your government-issued credit card to obtain a cash advance from an ATM machine, for official government business only. Ensure your Travel Authorization (TA) contains a statement that you are authorized to use an ATM to obtain cash advances and the maximum total amount authorized for your trip. ATM withdrawal for official travel is authorized based on 80% of your M&IE and estimated out of pocket expenses for the trip. Regardless of amounts indicated on your TA, ATM cash advances also may not exceed the weekly ATM withdrawal limit on your Travel Card account. This limit is established at the time that you apply for the travel card- based on a personal credit worthiness check. There are usually two fees associated with an ATM cash advance. The "Terminal Fee" assessed by the ATM terminal's owner/supplier and the "Cash Advance Fee" assessed by the bank. Currently, there are two formulas to calculate the reimbursable Cash Advance Fee using a 2.5% of the fee or a minimum of $3.00:

- Percentage – 2.5% multiplied by (Cash advance amount + ATM Terminal Fee).
- Minimum payment - $3 plus (Cash advance amount + ATM Terminal Fee).

The Cash Advance Fee is described in your credit card agreement. These amounts should be included on the Travel Authorization/Voucher along with receipts before reimbursement is made.

Additionally, there is an international fee charged if cash advances are taken during foreign travel.

The government reimburses employees for authorized expenses. The employee is responsible for making payment to the bank; the cardholder is solely responsible for the timely payment of travel card bills and that account is delinquent if not paid within 30 days after the first statement date.

Read and understand the “HHS Traveler’s Agreement for Government Contractor-Issued Travel Charge Card Users” before signing.

Immediately report a lost or stolen travel card to the bank and your Agency/Organization Program Coordinator (A/OPC) or travel coordinator.

If you do not have a government travel card and are required to travel, please contact your administrative officer about receiving a travel advance.

1.2.2 – U.S. General Services Administration (GSA) and Travel Management

GSA Federal Travel Regulations (FTR) summarizes the travel and relocation policy for all federal civilian employees and others authorized to travel at the government's expense. Federal employees and agencies may use the FTR as a reference to ensure official travel and relocation is conducted in a responsible and cost-effective manner.

Other important sites include:

- GSA Domestic Per Diem Lookup to assists travelers with finding Domestic Per Diem Rates.
- U.S. Department of State Foreign Per Diem Rates by Location to determine Foreign Per Diem Rates per location.
- GSA Airline City Pairs Search to assist travelers with finding the Airline City Pairs for the Current and Former Fiscal Year. For Domestic Travel, the traveler enters either the Departure City or three letter International Air Transport Association (IATA) code and the Arrival City or IATA code to find the Airline City Pair. For International Travel, the Departure and Arrival cities are required to query the Airline City Pair.

1.3 – Travelers' Health

Travelers' Health is a link to CDC's Travelers Health Section. The CDC/Traveler's Health website is committed to updating the public with current and accurate information regarding vaccines and medicines, along with travel advice/recommendations, notices, and resources. Investigators are encouraged to frequently review this site in advance of travel.

FDA Occupational Health Services has Health Units established for FDA employees to receive occupationally related medical services. Each health unit provides access to on-site first aid and urgent care services; onsite clinical care, referral, and follow-up for work related injury and illness; immunizations; health risk appraisals; health screenings; health counseling; and health and wellness education. Services are provided by appointment only. To request OHS services **Outside the National Capital region**, please send an email to occupationalhealthservices@fda.hhs.gov.

IOM Chapter 10 has additional traveler health and safety information.

1.4 – Division of Travel Operations

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

To assist OII travelers and travel preparers, DTO has created the Travel Resources SharePoint site intended to provide cumulative guidance to facilitate travel. The DTO site has information regarding domestic and foreign travel, gainsharing, travel tips & tricks, conference approvals, travel charge card information and travel processes and SOPs.

1.4.1 – Domestic Travel

1.4.1.1 – Domestic Travel Guide

OII travelers preparing for domestic travel should use the Domestic Travel Guide to help walk them through the TA process. The Domestic Travel Guide helps guide the traveler through what information and documents are needed to prepare travel authorizations and vouchers. Included in the guide are potential expenses to include on the TA, such as: Flights, Lodging, Lodging Tax, Hotel—Above Per Diem, First Bag Airline Fee, Taxi, Shuttle, Subway, Tips/Gratuity, POV information, Airport Parking, Rental Car, Gasoline for Rental Vehicles, Tolls, ATM fees, Internet Expense, Conference Attendance and Laundry/Dry Cleaning.

The guide also includes information on payment methods, what and how to add comments for each expense and the supporting documentation needed for both TAs and Vouchers. Required information to include in the TA Trip Details section, how to identify states that are exempt from lodging tax (and what this means) as well as the types of travelers are also covered.

Additional information on domestic travel, including forms, frequently asked questions and tips on using ConcurGov are available on the Travel Information for OII Employees.

1.4.1.2 – Domestic Travel Contacts

DTO Travel Specialists: Travelers can reach out to their respective Travel Specialist (also called a Federal Agency Travel Administrator or FATA) as identified on the OII Domestic Travel Specialist (FATA) Support by Program Area Site with questions or for assistance.

Some additional contacts you may need while traveling include:

- OMEGA World Travel: 1-855-326-5411
- Citibank Customer Service: 1-800-790-7206

Both OMEGA and Citibank are available 24 hours a day, 7 days a week. For any travel emergencies and concerns, contact your supervisor and OMEGA World Travel.

1.4.2– Foreign Travel

1.4.2.1 – Foreign Travel Information

International travel is important to achieving Departmental goals. However, such travel is typically very expensive and entails security concerns and other sensitivities. Therefore, managers must carefully monitor the frequency of the overseas travel performed by their employees and others authorized to travel for HHS. OpDiv/StaffDiv Heads must maintain proper delegations of authority to ensure they approve proposed official international travel only when it effectively and safely serves the goals of the Department.

When assigned to a foreign inspection, employees will be assigned a Trip Coordinator who will assist with coordinating the logistics of the trip, such as flights and lodging. The Trip Coordinator will provide the traveler with all pertinent information upon assignment on topics such as passports, visas, and immunization/health information. DTO has also captured materials and resources that serve as a supplement to the trip-specific communications that are sent to the foreign traveler on its Foreign Travel SharePoint site. Be sure to visit the: Pre-Travel, During Travel, Post-Travel, Contact Information, as well as the Resources section, to find links to useful information that may assist you through all aspects of the foreign travel process.

All Investigators conducting OII foreign inspections must take required courses and trainings prior to departure. Investigators should contact their Program Office for information on these courses. See the DTO Foreign Travel Security Training Requirements site for more information.

DTO has also prepared a timeline of the coordination process. While actual time for trip coordination will vary based on each trip's specifics, this timeline gives the traveler a good idea on what to expect during the coordination process. For foreign travel, be aware that there are differences in reporting requirements and reimbursable expenses. See the Guide to International Inspections and Travel, Chapter 2, Subchapter 215.2 – Reimbursable Expenses, for specifics.

1.4.2.2 – Foreign Travel Contacts

Travelers should always contact their DTO Trip Coordinator first. Before departure, travelers will also be provided a list of additional DTO contacts their travel itinerary for any questions they have during travel should their Trip Coordinator be unavailable.

Additional contacts that may be useful during foreign travel:

- Office of Inspections and Investigations Division of Foreign Food Investigations and Global Operations
- Office of Human and Animal Drug Foreign Inspectorate
- Office of Medical Devices and Radiological Health Inspectorate
- Division of Tobacco Inspectorate
- Office of Management Contacts
- OII Domestic Travel (FATA) Contacts
- Office of Security and Passport Operations
- Employee Resource Information Center (ERIC)
- Tricare Overseas Program (TOP): 1-888 777-8343
- Concur Government Edition (CGE)
- For Mailing Documents to the U.S.: UPS International Service Center: 1-800-782-7892
- FDA's Computer Security Incident Response Team (Certain designated countries only): Report if you suspect lost, misplaced, or stolen equipment or if you believe there has been a personally identifiable information (PII) breach.
- Disaster Evacuation Contact System (DECS) - Blue Card: DECS provides management of the status of FDA personnel and their family members, information crucial in determining resource allocation for continued FDA mission execution during emergencies/disasters.
- OMEGA World Travel: Always attempt to contact the Trip Coordinator prior to contacting OMEGA at 855-326-5411
- Citibank CitiManager**:** 1-800-790-7206 or CCJAXL1HelpDesk@citi.com

1.4.3 – Per Diem and Subsistence Allowances

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. Subsistence is the cost of lodging, meals, tips, and the miscellaneous expenses you incur while in travel status. FDA Approving Officials, as well as FDA travelers, must follow the provisions of the FTR and HHS travel policy guidelines in authorizing, incurring, and approving per diem and subsistence expenses. Current per diem rates can be found on the General Services Administration's (GSA) website.

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

The Program Support Center (PSC) has developed training and job aids to assist users with the most common travel processes in the online travel management system, ConcurGov. Each job aid includes simple step-by-step instructions for specific processes within the ConcurGov system. Topics include air travel, travel expense planning, booking travel, authorizations and vouchers, receipts, SmartPay and more.

The FTR requires traveling employees to exercise care in incurring expenses which includes claiming a federal exemption from payment of state and/or local taxes on lodging whenever this option is available. Not all states and localities offer tax exemption, and some locations do not specify a particular form. Please view GSA's tax-exempt state information to determine tax exemption status and forms by state.

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

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

Accurately record all your expenditures. See IOM 2.1.2 for information on recording expenses.

1.4.3.1 Per Diem Rates, Actual Expense Reimbursement, and Lodging

Section 5.1 of the HHS Travel Policy Manual provides guidance for HHS civilian employees, invitational travelers, and OpDiv/StaffDivs regarding allowable per diem and subsistence expenses for TDY travel. HHS employees are expected to travel on a lodging-plus per diem basis. Under the lodgings-plus per diem method, a maximum per diem rate is established for lodging, plus M&IE, at a specific location.

Travelers or designated personnel must make lodging reservations using the ETS and/or contracted TMC. First consideration must be given to establishments that are contracted by GSA under the FedRooms program to ensure that travelers stay in fire-safe accommodations at a rate that is at or below per diem.

For Mandatory Statements Required on Travel Vouchers - See IOM Exhibit 1-1 Allowable Expenses Chart for allowable expenses, receipts required, etc.

1.4.3.2 Miscellaneous Expenses

Section 5.2 of the HHS Travel Policy Manual provides guidance for HHS employees and invitational travelers on reimbursable miscellaneous expenses incurred during official travel. Each type of miscellaneous expense will be reported as a separate line item on the travel voucher, indicating the amount and dates when incurred. Unless otherwise specified, receipts are required only when the individual expense is greater than $75.

Miscellaneous Expenses per the HHS Travel Policy Manual include:

- Hotel taxes: GSA does not include hotel taxes in the lodging rates that are issued as part of the per diem rates for the continental U.S. Hotel taxes are a miscellaneous expense item. Travelers are required to request exemption from state and local taxes where applicable. When the tax exempt option is available and used, the completed form is required to be attached to the traveler's voucher. Lodging taxes should not be claimed when the tax emption form is used.
- Business and Personal Telephone Calls: Refer to Staff Manual Guide 2343.2 to determine the maximum allowable reimbursement for telephone calls home. Also addresses pre-paid phone cards, Employee-Owned Personal Communication Devices, Internet Fees, Wireless access (internet fees), Airport/airplane internet fees.
- Laundry, Dry Cleaning, and Pressing of Clothing
- Baggage Fees
- ATM Fees/International Transaction fees for foreign withdrawals
- Trusted Traveler Programs and PreCheck (TM) Custom's and Border Protection's (CBP) Trusted Traveler Programs
- Emergency and Other Authorized Miscellaneous Expenses

1.4.3.3 - Special Travel Situations

See HHS Travel Policy Manual section 5.4 for guidance regarding special travel situations including the use of annual and compensatory leave.

1.4.4- Transportation Allowances/Expenses

1.4.4.1– Transportation Expenses

Section 4.1 of the HHS Travel Policy Manual provides guidance for FDA/HHS employees, invitational travelers, and OpDiv/StaffDivs regarding allowable transportation expenses for TDY travel. General Transportation Expenses topics include:

- Transportation Method and Routing
- Transportation Gratuities: Limited to 15% of the charge for service. If there is no service charge, the limit for tips is $5.
- Procuring Common Carrier Transportation
- Mandatory Use of Contract Fares and When Contract Fares May Not Be Used. Refer to Federal Travel Regulation (FTR) 301-10.107 and 301-10.108 for additional information.
- Use of Privately Owned Vehicles (POVs), Rental Cars, and Other Special Conveyances

1.4.4.2 -Authorization of a Per Diem Allowance at the Official Station or within the Local Transportation (Formerly Local Travel) Area

Section 4.2 of the HHS Travel Policy Manual provides guidance regarding the authorization of a per diem allowance in conjunction with official business that takes place at the employee's official station or within the HHS defined local transportation (formerly local travel) area. It also applies to officers of the Commissioned Corps U.S. Public Health Service. Local transportation expenses do not require a no-cost travel order. Topics include:

- Criteria for Determining Allowable Local Travel Transportation Expenses

- Non-Reimbursable Local Travel Transportation Expenses
- Reimbursable Local Travel Transportation Expenses

1.4.5 – Furlough Guidance

1.4.5.1 - Ethics Rules During a Shutdown

As a federal employee, furloughed or not, you are still governed by the provisions set forth in the Standards of Ethical Conduct as well as the Hatch Act and other federal laws.

Things to Know:

- When seeking outside employment, no prior approval is required if not intending to work for a prohibited source. If you're seeking outside employment with a prohibited source, you must receive prior written approval.
- You cannot receive compensation for teaching, speaking, or writing that relates to your official duties.
- You cannot represent another person before any federal agency, department or court except for yourself, spouse, parents, and children (18 U.S.C. 205).
- You cannot receive compensation from anyone else for their representational services before any federal agency, department, or court that is provided by another, including an employer (18 U.S.C. 203).
- You cannot use your official title to imply the government sanctions or endorses your personal activity.
- All gift rules still apply.
- The Hatch Act rules still apply. Visit the Hatch Act Update page for an overview and more information regarding the Hatch Act.
- Standards of Ethical Conduct for Employees of the Executive Branch, HHS Supplemental Standards of Ethical Conduct, as well as the conflict of interest statutes still apply.
- All media inquiries regarding your professional capacity, or FDA business, including speaking engagements, must be referred to the FDA Media Affairs team by emailing fdaoma@fda.hhs.gov.

If you have any questions about your ethical obligations during the government shutdown, please contact OII Ethics Liaison. Find general furlough information in the OPM's Pay & Leave Furlough Guidance.

1.4.5.2 – Travel During a Lapse in Appropriations

Section 13 of the HHS Travel Policy Manual provides instructions and information concerning transportation and other expenses incident to travel in the event of a Lapse in Appropriations for HHS.

Travel in the event of a lapse in appropriations often involves unique or extraordinary travel scenarios for Federal employees and those traveling on behalf of HHS. However, all travel must be conducted in accordance with the FTR.

The policy guidance FAQs are intended to address those scenarios that occur most often, but it does not address every possible scenario.

Due to the fluid nature of a lapse in appropriations, visit the PCS website for the most recent information related to travel in the event of a lapse in appropriations.

During a lapse in appropriations, the Federal government may enact an Emergency Furlough. During an Emergency Furlough, the Office of Personnel Management (OPM) may issue guidance related to travel for employees impacted by an administrative furlough.
FDA Shutdown FAQs are contained in Exhibit 1-2. Additional guidance is in OPM's Shutdown Furlough Guidance webpage.

1.5 – Vehicle Accidents

When you are involved in a vehicle accident:

- Render first aid. If you are injured, obtain emergency treatment.
- Contact police.
- Report the accident to your supervisor as soon as possible.

1.5.1 – Government-Owned Vehicle (GOV)

Each GOV used for district operations should be furnished with a GSA Fleet Vehicle Packet (Exhibit 1-3) with a Fleet Vehicle Accident Kit-GSA 1627 (Exhibit 1-4). The US Government is self-insured, and additional information can be found on the Fleet Vehicle Accident Kit.

1.5.1.1 – Information to be Obtained

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

1.5.1.2 – Reporting

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor and local Fleet Vehicle Custodian from which the vehicle is assigned. Report the accident to the GSA Accident Management Control Center (Accident Management Center (AMC) | GSA) Call (866) 400-0411, and select option 2.

- Complete the following forms and submit as required:
  - Motor Vehicle Accident (Crash) Report (SF-91) (A blank copy of this form should be located in the vehicle)
  - Copy of a traffic regulation or ordinance which was violated.
  - Results of any trial or disposition of summons if any arrests were made or charges referred.
  - Claim for Damage, Injury, or Death (SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.) To be completed by claimant or non-government employee.
  - Investigation Reports and Policy Reports
  - Statement of Witness (SF-94)

  - Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
  - Statement listing date of purchase, purchase price and salvage value where repair is not economical.
  - Photographs of damage and/or scene of accident if available
- 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.
- Check with your personal insurance carrier for their requirements.
- Immediately submit to your supervisor any notice, summons, legal paper, or claim, which may subsequently arise from the accident.
- Check with your supervisor and local Fleet Vehicle Custodian to determine if additional reports or information are needed.
- Submit completed claims package electronically to the distribution list for supporting District Office
- .

Tort claims must contain the completed SF-91 (Motor Vehicle Accident Report) and the -SF-95 (Claim for Damage, Injury, or Death). Notify the FDA Fleet Management Team of the accident via email at FDAFleetManager@fda.hhs.gov
See also: FDA Fleet Vehicle Risk Management: Motor Vehicle Accidents/Incidents for additional information.

1.5.1.3 – Liability

The Federal Drivers Act (28 U.S.C. 2679(a)-(e)) was enacted to protect government drivers from personal liability while driving within the scope of their employment. This means you must be on official business to be covered. It relieves you from the burden of acquiring private automobile liability insurance for driving while on the job. The government's exclusive liability provided by this Act is predicated on its status as employer, without regard to whether the vehicle involved is government owned or privately owned.

The Military Personnel and Civilian Employees' Claim Act of 1964 allows for claims against FDA by employees, provided the loss or damage was within the scope of their employment and the employee (claimant) is free of negligence regarding those losses (See IOM 1.5.1.3.1). The Federal Tort Claims Act provides for claims generally coming from outside the Agency where the activities of the Agency or specific individual employees are negligent and cause death, injuries, or property loss or damage (See IOM 1.5.1.3.2).

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

1.5.1.3.1 – Military Personnel and Civilian Employees' Claim Act of 1964

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

1.5.1.3.2 – Tort Claims

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

1.5.1.3.2.1 – Property Damage or Personal Injury

Claim for Damage, Injury, or Death (form SF-95) or other written notification of an incident accompanied by a claim. (SF-95 or statement constituting a claim must be date-stamped by the office initially receiving the claim to document the exact date the claim was received.)

- Investigation Reports and Policy Reports
- Statement of Witness (SF-94)
- Itemized receipt of payment for necessary repairs or two itemized written estimates of cost of repairs
- Statement listing date of purchase, purchase price and salvage value where repair is not economical
- Photographs of damage and/or scene of accident if available

1.5.2 – Privately Owned Vehicle (POV)

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

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

If an accident was caused by your negligent operation of a vehicle, and your vehicle is damaged, the cost of repairing your vehicle will not be paid for by the government. **You should look to your own private insurance carrier for reimbursement, payable under the terms of your own automobile insurance policy.** You are protected from liability by the Federal Drivers Act. See IOM 1.5.1.3 for further information on this.

If the accident is determined not to have been caused by your negligence, the provisions of the Military Personnel and Civilian Employees' Claim Act of 1964 (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 HHS-481, Employee Claim for Loss or Damage to Personal Property, should be obtained, completed, and submitted electronically to the FDATortClaims@fda.hhs.gov Outlook e-mailbox or through regular mail to the FDA Fleet Manager, Logistics and Transportation Management, 10993 New Hampshire Ave., White Oak Bldg. 71, Room 2132 Silver Spring, MD 20993 with evidence establishing that the use of a POV was authorized for official purposes and that the accident was not caused by your negligence.

Liability - see IOM 1.5.1.3.

Reporting - Report vehicle accidents as instructed in IOM 1.5.1.

1.5.3 – Rental Vehicle

1.5.3.1 – Reporting

Report the accident to the police after rendering emergency first aid to the injured. Telephone your supervisor as soon as possible. Follow IOM 1.5.1.1 to obtain the necessary information (e.g., description of vehicles involved, license plate numbers, pertinent information about drivers and owners of other vehicles, etc.)

Contact the car rental company to report the accident. Even if the damage to the rental vehicle appears to be minor, do **NOT** drive the rental vehicle from the scene unless you have contacted the rental car company and have obtained permission to do so.

- If the rental car company, other driver(s) involved, or other parties inquire about the requirements for filing a tort claim or personal property claim, provide them the Claim for Damage, Injury, or Death (SF-95). Provide the SF-95 to all customers (e.g., other drivers, their insurance company, rental car company) by following the Example Email Communication to Claimant Regarding Form SF-95 Submission (Exhibit 1-5). All claimants will return their SF-95 forms to you for submission with the tort claims package.
  - If possible, capture the date FS-95 forms are returned to you. If the form is returned via email, save a copy of the email, and submit a copy of the email with the claims package.
- In addition to SF-95 forms, the following documents (as applicable) must be included in the claims package:
  - Motor Vehicle Accident (Crash) Report (SF-91)
    - Note: Since the accident did not involve a GSA fleet vehicle, sections X1 through XIII will not be completed.
    - SF-91 must be reviewed and signed by your supervisor.
  - Statement of Witness (SF-94), if any, or equivalent written statement.
  - Two repair estimates for claimant's vehicle
  - Copy of claimant's receipts
  - Police Report
    - If you do not have a police report, you must explain why.
  - Pictures of damages to rental vehicle
  - Pictures of damages to claimant's vehicle
- Submit completed claims package electronically to the FDATortClaims@fda.hhs.gov e-mailbox or by inter-office mail or by the U.S. Post Office:

  FDA Fleet Manager, Logistics and Transportation Management Branch
  10903 New Hampshire Ave, Bldg. 71, Room 2132
  Silver Spring, MD 20993

You will submit the claims package as described above even if you do not have SF-95 forms returned to you by the applicable claimants. Do not delay submission of the tort claims package. Explain which documents are not being submitted and why at the time the claims package is submitted to the Tort Claims Office. Missing documentation can be submitted as they become available (e.g., SF-95, police report).

Tort claims must contain the completed SF-91 (Motor Vehicle Accident Report) and the -SF-95 (Claim for Damage, Injury, or Death). Notify the FDA Fleet Operations Manager of the accident via email at FDAFleetManager@fda.hhs.gov.

1.6 – Transportation

Section 4.2.5 of the HHS Travel Policy Manual provides guidance for FDA/HHS employees, invitational travelers, and OpDiv/StaffDivs regarding modes of travel- public, private, government and rental.

Your agency must select the method most advantageous to the Government, when cost and other factors are considered. Under 5 U.S.C. 5733, travel must be by the most expeditious means of transportation practicable and commensurate with the nature and purpose of your duties. In addition, your agency must consider energy conservation, total cost to the Government (including costs of per diem, overtime, lost work time, and actual transportation costs), total distance traveled, number of points visited, and number of travelers".

1.6.1 – OII Government-Owned Vehicle (GOV)

GOVs for field operations are furnished by the regional GSA motor pool office. GOV users should follow the operating procedures in effect for the appropriate GSA motor pool. Each District office has an assigned Fleet Vehicle Custodian that can answer general GOV questions as needed.

You are required to have a valid state, District of Columbia, or commonwealth operator's permit for the type of vehicle to be operated, and a valid DHHS identification document (such as your PIV Card, credentials, building pass, etc.).

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

Purchase fuel and oil for your GOV with GSA Fleet Credit Cards. Receipts are to be turned into the local FDA Fleet Vehicle Custodian servicing your location. Follow your office's procedure for submitting credit card receipts. Make emergency purchases with cash only when the GSA Fleet Credit Card is refused. You also have the option to contact GSA's Maintenance and Control Center (MCC) which provides GSA Fleet customers and vendors with one-stop service for mechanical repairs. The MCC provides authorization for repairs and services over $100, or for any tire and battery replacement, regardless of cost. Please consult your local Fleet Vehicle Custodian and supervisor for specific instructions and guidance.

To contact the MCC, call 1-866-400-0411, and follow the menu options. The GSA Fleet Vehicle Assistance Card can be printed and carried with you for reference (Exhibit 1-6).

You are responsible for all traffic violations, including parking fines, you incur during the use and operation of a GOV. See Staff Manual Guide (SMG) 2173.1, Attachment D 1.H.

While traveling on official business, you may be reimbursed for parking fees or overnight storage charges. Provide for the safe and proper overnight storage of GOVs while you are in travel status and put the 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.

Other resources available include: FDA Fleet Vehicle Operator Training: Prerequisite for GOV operation and FDA Fleet Vehicle Operation: Use and Care of Government Vehicles.

1.6.1.1 – Care and Custody of U.S. Vehicles

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

- The car should be locked when parked in public areas, in private lots, or in open government parking areas.
- The vehicle operator is responsible for the keys and WEX card. They should be returned to the Fleet Vehicle Custodian's office or KeyTrak system (if installed) and secured in a locked environment daily/nightly. These items should be kept in a safe place in the office if the vehicle is stored at a location other than assigned FDA GOV storage.
- It is permissible to turn over a GOV to either parking lot attendants or valet parking attendants who must park the vehicles at locations where the drivers/operators are not permitted to park the vehicles themselves when no self-parking options are available. You must remove the WEX credit card from the GOV, keep it secure when handing the vehicle off to the valet or parking attendant, and keep it with you in a safe place.
- The credit card may only be used to purchase fuel and vehicle lubricants or other vehicle appropriate items listed on the back of the card for the vehicle identified and not used for other vehicles.
- 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. Submit a copy or original to the Fleet Vehicle Custodian for your appropriate district for monthly reporting requirements.
- Odometer readings can also be reported by using Get Odometer Reading at the Pump (GORP) when time to refuel a vehicle.
- Filling the government-owned vehicle with fuel is the responsibility of the authorized driver. Follow district guidelines for submitting fuel receipts.
- The use of tobacco products is prohibited in government-owned or commercial leased vehicles.
- In accordance with Executive Order 13513, "No Texting While Driving", federal employees shall not engage in text messaging (a) when driving GOV, or when driving POV while on official government business, or (b) when using electronic equipment supplied by the government.

Refer to the HHS Program Support Center Fleet Management Resources website for more information.

1.6.1.2 – Use of a GOV between Your Residence and Place of Employment

No FDA/OII employee shall use a GOV for transportation between their home and place of employment without the expressed written approval of the Secretary of Health and Human Services. Requests for Home-To-Work Authority must be submitted in writing via an HHS-16 request form by the supervisor of requesting individual to the FDA Fleet Operations Manager at FDAFleetManager@fda.hhs.gov. See also: Staff Manual Guide 2173.1 and FDA Fleet Vehicle Operation: Home-to-Work Policy for Use of Government Vehicles.

Vehicles assigned to or purchased or leased by FDA are intended for official business as authorized by Federal Management Regulation 102-34.220. **FDA motor vehicles are not provided for the convenience of FDA employees**.

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

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

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

Government vehicles should only be used when it is: (1) the least costly method of transportation available (considering the value of employee time and actual transportation costs) or (2) when no other practical method of transportation is available considering the mission to be performed; the location; and any equipment needed to be transported to support the mission.

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

The Daily Log must be kept for at least a period of three years and must be available for audit purposes. Please work with your Fleet Vehicle Custodian to get the completed FDA-3369 forms uploaded to the appropriated vehicle on the Fleet Management Program (FMP) SharePoint site. If you need access to the site for uploading the form, please email the FDA Fleet Operations manager at: FDAFleetManager@fda.hhs.gov.

1.6.1.3 – Roadside Assistance for U. S. Vehicles

For situations that may require emergency towing, changing flat tires, or lock-out service, the following options are available:

- For roadside assistance from Monday through Friday from 7:00 AM to 8:00 PM ET, contact GSA Fleet MCC at 866-400-0411, choose option 1.
- For roadside assistance outside of the timeframe listed above, roadside assistance is offered by the manufacturers for vehicles under warranty. The contact for specific manufacturers can be found at GSA Roadside Assistance.

1.6.2 – Privately Owned Vehicle (POV), Rental Vehicle, and Other Special Conveyances

See HHS Travel Policy Manual section 4.1.10.

1.6.2.1 – Privately Owned Vehicle (POV)

On official business, you may use your POV instead of a GOV, if authorized. However, reimbursement for mileage will not exceed the cost of using a GOV. Mileage is payable to only one employee when two or more employees travel in the same vehicle on the same trip. The employee claiming reimbursement will list on the voucher the names of other passengers accompanying him or her. See current POV Mileage Reimbursement Rates.

You should carry a set of government accident reporting forms whenever you use your POV for official business. See IOM 1.5 for accident reporting requirements.

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

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

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

1.6.2.2 – Rental Vehicle

GSA and the Department of Defense (DOD) both provide employees with a nationwide commercial auto rental program. Agency policy dictates leasing the least expensive auto to satisfy the transportation requirements. If a rental vehicle is determined to be the most advantageous mode for travel, there must be specific written authorization or prior approval to obtain this service. See your Administrative Officer for additional information and necessary form to be uploaded into ETS.

When an employee is authorized in advance to hire a rental vehicle for official travel, the employee may use the rental vehicle for official purposes while at the TDY station, including travel to and from restaurants near the work site or hotel. Employees should be aware that the Government will deny liability for any loss or damage to a vehicle rented for official business purposes using a government travel charge card if that loss/damage arises from activities outside the scope of official business travel. Refer to the HHS Travel Policy Manual section 4.1.10.2 (Rental Vehicles) for more information rental car fuel, usage, default rental car size, responsibility for violations, etc.

Optional Collision Damage Insurance, known as CDW, will not be reimbursed for domestic travel. Participating rental companies have agreed to settle any claim for damages with the FDA. CDW is required for foreign travel and will be reimbursed. The government will not pay or reimburse you for Personal Accident Insurance (PAI) for domestic or foreign travel.

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

1.6.2.3 – Public Transportation

Public transport (also known as public transportation, public transit, or mass transit) is a system of transport for passengers by group travel systems available for use by the general public unlike

private transport, typically managed on a schedule, operated on established routes, and charge a fee for each trip. Examples of public transport include city buses, trolleybuses, trams (or light rail) and passenger trains, rapid transit (metro/subway/underground, etc.) and ferries. Public transport between cities is mostly conducted by airlines, coaches, and intercity rail.

Public transportation should be used when practical between points where official business is being conducted and employees may be reimbursed for use of public transportation when using to conduct official government business.

1.6.2.4 – Bus

There are no government-preferred providers for bus service. If a traveler wishes to use bus as a means of common carrier transportation, it requires pre-authorization by the AO. Refer to the HHS Travel Policy Manual section 4.1.10.3 (Buses) for more information.

Shuttles/buses are an optional mode of transportation between sites when on TDY travel (e.g., between residence and carrier terminal, place of lodging and temporary work site, carrier terminal and place of lodging). Reimbursements for use of shuttles/buses in these instances will only be allowed when authorized on your TA. Use of a shuttle or bus for domestic local travel between sites (examples above) does not require supporting documentation to be uploaded in your TA. These transportation costs must be broken down into daily expenses. Receipts are mandatory if cost is over $75.00.

Per the HHS Travel Policy Manual section 4.1.3 (Transportation Gratuities), tips to a taxi, shuttle service, or courtesy transportation driver are limited to 15% of the charge for service. If there is no service charge, the limit for tips is $5. Employees are expected to make maximum use of courtesy transportation (e.g., free airport/hotel shuttle service) in lieu of incurring charges for the same transportation. Transportation Gratuities should be listed as a miscellaneous expense on the Travel Voucher.

1.6.2.5 – Other and Special Conveyances for Transportation

Refer to the HHS Travel Policy Manual section 4.1.10.4 for more information on other types of conveyances such as public transportation (e.g. subway, train, ferry). TA and receipt requirements for public transportation between sites when on TDY travel are the same as described above for shuttles/buses (IOM 1.2.2.3).

1.6.2.6 – Authorization of and Reimbursement for the Use of Transportation Network Companies

In practice, employees shall consider courtesy shuttles, public transportation, multiple party transportation, and taxicabs before using a Transportation Network Company (TNC). Some fees particular to TNCs such as "surge" or "peak hour" fees shall not be reimbursed.

Refer to the HHS Travel Policy Manual section 4.1.10.5 for more information.

TA and receipt requirements for TNCs between sites when on TDY travel are the same as described above for shuttles/buses (See IOM 1.6.2.4). See IOM 1.4.4.1 for more information on allowable transportation gratuities/tips.

1.6.2.7 – Taxi

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

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

1.7 - Media Interactions During Inspections

The inspectional and investigational activities of the FDA receive extensive coverage in online/social, electronic, broadcast and print media. OII field inspectional staff are occasionally requested by the media to comment or provide information on their individual inspectional activities. Such requests can include being interviewed and filmed during inspections, investigations, and sample collections. If media representatives contact you, be courteous and helpful, but refer all requests for information, interviews, and personal appearances to your supervisor. Those requests must be approved in advance and should be referred to OIIpress@fda.hhs.gov for coordination with FDA's Office of Media Affairs.

Remember that you are always on the record, even during your initial contact with a reporter. Never tell a reporter you must obtain clearance first; instead, obtain contact information, topic/questions and response timeframe for follow-up with the OII Press Team. A request for information and a request for an interview should be treated the same way. When fielding a question(s) in person at an event or via the telephone if the person asking questions does not first identify themselves as a member of the news media, it is ok for you to ask if they are a member of the news media. If they are not a member of the news media then follow existing protocol to direct people to the appropriate location at the FDA's website, www.fda.gov for the most up to date information on any topic.

The reason you should ask if the person is a member of the media is to ensure that any message shared with the public via a news organization is the latest vetted messages that have undergone close coordination with our scientific and policy experts at FDA headquarters.

Do not solicit media interviews or on-camera appearances. There may be occasions when management of a firm you are inspecting invites representatives from the news media to observe the inspectional process. Please see IOM 5.5.9.3 for instructions on how to appropriately handle such events.

1.7.1 – Media Resources

- OII Media Engagement
- Mobile Support Instructions (Exhibit 1-7)
- OII Media Fact Sheet
- Media Tip Card (Exhibit 1-8)
- Media Preparedness Training
- OII Media SharePoint Links
- Contact: OIIpress@fda.hhs.gov
- Office of Media Affairs Contacts
- OII Media Engagement Communications Toolbox

1.8 - Equipment

You are responsible for the proper acceptance, use, protection, and surrender of any Government property assigned to your custody or control; you may be held liable for violations of such responsibility when they result in losses to the Government. The Personal Property Management Program (PPMP) oversees the integrity, proper use, and safe guarding of equipment.

Per PPMP policy:

- Accept property only when properly assigned to you and do not remove any property without consent.
- Do not use, or permit any other person to use, FDA property for any purpose other than official use.
- Coordinate the disposition of all property through the PPMP or the Center/Office Accountable Property Officer (APO).
- An employee leaving any jurisdiction shall return any property or account for all personal property and other items for which personally responsible.
- Assure proper care of property entrusted to you (safe parking for vehicles, keeping inspectional and investigational equipment securely locked in the trunk of the car, not leaving valuable equipment in the car's trunk while the car is in for servicing, not leaving electronic equipment/computers in the trunk of the car for extended periods in extreme hot or cold weather conditions, storing all property in safe, secure areas…).

All FDA property related questions should be directed to your supervision who will then reach out to the Property Custodial Officer or the Center/Office's APO.

For lost or stolen equipment, immediately contact your supervisor, the FDA IT Security Operations Center, and your foreign travel trip planner as applicable if you suspect lost, misplaced, or stolen equipment (for example, laptop, cell phone, etc.). For equipment that contains personally identifiable information (PII) such as a person's home address or social security number, or other sensitive non-public information use the IT Security Incident Checklist (Exhibit 1-9) as a guide, immediately contact the FDA Systems Management Center at:

- Email: FDASystemsManagementCenter@fda.hhs.gov
- Toll Free Number: 855-5FDA-SMC (855-533-2762)

Additionally, a memorandum should be prepared detailing

- the circumstances surrounding the loss
- a full description of the article including FDA barcode/tag/serial number as available
- the comprehensive steps you took to recover the item(s)

In the case of theft, obtain a police report and provide a copy of the report within two days of the incident.

Follow your District procedures for any additional requirements.

Responsibilities for government property in your custody are also outlined in the Staff Manual Guide 2280.5.

1.8.1 – Equipment Care and Calibration

First-line maintenance rests with you as the custodian of the items entrusted to you. Generally, common sense and handling the equipment as if it belonged to you, should suffice, such as in equipment that 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.

Needed repairs, defects, or inoperative equipment, 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.

You are responsible to assure equipment assigned to you is calibrated for accuracy prior to using in inspectional activities. This includes thermometers, pyrometers, balances, scales, stopwatches, etc.

Thermometers are used for evidence development during inspectional activities to enforce the Federal Food Drug and Cosmetic Act and other statutes in the specific OII programs. Refer to SOP-000735 Thermometer Maintenance Procedure, in the Quality Management Information System (QMiS), for details.

Stopwatches may be calibrated using the atomic clock at the U.S. Naval Observatory in Washington D.C., using the commercial numbers 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 are also available on the U.S. Naval Observatory's Website. For more detailed stopwatch/timing devices calibration instructions, see the National Institute of Standards and Technology (NIST) procedure SOP 24.

1.8.2 – Information Technology (IT) Devices/Equipment

FDA's IT Hub provides FDA employees with the latest IT news, updates, and informational resources about technology services, programs, systems, and applications used agency wide.

1.8.2.1 - FDA Information Systems Security and Privacy Guide

The guide documents FDA control parameters and consolidates and aligns FDA IT Security Policies with requirements and standards. This document is an addendum to the Staff Manual Guide 3251.12 and establishes comprehensive IT security and privacy requirements for the FDA IT security program and information systems.

1.8.2.2 – Frequently Asked Questions (FAQs)

Refer to this site to answer for information on telework, lost/stolen IT equipment, virtual meetings, etc.

1.8.2.3 - Mobile Devices Security Awareness

At FDA, a "Mobile Device" is an interactive mobile computing device, such as BlackBerry devices, laptops, and mobile phones with text capabilities. These devices can be used remotely and used both in and out of the Agency. If you have a mobile device for work or personal use, make sure to protect both the machine and the information it contains.

Examples of mobile devices include:

- Laptops, tablets, and iPads
- iPods and MP3 players
- Global Positioning System (GPS) satellite receivers
- BlackBerry devices
- Cell and smart phones
- PIV Card Readers
- Small (pocket-size) USB and FireWire (IEEE1394) hard drives
- USB flash drives (also known as thumb drives) and other removable memory devices (flash memory, SD cards)

Risks and Concerns with Mobile Devices:

- Mobile devices often have removable memory cards that create the potential for data leaks or loss.
- USB flash drives can be an immense source of data leakage. Thumb drives are easy to keep hidden because they are small. An employee with bad motives can easily slip one in and out of a facility, stealing Gigabytes of data.
- Centralized systems are not able to easily manage portable devices.
- Putting adequate safeguards in place to check what data is coming and going can be difficult.
- Mobile device breaches are often more difficult to detect than non-mobile breaches because users may not know about the loss for days or weeks.
- Social media applications and other applications can pull more information than intended. Personal information including your location, phone number, and address can be revealed. Be cautious and check the permissions of an application before it is installed.

Reporting an Incident: Report an incident to the FDA IT Security Operations Center if you suspect lost, misplaced, or stolen equipment (e.g., cell phones, laptops, badges, documents/paperwork, etc.) or if you believe there has been a Personally Identifiable Information (PII) Breach. Consult the FDA Reporting a Security Incident page for more information.

- Do NOT put FDA information on your personally owned mobile and portable devices.
- Keep an eye on your equipment at all times and report lost or stolen equipment by Reporting an Incident to the FDA Cybersecurity Operations Center immediately.
- Use FDA-approved mobile devices and media with encryption on FDA systems.
- Do not use personal flash drives or thumb drives in FDA equipment.
- FDA now offers a secure flash drive, called the IronKey.
- Do not place non-FDA-owned or authorized portable devices on FDA networks or sync to FDA PCs without prior written authorization from the FDA CISO. "It is against FDA Policy to connect any personal IT equipment (including laptops, printers, etc.) to the FDA network or to FDA equipment."

Only Agency approved mobile devices will be used with FDA data or the FDA network. All mobile devices shall be marked with appropriate FDA property tags.

Encryption is a process that transforms plain text or data using a mathematical formula/algorithm and a "key" making it unreadable to an outside party. Only those that have the "key" can decrypt

the data. The more extensive the key, the harder it is to solve the encryption. Encrypt all sensitive information including the following:

- FDA information or data that is accessed remotely
- Messages containing sensitive information that are sent outside of FDA's network

The following MUST be encrypted:

- Laptops or other mobile devices with sensitive information
- Equipment that is transported and/or stored offsite

1.8.2.4 - Risks of Connecting Personal Devices to the FDA Network

Any personal or contractor-owned device that is connected to the network that is not authorized or does not meet government security standards is not allowed. Many types of personal devices could contain a vulnerability that could put the network at risk. Follow FDA/HHS policies and the HHS Rules of Behavior to help protect the FDA network. If you believe you may have accidentally connected a device to the network and/or feel malware has infected your computer, contact ERIC immediately. Note that if your office purchases a USB drive or other device that is not on the Master Approved Technologies (MAT) list, you should not connect this device to the network. You can locate the MAT list of approved software, hardware and devices at Request-IT.

1.8.2.5 - Traveling outside of the US with Government Furnished Equipment

1.8.2.5.1 - Use of Government Furnished Equipment (GFE) During Foreign Travel

Note: Department of Health and Human Services (HHS) policy strictly prohibits the use of government furnished equipment (GFE) on personal foreign travel/unofficial travel to all countries.

Do not take government furnished equipment on personal foreign travel unless an exception has been granted as outlined below. Due to the cybersecurity and counterintelligence risks that such activity poses to FDA systems, networks, and sensitive data, unauthorized telework sessions will be disconnected, and the individual's account disabled to prevent access to FDA network resources.

HHS allows Operating Divisions to grant exceptions to this policy on a case-by-case basis when legitimate, mission critical business requirements exist. Based on this policy, any FDA employee, contractor, or individual who wants to take their FDA computer, phone, or storage device to a foreign country while on personal travel must obtain approval prior to departing the United States. To obtain approval, the individual must first coordinate with their supervisory chain. The responsible Division Director may then submit a request with the legitimate business justification to the foreign travel team at foreigntravelbriefings@fda.hhs.gov for review and consideration for approval.

This policy does **not** apply to HHS personnel participating in official foreign travel on behalf of the FDA.

Before you bring FDA technology assets on international travel on behalf of the FDA, remember:

- If you do not need a laptop or iPhone, do not take it.
- Do not leave IT equipment unattended.
- Do not connect unauthorized IT equipment to your laptop or iPhone (i.e., thumb drives, hard drives, etc.).

- USB thumb drives are prone to malware infections. Rewritable discs (i.e., CD-RW, DVD-RW) and IronKeys are an excellent substitute to thumb drives.
- Loaner laptops and iPhones issued solely for international travel should NEVER be connected to the FDA network upon return.
- Return all FDA loaner IT equipment the next business day upon arriving back to the office.
- Contact IT-FOREIGNTRAVELSECURITY@FDA.HHS.GOV for loaner equipment requests or questions.

Effective October 2017, all FDA Federal Employees and contractors traveling or planning to travel to China and its territories (i.e., Hong Kong) on official business must attend a counterintelligence awareness briefing prior to making travel arrangements. The U.S. Embassy will not approve an Electronic Country Clearance (eCC) until this requirement is met. This eCC represents official approval from the U.S. Embassy for U.S. government employees to enter the country. This briefing should be at the level of your security clearance (unclassified for Public Trust holders or classified for SECRET or TOP SECRET clearance holders). The briefing is good for one year.

Beginning April 2024, FDA has modernized Foreign Travel Security Operations and Support Services from manual email requests to ServiceNow to enhance customer service experience, improve equipment accountability, and ensure response timeliness.

To request foreign travel loaner equipment and/or counterintelligence awareness briefings in ServiceNow, please navigate to the Service Catalog, then choose Information Technology and select IT Security. Upon selecting one of these options, there will be a form to input travel information. The request will be sent to the Foreign Travel Security Operations and Support Services Team for action.

For any questions or further assistance, please contact the Foreign Travel Security Operations and Support Services Team at: IT-FOREIGNTRAVELSECURITY@FDA.HHS.GOV**.**

Remember that you have no expectation of online privacy in most countries. For that reason, you should be aware of the following items, whether you are traveling for business or pleasure.

- Expect that transmission of information is being intercepted and read at any location where networks are controlled by another government. Foreign network providers can disable mobile device encryption and then turn it back on after information is intercepted. How to protect the data: Do not process or transmit sensitive information. Do not take FDA or personal technology assets (laptop, iPhone, cell phone, etc.) if you do not need them or connect to the FDA network via the virtual private network (VPN) or access FDA email (i.e., webmail or Outlook). Click here to view the FDA Information Systems Security & Privacy Guide (SMG 3251.12a) Appendix U: Mobile Equipment for Overseas Travel to Designated Countries.
- When overseas, foreign communication networks can intercept wireless device signals. Assume that all forms of communication with wireless devices are monitored and subject to compromise. Hacker software can be used to locate and connect to vulnerable Bluetooth-enabled cell phones, allowing address book information, photos, calendars, and SIM card details to be downloaded. Unauthorized long-distance phone

calls could also be made using the hacked device. How to protect the data: Power off mobile devices when not in use and only use the Bluetooth function if absolutely necessary. (Do not use the Bluetooth function if traveling for business). Remove the battery from your mobile device and store it separately from the device.

- Anywhere facilities (i.e., hotel) are controlled by another government, you should expect tampering with unattended electronic devices. Hotel rooms and safes are accessible by hotel staff and possibly local authorities. How to protect the data: Avoid leaving electronic devices unattended in a hotel room. If that is not possible, remove the battery, and hard drive as accessible, and store separately from the device.
- Be aware that public Internet kiosks and cafes are breeding grounds for malicious software that can capture private information (passwords, bank account or credit card numbers, phone numbers, names, etc.). How to protect the data: Avoid connecting to public Wi-Fi hot spots and always use FDA provided systems and solutions using the Virtual Private Network (VPN) for remote access. Click here to view the FDA Information Systems Security & Privacy Guide (3251.12a) Appendix M: Remote Access.
- When passing through airport security, watch your laptop and other equipment until it enters airport scanners.
- Do not check a laptop with your baggage.

Immediately report any suspected tampering, unauthorized use, loss, or theft of any FDA asset to the SMC/Cybersecurity Operations at FDA_Systems_Management_Center@fda.hhs.gov or 855-533-2762 (24x7).

1.8.2.5.2 Foreign Travel FAQs

- Foreign Travel FAQs (pdf)

1.8.2.6 - Reporting an IT Security Incident

1.8.2.6.1 – Reporting IT Security Incident Checklist

- Reporting IT Security Incident Checklist (Exhibit 1-9)

1.8.2.6.1.1 Immediately contact

- Email: SMC@fda.hhs.gov
- Toll Free Number: 855-5FDA-SMC (855-533-2762)

1.8.2.7 - Employee Resource & Information Center (ERIC)

- Online: Submit your own ERIC ticket via the FDA Service Portal.
- By phone: 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742)
- By email: ITCallCenter@fda.hhs.gov for IT-related issues OR ERIC@fda.hhs.gov for all other issues.

1.9 – Official Identification

1.9.1 - Credentials/Badges

SMG 2280.3 provides instructions for the issuance and control of FDA Credentials and Badges including expiration, renewal, transfer, separation, and retirement. Contact your supervision and fda-ospocredentials@fda.hhs.gov for additional information and questions.

1.9.1.1 - Policy, Authority

Official credentials are for issuance to investigators and inspectors who are regularly engaged in investigational and inspectional activities; however, on occasion they may also be issued to other FDA personnel when it is necessary for these employees to engage in inspectional activities which would require credentials. By virtue of their position, credentialed employees are recognized as authorized to perform the duties assigned.

Badges may only be issued to holders of FDA credentials to facilitate performance of their duties when it is determined that the possession of a badge would be advantageous. **Investigator badges shall not be used in routine operations.** They shall be used only in those situations where display of a badge is essential for rapid identification to indicate authoritative presence to facilitate FDA operations. Division Staff Manual Guide, FDA 2280.3, 5b, outlines situations in which use of the badge may be appropriate.

FDA official credentials and badges shall be used for OFFICIAL business only. They shall not be used as a means of personal identification or for personal purposes. Show your credentials to appropriate firm personnel during all non-undercover investigations, inspections, sample collections, recall effectiveness checks, etc.

Precautions against photocopying your credentials: although firm management may examine your credentials and record the number and your name, do not permit your credentials to be photocopied. Federal Law (Title 18, U.S.C. 701) prohibits photographing, counterfeiting, or misuse of official credentials. Credentials must not be shown over video during remote activities, such as a remote regulatory assessment. Do not permit a firm to take your fingerprints. Contact your SCSO for more information as necessary.

To apply for official credentials, you must complete FDA 2115 and submit it to oiibadgesandcredentials@fda.hhs.gov for processing. Please see your Administrative Officer for additional information.

1.9.1.2 - Renewal/expiration

Though issuing officials will notify credential and badge holders no later than 30 days prior to the expiration date that their credentials/badge will expire, check your credentials periodically, prior to performance of duties, to ensure they are not expired.

1.9.1.3 - Care of Credentials, Badges

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. Do not carry them in the upper pockets of your clothing where they may fall out if you bend over. Carrying your credentials and badge in the glove compartment of your car or leaving them in the pocket of an unattended coat or jacket are invitations to loss or theft.

1.9.1.4 - Lost or Stolen Credentials, Badges

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

number of the credentials/badge can be entered into the National Crime Information Center (NCIC) system.

A written report containing the police report number and a statement that the local FBI field office was notified must be submitted to your supervisor and the issuing official. Replacement credentials will be issued at the discretion of the authorizing official.

1.9.2 - Personal Identity Verification (PIV) Card

The Personal Identity Verification (PIV) card is a multi-purpose card that includes a magnetic strip (for card access) and a barcode (for employee identification programs). The purpose of your PIV card is to ensure that only authorized personnel gain access to FDA facilities, to electronically sign documents and to logon certain government websites. The badges are encoded to limit an individual's access to designated security areas. PIV Card FAQs discusses PIV issues such as login, PIV pins, signing a document, remote networking, lost PIV and how to get PIV assistance.

1.10 - Business Cards

Business Cards are defined as cards of introduction bearing the name, address, phone number, fax number and e-mail address of active agency representatives. The distribution of business cards facilitates prompt and efficient communications by the persons and organizations with whom the Agency transacts business. The purpose of the business card is to further the Agency's statutory mission and therefore, the purchase constitutes a proper expenditure. 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.

Resources:

- Memorandum on Ordering Business Cards
- OII Visual Identity Resource Center

1.11 - Ethics and Integrity

The FDA ethics program is structured to provide advice and assistance to current and former employees to help ensure that decisions they make, and actions they take, are not, nor appear to be, tainted by any question of conflict of interest. The ethics laws and regulations were established to promote and strengthen the public's confidence in the integrity of the federal government. The FDA ethics program, including prohibited financial interests, political activity, laws and regulations, gifts, conduct and outside activities, is available publicly at FDA.gov and internally through the OII Ethics and Integrity SharePoint site.

1.11.1 - Expected Conduct

As you work to advance the health and welfare of the public, seek to maintain the highest standards of ethical conduct. You are responsible for complying with the regulations, obtaining advice from your supervisor, personnel, or local administrative staff, and when required, obtaining advanced approval for certain outside activities.

FDA employees must be persons of unrivalled integrity and observe the highest standards of conduct. Because of FDA's special regulatory responsibility, its personnel must carry on the agency's business

effectively, objectively, and without even the appearance of impropriety. Their actions must be unquestionable, and free of suspicion.

The Principles of Ethical Conduct were established by Executive Order 12674, modified by Executive Order 12731, as basic principles regarding the conduct of federal employees. It is important that federal employees observe these principles to promote confidence in the integrity of the federal government.

United States Code, Title 18 contains the criminal conflict of interest statutes applicable to employees in the executive branch of the government. Included in Title 18 is a prohibition against solicitation or receipt of bribes; a prohibition against acting as an agent or attorney before the government; post-employment restrictions; a prohibition against participating in matters affecting personal financial interest; and a prohibition against receiving supplementation of salary as compensation for government service.

Standards of Ethical Conduct for Employees of the Executive Branch

The Standards were developed by the Office of Government Ethics and set forth the basic obligation of public service. The standards contain regulations regarding matters such as conflicting financial interests, impartiality in performing official duties, and misuse of position.

HHS Supplemental Standards of Ethical Conduct

On February 3, 2005, The Department of Health and Human Services (HHS) amended the Supplemental Standards of Ethical Conduct (5 CFR 5501) and Supplemental Financial Disclosure Requirements section (5 CFR 5502), both effective on that date. On August 31, 2005, HHS published the Final Rule for both sections.

Department of Health and Human Services--Standards of Conduct

These regulations were superseded in 1992 by the Office of Government Ethics "Standards of Ethical Conduct for Employees of the Executive Branch." However, certain portions of the HHS Standards of Conduct remain applicable. This link contains the remaining relevant portions of 45 CFR Part 73.

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.

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 essential.

As a government official, your actions are under constant scrutiny. You must comply with the statutes and regulations listed above and epitomize integrity more broadly noting:

- Cameras/video/audio recording are everywhere.
- Integrity means doing the right thing even if no one is watching.
- In dealing with management and the public, your approach must be mature, dignified, authoritative and cordial.
- As a law enforcement officer, you must employ authority with discretion.
- Depend on tact, diplomacy, and persuasion to obtain the desired information.
- Be courteous and frank when calling attention to potentially violative practices and conditions.

- Be fair and responsive.
- Do not assume the role of a consultant.
- Do not be argumentative.
- Avoid replies that are likely to appear arbitrary or bureaucratic.
- Never recommend the products or services of a particular firm.
- Keep information obtained during inspections and investigations confidential.
- Avoid situations that may be or appear to be a conflict of interest.
- Your reports should be complete, concise, accurate and objective.
- Your personal habits must be above reproach.
- Look professional and effective in dress, grooming, and demeanor.
- Take pride in your work.
- Never use Government equipment/supplies for personal use.
- Never use public office for private gain.
- Never give preferential treatment to any person or organization.
- Never impede Government efficiency or economy.
- Maintain independence from outside influences and impartiality in performance of duties.
- Never make a government decision outside of official channels.
- Never undermine the confidence of the public in the integrity of the government.

1.11.2 - Gifts

Gifts are anything of monetary value (gratuity, favor, discount, entertainment, hospitality, loan, forbearance; includes services, training, transportation, local travel, lodging, meals). It DOES NOT include:

- Modest items of food and non-alcoholic refreshments such as soft drinks, coffee and donuts offered other than for a meal.
- Greeting cards and items of little intrinsic value, such as plaques, certificates, and trophies, meant primarily for presentation.
- Loans and discount opportunities from financial institutions that are available to the general public.
- Rewards and prizes given to competitors in contests or events, including random drawings open to the public, unless the employee's entry into the contest is required as part of his official duties (for example, attending a conference where attendees are all entered into a drawing).
- Anything for which the Government pays, e.g., items purchased with Government funds.
- Any gift accepted by the Government, e.g., sponsored travel.
- Anything for which the employee pays market value.
- Free attendance at an event provided by the sponsor of the event to an employee who is assigned to present information on behalf of the FDA, or an employee whose presence is deemed essential by the FDA to the presenting employee’s participation, on any day when the employee is presenting.

For additional information, visit the Ethics Topics: Gifts SharePoint site.

Notwithstanding any of the exceptions provided above, an employee shall not:

- Accept a gift in return for being influenced.

- Solicit or coerce the offering of a gift.
- 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.

1.11.2.1 - Gifts Between Federal Employees

In general, FDA employees may not:

- Give a gift to an official superior (an employee, including but not limited to an immediate supervisor, whose official responsibilities include directing or evaluating the performance of the employee's official duties or those of any other official superior of the employee). This includes making a contribution toward a gift.
- Solicit a contribution from another employee for a gift to an official superior of either employee.
- Accept a gift from subordinates in the employee's chain of command.
- Accept a gift from a lower-paid, non-subordinate employee, unless there is a personal relationship that justifies the gift.

1.11.2.2 - Gifts From Outside Sources

If an FDA employee solicits or accepts a gift from an outside source that does business with or seeks official action from the employee or the employee's agency (a "prohibited source"), the public may be concerned that the donor will receive favored treatment as a result of the gift. Even if a gift is from a person or organization that has no official dealings with the employee's agency, accepting a gift offered because of the employee's official position may create an appearance of using public office for private gain. FDA employees may not solicit or accept gifts from a "prohibited source" or given because of the employee's official position, unless an exception applies, or the item is excluded from the definition of a gift.

1.11.2.3 - Gifts From Foreign Governments or International Organizations

As a Federal Government employee, you may not accept gifts from foreign governments or international organizations except as permitted under the Foreign Gifts and Decorations Act (FGDA). The FGDA allows an employee to accept a gift with a market value of less than $480 from a foreign government or an international organization so long as the gift is intended as a souvenir or mark of courtesy. An international organization in this context refers to one which the US is not a member, such as the European Union (to clarify, a state-owned or operated company is NOT a foreign government for purposes of this statute). This statutory restriction extends to the spouse and dependents of the employee.

In the HHS General Administration Manual Chapter 20-25, Foreign Gifts and Decorations, the section on Gifts of Minimal Value states that, with specific exceptions, "an employee may not accept a gift of more than minimal value unless it appears that to refuse the gift would likely cause offense or embarrassment or otherwise adversely affect the foreign relations of the United States. If an employee accepts a tangible gift of more than minimal value, such a gift is deemed to have been accepted on behalf of the United States and, upon acceptance, becomes the property of the United States."

Procedures for appropriate disposition of such gifts are also included in the HHS Chapter. If you accept a gift from a foreign government or international organization on behalf of the U.S.

Government, you must immediately contact an Ethics Specialist at the Ethics Hotline (240) 402-1111 or email FDAEthics_Advice@fda.hhs.gov when you return to the office.

1.11.3 - Attempted Bribery

Bribery is the practice of offering or soliciting 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:

- Attempt to obtain a clarification of the offer (for example, ask questions like, "What is this for?").
- Do not accept or refuse the offer. Appear to vacillate and keep the door open for future contact.
- Calmly terminate the exchange.
- As soon as possible, prepare detailed notes concerning what transpired.
- Contact your supervisor as soon as possible. The Division should notify the Office of Criminal Investigations, Office of Internal Affairs immediately at Contact.OIA@fda.hhs.gov or 1-240-276-9393.

1.12 – Quality Management

Quality Management Information System (QMiS) is the repository for OIIs internal procedural documents and quality reports. Standard operating procedures, work instructions, templates, checklists, transmittal notifications, and reports are organized by component and document type.

1.13- OII Time Reporting

1.13.1 - eNSpect (also known as MARCS Field Client)

eNSpect is the first phase of the modernization of the FDA Field Accomplishments and Compliance Tracking System (FACTS) network. FACTS is still available and slowly over time more and more functionalities will move into eNSpect. Currently, eNSpect supports multiple roles, components and functions and can be used online or offline. The bulk of the Investigator's work is performed in the Field Client.

1.13.2 - Insight Time Reporting (ITR)

Insight Time Reporting (ITR) is an activity-based time reporting system that will enable OII to report the work we do and identify the resources we need before we need them.

1.13.3 - OII Activity Code Structure

Insight Time Reporting (ITR) activity code structure includes the activities and definitions that were specifically developed for OII. Refer to it when entering your time into the system.

1.13.4- Field Accomplishments and Compliance Tracking System (FACTS)

An agency-wide information system that provides automated support for the daily activities conducted by the FDA OII headquarters and field offices. FACTS provides a central data repository for workload management, sample collections, investigative operations, and compliance operations through inspections, reporting, and tracking.

Exhibits

1–1 Allowable Expenses Table

This Table lists allowable expense items and the requirements that must be met to assure reimbursement. Unless indicated, there are no special requirements for reimbursement. Please see your administrative staff or supervisor for additional information.

EXPENSE ITEM	Specific authorization or approval	Receipt	Justification on voucher for any amount
BAGGAGE 1. All fees pertaining to the first checked bag	Yes	Yes	
2. Additional charges relating to the second and subsequent bags may be reimbursed when the Agency determines those expenses are necessary and in the interest of the Government (See FTR 301-70.300)	Yes	Yes	Yes
3. Excess Baggage Charges for government property	Yes	Yes	Yes[1]
4. Service Charge for checking baggage by checking agent where such charges for checking baggage in baggage rooms, or station or air terminal	Yes	Yes	Yes
5. Storage Charges (e.g., when traveler stores baggage or equipment when such charges are result of official business.)	Yes	Yes	Yes[2]
6. Transfer Charges - when necessary for official travel (e.g., when changing between stations where free transportation is not issued by common carrier.) CAUTION: Where the traveler's plans are changed, he/she shall make sure that baggage has been checked beyond the point where he/she leaves the train is stopped or transferred. If baggage cannot be intercepted or transferred and is carried to original destination on unused portion of ticket, the traveler shall give full explanation of facts when submitting unused portion of ticket. Failure to do so will result in any excess cost being charged to traveler.	Yes	Yes	Yes
FEES OR TIPS 1. Tips – Allowable tips are 15% of the reimbursable fare.	Yes	Yes over $75	
2. Parking Fees - charges for parking automobiles	Yes	Yes > $75	
3. Porter - allowable only at transportation terminals for handling Government property carried by travelers. NOTE: Porter fees for personal property, briefcases, etc. are not allowed.			Yes[3]
4. Traveler Checks Money Orders Certified Checks Transaction Fees for use of Automated Teller Machines (ATMs) – Government contractor issued travel card	Yes Yes Yes Yes	Yes Yes Yes Yes	
Registration Fees – Attendance at local non-government sponsored meetings Payment of registration fee should be made via the Citibank government Purchase Card if the organization(s) will accept credit cards. Citibank Convenience Checks If the credit card cannot be used, and the organization accepts the	Yes	Yes	Yes

purchase order, HHS-99 or SF-182 the organization may bill FDA directly. Please see your Administrative Officer for additional information and guidance when requesting payment of registration fees.	Yes Yes Yes	Yes Yes Yes	Yes Yes
Exchange of Currency Allowed during foreign travel	Yes	Yes	
Fees for cashing U.S. Government checks or drafts reimbursing traveler for travel expenses only incurred in foreign countries. Commissions for conversion of currency in foreign countries 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.	Yes Yes Yes	Yes[4] Yes Yes	
7. Special Expenses for Foreign Travel - Passports, visa fees, costs of photographs for passports and visas, costs of certificates of birth, health, identity, and of affidavits, and charges for inoculations not obtainable through a federal dispensary	Yes	Yes	
HIRE OF ROOM Allowed when necessary to engage a room in a hotel or other place to transact official business	Yes	Yes	Yes[6]
2. Not allowed for personal use (cost included in subsistence allowance).			
PERSONAL SERVICES enographic and typing services, guides, interpreters, drivers of vehicles, etc.	Yes	Yes	Yes[5]
POSTAGE Postage necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	Yes	Yes	Yes[7]
POST OFFICE BOX RENTAL Where necessary for official airmail, foreign, or parcel post mail; and for official registered and special delivery mail.	Yes	Yes	Yes
PUBLIC TRANSPORTATION WHILE IN TRAVEL STATUS Public transportation fares are allowed from (or to) common carrier, or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business.	Yes	Yes (over $75)	Yes[8]
Public transportation fares between places where meals are taken, and places of business or places of lodging are not allowed, except where nature and location of work at temporary duty station is such that suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.			
TAXICABS WHEN USED LOCALLY WHILE IN TRAVEL STATUS Taxicabs are allowed from (or to) common carrier or other terminals, to (or from) place of abode or place of business and between place of abode and place of business, or between places of business where cheaper mode of transportation is not available or is impracticable to use.	Yes	Yes (over $75)	Yes[8]
Taxicabs are not allowed between places where meals are taken and places of business, except where nature and location of	Yes	Yes (over $75)	Yes[8]

suitable meals cannot be procured there - allowance will be made for transportation to the nearest available place for such meals.			
Limousine service plus taxicab tip rates between airport and limousine pick-up or discharge point	Yes	Yes (over $75)	
TELEPHONE CALLS / INTERNET CHARGES Official Business – Charges for local and long-distance calls are allowed when made on official business		Yes[9, 10]	
2. Personal Calls – Employee traveling overnight within CONUS may be reimbursed for one brief telephone call per day to her/his residence in accordance with government-wide rules and regulations. Reimbursement is limited to actual expenses, not to exceed $5.00 times the number of consecutive nights of travel on official business; applicable only when the employee is authorized to be on travel for one or more consecutive nights; and conditioned upon the unavailability of government-provided long distance telephone systems and services (including government-issued telephone calling cards) during each day of travel on which expenses are incurred.		Yes	
a. OCONUS Travel may be reimbursed only for telephone call(s) home from a foreign country which have been authorized prior to the beginning of travel and are shown on the travel authorization. Permitted frequency and cost must be stated on the travel authorization and adhered to by the employee.			
3. Internet Charges – (Federal and Departmental policy requires specific written or electronic authorization when the use of internet services is required for official business.)	Yes	Yes (over $75)	
RECORDS Charges for copies of records furnished by State officials, such as Clerks of Courts, etc., when necessary for performance of official business		Yes	Yes[5]
SHIPMENTS (FREIGHT OR EXPRESS) - see IOM 4.7.5		Yes	Yes[12]
MISCELLANEOUS EXPENSES Cash used in lieu of transportation request for passenger transportation and accommodations. Purchase of emergency supplies. Any other miscellaneous expenditure incurred by traveler in performance of official business, such as samples of drugs, cosmetics, etc., purchased by FDA inspectors and investigators.	Yes Yes Yes	Yes Yes Yes	Yes[5]
LAUNDRY EXPENSES Employees will be reimbursed for laundry, cleaning, and pressing expenses equal to the number of travel days multiplied by $5. For CONUS travel, employees must be on travel for four or more nights. Employees on OCONUS travel are not permitted to claim separate laundry expenses		Yes	

FOOTNOTES:

[1] Voucher must show weight of baggage and points between which moved.
[2] State that storage is solely on account of official business.
[3] State that porter fee was for handling Government property carried by traveler.
[4] Voucher shall show rate of conversion and commission charges.
[5] Voucher shall show date of service, quantity, unit, and unit price.
[6] In addition to information required in footnote #5, state necessity for hire of room.

[7] State that postage was used for official mail.
[8] State necessity for daily travel.
[9] For telegrams, faxes, cablegrams, and long-distance telephone calls, show points between which service was rendered, date, amount paid on each and "official business".
[10] For local telephone, calls show number of calls, rate per call, total amount expended each day, and "official business".
[11] When government Bill of Lading is not used, explain circumstances.
[12] Continental United States (CONUS) is defined as the 48 contiguous states and the District of Columbia.

1–2 FDA Furlough Shutdown FAQs

"What if I am on travel during a Lapse in Appropriations?"	If you are identified as a non-excepted employee who is to be placed in a furloughed status due to a lapse in appropriations while you are on TDY, you will need to arrange to return home within the next 24 hours or the first available flight. However, if your OpDiv/StaffDiv has identified you as an excepted employee, you may be eligible to stay in a TDY status. Please contact the TMC to make any necessary travel arrangements. Once Congress passes and the President signs a new appropriation or continuing resolution, accommodations for a return to TDY will be addressed on a case-by-case basis. HHS will only pay expenses for the time that it takes you to return to your official duty station. After that, you will be in a furloughed status and the agency will not pay for any additional expenses.
"Must agencies cover travel expenses during a furlough day, if an employee's travel status requires a stay that includes a furlough day?"	Yes, agencies must provide per diem or actual expenses to excepted employees whose travel status requires a stay that includes a furlough day. If you are identified as a non-excepted employee, you will need to arrange to return home with the next 24 hours or the first available flight. If excepted employees are authorized Per Diem (Lodging, Meals & Incidental Expenses) they are entitled to the full amount of Meals and Incidental Expenses or 75% on a travel day. If an excepted employee is on actual expenses, they can be placed on Actual Expenses for: up to 300% of Lodging, only up to 300% of M&IE, only up to 300% of both Lodging and M&IE. If an employee is on actual expenses, the employee is required to provide a receipt for all items, including meals. Without a valid receipt, the OpDiv/StaffDiv would not be responsible for reimbursement. It should be clearly stated that they are on actual expenses and that receipts are required for all expenses, even those that fall below the $75 threshold.
"Can I still use my Government Travel Card?"	The Government travel charge card may remain active during a lapse in appropriations, but only excepted employees should use them. You should contact the travel charge card vendor's customer service at the number on the back of the card should you experience problems with your card. In addition, you will not be able to submit your voucher until the Federal Government reopens for business. The Government will not reimburse you while there is a lapse in appropriations (more commonly referred to as a "shutdown"). As always, all charges on your government issued travel card are your responsibility.
"Can I stay at my TDY location while in a furloughed status?"	In general, the Department cannot obligate funds for TDY expenses or accept voluntary services in the absence of appropriations for non-excepted activities. By remaining on TDY, you are acting in an official capacity. Therefore, the general rule state above pertains: if you are

	identified as a non-excepted employee who is to be placed in a furloughed status due to a lapse in appropriations while you are on TDY, you will need to arrange to return home with the next 24 hours or the first available flight. If you are not an excepted employee that is currently on TDY, long term or not, and elect to stay at the TDY location, you need to be aware of the following: 1. Once you are furloughed you will no longer be covered under the Federal Employee's Compensation Act for workers compensation insurance; 2. You will not be reimbursed for per diem, including lodging, meals and incidental expenses (M&IE); you will be responsible for all costs incurred once you are in a furlough status; 3. If you are currently in long-term housing under a lease arrangement, your situation will be reviewed on a case-by-case basis, depending on when the next lease payment is due; and 4. During the furlough, no work is allowed to be performed as agencies may not permit voluntary performance of non- excepted services as covered in 31 U.S.C. 1342. a. These restrictions are enforced by criminal penalties. An officer or employee of the United States who knowingly and willfully violates the restrictions shall be fined not more than $5,000, imprisoned for not more than 2 years, or both. 31 U.S.C. 1350.
"Can I use the ETS?"	No, since you will not be on official Government travel, you cannot use the ETS; you will also not be able to: 1. Use the ETS to make travel authorizations or submit vouchers; 2. Use City Pair Fares for flights; 3. Use the Government Car Rental Agreement managed by the Defense Management Travel Office (DTMO); and 4. Use the FedRooms program; Hotels may choose to offer you a "government rate" but that is at the hotel's discretion.
"Can an employee use personal funds by travelers to complete the Agency's mission by attending an already planned conference?"	No. In attending a conference on behalf of the Department, you are acting in an official capacity. The Department cannot accept voluntary services in the absence of appropriations for non-excepted activities.
"Do relocation benefits stop during a Government shutdown?"	No, the monies for relocation come from already approved money and must be obligated up front for a relocation move, also referred to as a Permanent Change of Station (PCS). Each agency should have a plan in motion for those who may need assistance to include extensions to Temporary Quarters Subsistence Expenses (TQSE), etc.
"Do people who are in Temporary Quarters still receive benefits?"	As TQSE is reimbursed at the new PDS, there is no "old" PDS to recall the employee to. Since no permanent residence has been purchased yet, TQSE is the employee's only option. There is no case law that covers this issue; however, based upon the reasoning above, GSA legal is of the opinion that the expenses can still be incurred, particularly if the relocation monies have been obligated prior to beginning the move, but

	reimbursement cannot be made until the lapsed funds can be accessed again.
"Can the employee accept an offer during the shutdown period and therefore bind the government to the fee? Can contractors continue to order appraisals and inspections during the period the government has no money?"	First, there is no case law on this point. Thus, it is GSA legal' s contention that if the fair market value of the home was obligated when the contract with the Relocation Service Provider (RSP) was executed, and the amount is from a revolving fund or a fund that does not lapse under a furlough situation, then the offer can be accepted. However, if the fair market value of the home was not obligated, then there are no funds available to bind the Government, and the employee must wait until the applicable appropriation is passed to accept an offer. General rules regarding continuation of contractual arrangements should be followed. As for appraisals and inspections, these need to wait until the applicable appropriation is passed if the transactions are not covered by a revolving fund or a fund that does not lapse under a furlough situation.
"Can I proceed to start my enroute travel to an OCONUS foreign post during a government shut down?"	Per the State Department Regulation, staff policy office: "This is not to be treated any differently than a domestic move. All monies spent on relocation are monies already approved and pre obligated. In addition, the employee may present their credentials to the foreign country with no problems."
"What about other types of relocation allowances such as pre-departure, temporary quarters, and Household Goods (HHG)? Are these considered entitlements that should be obligated, and expenses incurred, or should these future relocation expenses be stopped and not obligated?"	If relocation has been approved and obligated prior to the shutdown, it may move forward. If it has not been approved and obligated prior to the shutdown, it cannot be started until after the budget is resolved. However, even if the funds have been obligated for a relocation, an agency should confirm with Human Resources if an employee should perform a House Hunting Trip (HHT) during the furloughed timeframe since an employee is normally in a "pay status" while on an HHT. It also applies for an enroute travel – they are in a pay status for the authorized number of days. Questions that may come in to play include "are the employees covered (insurance/disability) during those days if they travel and also furloughed." Check with your HR office for further guidance.

1–3 GSA Fleet Vehicle Packet

Maintenance and Accident Instructions:

GSA Fleet – Vehicle Assistance Centers Call 1 (866) 400-0411

Press 1 - Maintenance Control Center (MCC) – mechanical or tire problems
Press 2 - Accident Management Center (AMC) – accident body damage and glass
Press 3 - Fleet Service Card acceptance problem
Press 4 - Vendor with a payment problem

Fueling Instructions:

1. Using your Fleet Service Card, select Credit at the pump
2. Enter 6 Digit PIN
3. Enter odometer reading
4. Choose proper fuel. Use of mid-grade, premium or full-service fuel is prohibited.

These Require Prior MCC Approval

- Repairs over $100
- Replacement of:
  - Tires
  - Glass
  - Batteries



www.gsa.gov
March 2019
05-19-00532

Involved in an accident? See Accident Reporting Kit inside.

GSA

U.S. General Services Administration

GSA Fleet Vehicle Packet

Zone 1

Hartford, CT: (860) 240-3314
Baltimore, MD: (410) 406-2201
Hooksett, NH: (603) 666-7957
Buffalo, NY: (716) 551-4596
New York Metro Area: (732) 906-5605
Harrisburg, PA: (717) 770-4575
Philadelphia, PA: (215) 446-4832
Pittsburgh, PA: (412) 294-4001
San Juan, PR: (787) 749-4440
Franconia, VA: (703) 605-9350
Richmond, VA: (804) 279-6807
Chesapeake, VA: (757) 424-2389
Huntington, WV: (304) 529-5584

Zone 2

Alabama/Mississippi/
NW Florida: (850) 581-2036
Montgomery, AL: (334) 450-0796
Florida: (321) 213-6052
Georgia: (770) 435-7806
Fort Gordon, GA: (404) 215-8625
Chicago, IL: (630) 655-3464
Southern IL: (618) 622-5807
Indianapolis, IN: (312) 350-2286
Kentucky/Tennessee: (502) 909-3895
Livonia, MI: (313) 226-2391
Twin Cities, MN: (612) 725-4002
Jackson, MS: (601) 965-4192
North/South Carolina: (910) 436-2649
Camp Lejune, NC: (910) 451-2698
Cleveland, OH: (330) 342-0272
Dayton, OH: (937) 427-5639
Charleston, SC: (843) 727-4043
Fort Jackson, SC: (803) 751-7603
Nashville, TN: (615) 907-6208
Milwaukee, WI: (414) 769-5644

Zone 3

Little Rock, AR: (501) 324-5514
Denver, CO: (303) 236-7221
Baton Rouge, LA: (225) 757-7635
Kansas City, MO: (816) 823-3620
St. Louis, MO: (314) 263-3023
Helena, MT: (406) 449-5265
Bismarck, ND: (701) 250-4318
Albuquerque, NM: (505) 248-7347
Gallup, NM: (505) 863-9324
Los Alamos, NM: (505) 346-8601
Oklahoma City, OK: (405) 231-4436
Rapid City, SD: (605) 341-3842
El Paso, TX: (915) 772-1165
Houston, TX: (832) 397-8415
San Antonio, TX: (210) 306-2342
Dallas/Ft. Worth/
Ft. Hood, TX: (817) 850-8248
Utah: (801) 625-5020

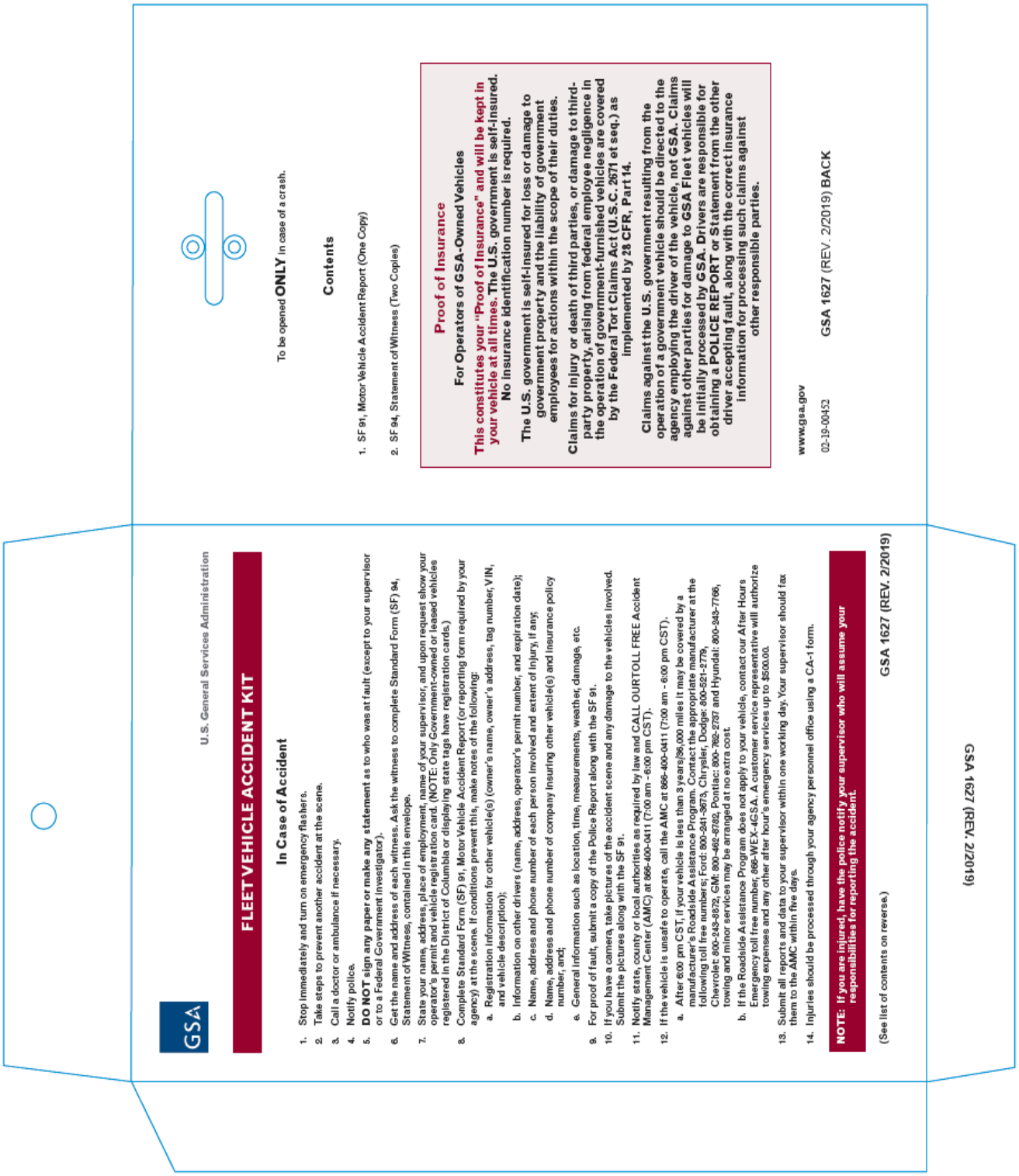
Zone 4: (415) 522-2858

Phoenix, AZ
Los Angeles, CA
San Diego, CA
San Francisco, CA
Honolulu, HI
Auburn, WA
Vancouver, WA

Visit www.gsa.gov/gsafleetfmcs for the most up to date contact information

Ask your FSR for information on the GSAFleet2Go App
Download the App on the Apple App Store or on Android's Google Play

1–4 Fleet Vehicle Accident Kit-GSA 1627



GSA

U.S. General Services Administration

FLEET VEHICLE ACCIDENT KIT

In Case of Accident

1. Stop immediately and turn on emergency flashers.
2. Take steps to prevent another accident at the scene.
3. Call a doctor or ambulance if necessary.
4. Notify police.
5. **DO NOT** sign any paper or make any statement as to who was at fault (except to your supervisor or to a Federal Government investigator).
6. Get the name and address of each witness. Ask the witness to complete Standard Form (SF) 94, Statement of Witness, contained in this envelope.
7. State your name, address, place of employment, name of your supervisor, and upon request show your operator's permit and vehicle registration card. (NOTE: Only Government-owned or leased vehicles registered in the District of Columbia or displaying state tags have registration cards.)
8. Complete Standard Form (SF) 91, Motor Vehicle Accident Report (or reporting form required by your agency) at the scene. If conditions prevent this, make notes of the following:
   a. Registration information for other vehicle(s) (owner's name, owner's address, tag number, VIN, and vehicle description);
   b. Information on other drivers (name, address, operator's permit number, and expiration date);
   c. Name, address and phone number of each person involved and extent of injury, if any;
   d. Name, address and phone number of company insuring other vehicle(s) and insurance policy number, and;
   e. General information such as location, time, measurements, weather, damage, etc.
9. For proof of fault, submit a copy of the Police Report along with the SF 91.
10. If you have a camera, take pictures of the accident scene and any damage to the vehicles involved. Submit the pictures along with the SF 91.
11. Notify state, county or local authorities as required by law and CALL OURTOLL FREE Accident Management Center (AMC) at 866-400-0411 (7:00 am - 6:00 pm CST).
12. If the vehicle is unsafe to operate, call the AMC at 866-400-0411 (7:00 am - 6:00 pm CST).
    a. After 6:00 pm CST, if your vehicle is less than 3 years/36,000 miles it may be covered by a manufacturer's Roadside Assistance Program. Contact the appropriate manufacturer at the following toll free numbers; Ford: 800-241-3673, Chrysler, Dodge: 800-521-2779, Chevrolet: 800-243-8872, GM: 800-462-8782, Pontiac: 800- 762-2737 and Hyundai: 800-943-7766, towing and minor services may be arranged at no extra cost.
    b. If the Roadside Assistance Program does not apply to your vehicle, contact our After Hours Emergency toll free number, 866-WEX-4GSA. A customer service representative will authorize towing expenses and any other after hour's emergency services up to $500.00.
13. Submit all reports and data to your supervisor within one working day. Your supervisor should fax them to the AMC within five days.
14. Injuries should be processed through your agency personnel office using a CA-1 form.

NOTE: If you are injured, have the police notify your supervisor who will assume your responsibilities for reporting the accident.

(See list of contents on reverse.)

GSA 1627 (REV. 2/2019)

To be opened **ONLY** in case of a crash.

Contents

1. SF 91, Motor Vehicle Accident Report (One Copy)
2. SF 94, Statement of Witness (Two Copies)

Proof of Insurance

For Operators of GSA-Owned Vehicles

This constitutes your "Proof of Insurance" and will be kept in your vehicle at all times. The U.S. government is self-insured. No insurance identification number is required.

The U.S. government is self-insured for loss or damage to government property and the liability of government employees for actions within the scope of their duties.

Claims for injury or death of third parties, or damage to third-party property, arising from federal employee negligence in the operation of government-furnished vehicles are covered by the Federal Tort Claims Act (U.S.C. 2671 et seq.) as implemented by 28 CFR, Part 14.

Claims against the U.S. government resulting from the operation of a government vehicle should be directed to the agency employing the driver of the vehicle, not GSA. Claims against other parties for damage to GSA Fleet vehicles will be initially processed by GSA. Drivers are responsible for obtaining a POLICE REPORT or Statement from the other driver accepting fault, along with the correct insurance information for processing such claims against other responsible parties.

www.gsa.gov

02-19-00452 GSA 1627 (REV. 2/2019) BACK

GSA 1627 (REV. 2/2019)

1–5 Example Email Communication to Claimant Regarding Form SF95 Submission



Return Address

Date of Communication

Address of Recipient

Good Day,

Per our conversation, attached is a copy of the **SF-95 form**. This form is used to file a claim against the government for damage, injury, or death. As a result of the incident that occurred on XX/XX/XXXX, I am required to notify you of your right to file, if you should desire. If you chose to file a claim, complete the form, and please return the completed form to me via email for initial review and submission to the FDA Claims Liaison.

If you need additional information, please let me know.

Space for signature

Name and title of communication author

1–6 Fleet Vehicle Assistance Card



U.S. General Services Administration

GSA Fleet Vehicle Assistance Centers

Call 1 (866) 400-0411

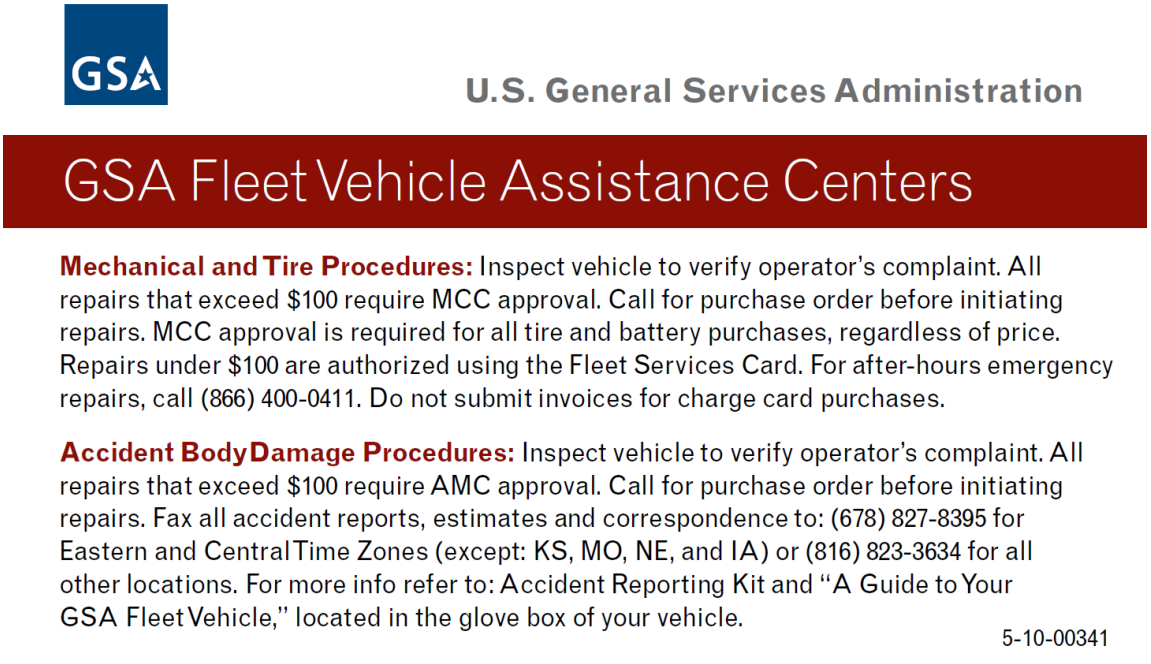
Press 1 – Maintenance Control Center (MCC)– mechanical and tire problems

Press 2 – Accident Management Center (AMC)– accident body damage

Press 3 – Fleet Service Card acceptance problem

Press 4 – Vendor with a payment problem

(3/10) (over)



U.S. General Services Administration

GSA Fleet Vehicle Assistance Centers

Mechanical and Tire Procedures: Inspect vehicle to verify operator's complaint. All repairs that exceed $100 require MCC approval. Call for purchase order before initiating repairs. MCC approval is required for all tire and battery purchases, regardless of price. Repairs under $100 are authorized using the Fleet Services Card. For after-hours emergency repairs, call (866) 400-0411. Do not submit invoices for charge card purchases.

Accident Body Damage Procedures: Inspect vehicle to verify operator's complaint. All repairs that exceed $100 require AMC approval. Call for purchase order before initiating repairs. Fax all accident reports, estimates and correspondence to: (678) 827-8395 for Eastern and Central Time Zones (except: KS, MO, NE, and IA) or (816) 823-3634 for all other locations. For more info refer to: Accident Reporting Kit and "A Guide to Your GSA Fleet Vehicle," located in the glove box of your vehicle.

5-10-00341

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1–7 OII Mobile Media Support



OII MOBILE MEDIA SUPPORT

- Thank them for their interest!
- State that you would be more than happy to speak with them, but you need to refer them to the OII Press Team
- Email address: OIIPress@fda.hhs.gov
- DO send a "Heads Up" email with the reporters **name, organization, nature of their inquiry & location of contact** to OIIpress@fda.hhs.gov
- DON'T say, "No Comment"
- DO refer them OIIpress@fda.hhs.gov
- REMINDER: not sure what to do re: a press or media inquiry? Contact OOIIPress@fda.hhs.gov

1–8 Media Tip Card



Office of Inspections and Investigations / OII

CAN WE TALK? A Guide to Dealing with the Media

FDA

The Division of Organizational Communication and Engagement is here to assist you!

WHEN YOU ARE CONTACTED BY A REPORTER....

By phone or email:
forward the message to OIIPress@fda.hhs.gov.

At a conference or speaking event:
Provide them with OIIPress@fda.hhs.gov for follow-up.

- We will work with the reporter to find out the deadline and focus of the request.
- When an interview is requested, we will coordinate with you and the Office of Media Affairs to set up the terms and scope of the interview.
- We will help prepare you for the interview by identifying key points you want to make during the interview and secure all required clearances.

NOTE: Never tell a reporter you have to obtain clearance first.

Suggested Response:
Let me get your contact information, your topic or questions, and deadline. I will have a member of the OII Press Team follow-up with you to schedule time for us to talk.

WHEN YOU TAKE AN ACTION THAT MAY ATTRACT MEDIA ATTENTION

(e.g., establish guidance, exercise an enforcement)...

- We will work with you to determine whether a press announcement is appropriate and feasible.
- Please contact us as early as possible via email to OIIPress@fda.hhs.gov.

SOME HELPFUL TIPS

Before the interview

- Decide on the **3 or 4 most important aspects** of the action or topic and **make them the focus** of your comments.
- **Make your message concise** and easy to understand.
- **Use data or analogies**, when appropriate.

During the interview

- **Place** your topline messages and supporting points in front of you.
- If you are being filmed while seated, **sit up straight and lean slightly forward**. Avoid wearing white or clothing with busy prints or oversized jewelry that might distract the viewer.

Do's and Don'ts during the interview

- **DO** restate your primary message in several different ways during the interview. End with your most important point.
- **DO** mention our website www.fda.gov. Newspapers and other media organizations are increasingly interested in using graphics and referring readers to online content.
- **DO** take a moment if you feel you need time to think.
- **DO** redirect the conversation with a positive response if a reporter poses a question with a negative slant. For example, use phrases like: "On the contrary..." or "Not so; we strive..."
- **DO** avoid using jargon and acronyms. For example, refer to the "Office of Inspections and Investigations," not "OII."
- **DON'T** say "no comment." If you don't know or can't provide an answer, explain why. Direct the reporter back to OII Press for help in providing follow-up information or resources.
- **DON'T** speculate if a reporter asks "What if...?" questions. One possible response is something like, "More work is needed within the scope of the FDA's mission."

Developed by OII/Office of Inspections and Investigations
Division of Organizational Communication and Engagement - 12/2024

1–9 Reporting IT Security Incident Checklist

Please include the following pieces of information, so that we can quickly and efficiently respond:

Customer Information:

- Your full name
- Your FDA email address
- Your best immediate phone number contact
- A brief explanation of the circumstances
- When did the incident occur (Date, Time)?
- Location of the incident
- What country were/are you in?

Device Information:

- Type of device stolen (e.g., Laptop/Desktop/Iron Key/Storage Drive/RSA Token/Blackberry)
- FDA Asset Tag or Serial#
- Brand/Series/Model
- Encryption Type
- Sensitive Information or PII

Important:

- To request new equipment click here. The FDA SMC does not handle "IT Acquisition" requests.
- Please notify your center Property Custodial Officer (PCO) and/or Accountable Property Officer (APO) of this theft as soon as possible for a replacement. You can determine your center's PCO/APO by searching on http://inside.fda.gov.
- To learn how to report a suspected PII loss, click here.

Note: Security personnel will receive your email and respond to you immediately. **DO NOT** try to handle the security incident yourself; wait for a member of the security team to contact you and direct you.

Tips for Protecting FDA Equipment and Information:

- Lock your equipment at all times and do not leave your equipment unattended when outside of FDA facilities *(e.g., car, metro)*.
- Be alert and aware of your work environment. If you notice unknown individuals not wearing a badge, offer to escort them or report it to the FDA Security Command Center at (301) 796-2409.