

# US Department of Health and Human Services

## Privacy Impact Assessment

**Date Signed:**

09/12/2016

**OPDIV:**

FDA

**Name:**

Administrative Applications: Office of International Programs Travel Applications

**PIA Unique Identifier:**

P-5307295-012433

**The subject of this PIA is which of the following?**

Minor Application (child)

**Identify the Enterprise Performance Lifecycle Phase of the system.**

Operations and Maintenance

**Is this a FISMA-Reportable system?**

Yes

**Does the system include a Website or online application available to and for the use of the general public?**

No

**Identify the operator.**

Agency

**Is this a new or existing system?**

New

**Does the system have Security Authorization (SA)?**

Yes

**Indicate the following reason(s) for updating this PIA.****Describe the purpose of the system.**

FDA previously prepared a single Privacy Impact Assessment (PIA) for the Agency's Administrative Applications system (AdminApps or "the system"). To address privacy issues in a more detailed way, FDA is now assessing the applications in multiple PIAs. This is one such PIA. Each PIA addresses a specific set of applications. They are grouped together on the bases of similarity in data handled, the function and purpose of the application and data use, disclosure practices, and the legal authorities supporting the collection of PII.

This PIA addresses an application within the overarching AdminApps system. This application is operated by FDA's Office of International Programs (OIP), which works with representatives of the various program components and international health and regulatory partners on health and regulatory issues, exchanges of public and non-public information and documents, technical cooperation and training, personnel exchanges, and certification of certain products exported to and from the United States. The Federal Food, Drug and Cosmetic Act requires FDA to work with with foreign regulatory authorities to reduce regulatory burdens, harmonize regulatory requirements, and establish appropriate reciprocal arrangements.

The application is OIP International Travel Management, which tracks the international travel, government passports, and travel document requirements for all travel managed by FDA. It permits OIP staff to administer government-issued passports for FDA personnel to whom they are issued. Employees have the ability to submit their travel request and apply for a new or renewal of a government passport through application. This is available to all FDA staff with access to the FDA Intranet.

FDA may modify this PIA in the future if OIP develops or activates additional applications that can be addressed in this document.

**Describe the type of information the system will collect, maintain (store), or share.**

OIP International Travel Management contains PII including name and contact information, including both work and home e-mail addresses, mailing addresses, and phone numbers. Other information includes dates and destinations of past and future travel, military and employment status, Social Security number (SSN), date of birth (DOB), travel documentation (passports, the "Notice of Foreign Travel") and compliance status, records of communications concerning planned travel, passport information, and funding information.

Retrieval from the application is by individual employees' names and by passport number.

This application does not require FDA users or system owners to have application-specific logon credentials. Instead, it uses a single-sign on scheme.

**Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.**

Employees that are scheduled to conduct international travel are required to submit several forms in advance of their travel. International Travel Management is used to track the submission, approval, and issuance of various documents, including:

An international passport. Employees that apply for and receive government passports apply for them through the Department of State, and then these are sent to OIP. OIP then provides them to staff when they travel internationally for FDA business, and then must return them to FDA when they return to the United States. The tracking application is used to record dates international passports are received; issued to staff; and returned.

A Notification of Foreign Travel (NFT). Staff are required to submit an NFT form to OIP in advance of international travel (no less than 37 calendar days in advance and in some cases several weeks longer). This form contains information identifying the traveller, the intended destination(s), the purpose of travel, and the dates travelled. Approval must be provided by the Director of the International Operations Branch (IOB) prior to travel.

A Country Clearance Cable. This is an official document from the destination country confirming the destination country will permit travel for the specified purpose to the appropriate person. It is required for some foreign destinations.

Evidence of completion of a security briefing, required for all international travel.

Receipt of a visa to enter the country if required.

Information about employees is populated from the Enterprise Administrative Support Environment (EASE) application, another AdminApps application, discussed in a separate PIA that is also available for review. EASE holds essential personnel, organization, and locator information. EASE receives electronic updates nightly from the HHS Employee Human Resource Program system (EHRP) with official data on all active FDA civilian personnel and receives similar updates nightly from the Commissioned Corps personnel system.

The primary key between EHRP, the Commissioned Corps system and EASE is the SSN. This data flows one way; EASE does not send data to the EHRP or the Commissioned Corps system.

**Does the system collect, maintain, use or share PII?**

Yes

**Indicate the type of PII that the system will collect or maintain.**

Social Security Number

Date of Birth

Name

E-Mail Address

Mailing Address

Phone Numbers

Certificates

Military Status

Employment Status

Foreign Activities

Passport Number

Dates of travel

Passport issuance dates

Travel related documents: the Notice of Foreign Travel and a foreign visa if required

**Indicate the categories of individuals about whom PII is collected, maintained or shared.**

Employees

Vendor/Suppliers/Contractors

"Contractors" is selected because it is possible that some developers will be direct contractors.

**How many individuals' PII is in the system?**

500-4,999

**For what primary purpose is the PII used?**

PII is used to coordinate international travel for staff required to visit foreign countries in order to execute FDA missions. Activities abroad may include inspection of manufacturing or exporting facilities, execution of memoranda of understanding, communication or technical assistance to foreign producers or manufacturers, and receiving training or education.

**Describe the secondary uses for which the PII will be used.**

None

**Describe the function of the SSN.**

Social Security number of agency personnel is used consistently with Executive Order 3397 to accurately process new personnel, for purposes of the single sign-on process for a time and attendance system, to reconcile personnel data incorporated from other HHS systems, and to administer security clearances and provide government passports to personnel.

**Cite the legal authority to use the SSN.**

Executive Order 3397

**Identify legal authorities governing information use and disclosure specific to the system and program.**

International Travel Management is operated in order to comply with FDA missions that require foreign travel to inspect many kinds of facilities, including food-related facilities, drug manufacturing facilities, and manufacturers of radiation-emitting electronic devices. For example, provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371 et seq) at section 384c(a)(2) (Inspection of foreign food facilities) require the Secretary of HHS to "direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States." Similar provisions exist for foreign manufacturers of drugs (see, e.g., 21 U.S.C. 360(i), requiring registration for "(e)very person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States...." and "

The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment..., if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 381 (a) of this title.") Similar provisions exist for radiation emitting electronic products (FFDCA, Subchapter C - Electronic Product Radiation Control), other devices, veterinary drugs, and biologics.

Further, the Food Safety Modernization Act (See 21 USC 421(a)(2)(D)) states that "In the 1-year period following the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall inspect not fewer than 600 foreign facilities."

**Are records on the system retrieved by one or more PII data elements?**

Yes

**Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.**

SORN 09-90-0018, Personnel Records in Operating Offices

**Identify the sources of PII in the system.**

**Directly from an individual about whom the information pertains**

In-Person

Email

Other

**Government Sources**

Within OpDiv

Other HHS OpDiv

Foreign

Other Federal Entities

**Identify the OMB information collection approval number and expiration date**

The POC is in the process of coordinating with Records Management Staff to determine if an information collection approval number is necessary.

**Is the PII shared with other organizations?**

Yes

**Identify with whom the PII is shared or disclosed and for what purpose.**

**Other Federal Agencies**

Coordinated with Department of State to receive government passport, agreements with foreign governments and US Embassies abroad to authorize travel, etc.

**State or Local Agencies**

Foreign government for the purpose of seeking approval for foreign travel

**Describe any agreements in place that authorizes the information sharing or disclosure.**

Disclosures from these systems are made for the purposes of planning travel and require communication with many bureaus and offices, including some that are overseas. While all transactions are conducted consistently with relevant laws and guidance, communications are too numerous and distinct to capture in a standing contract or agreement.

**Describe the procedures for accounting for disclosures.**

Disclosures from these applications are unlikely to be made. If Privacy Act records are disclosed, the disclosing office would be required to maintain an accounting. If necessary, the Privacy Office will provide OIP with guidance on how to create and update a document that will contain all the required elements of an accounting of disclosures as set out in the Privacy Act of 1974 at 5 United States Code (U.S.C.) 552a(c).

**Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.**

Individuals submit most of the PII used in this application themselves at the time of collection as part of the hiring and onboarding process. Data subjects are notified at the time of collection about the reason their PII is being collected and what will be done with it; data subjects are employees and understand that the FDA as their employer will need their PII in order to pay them, assign duties, provide benefits, and provide them with supplies, and specifically in the case of these systems, arrange for and plan their travel. Individuals whose PII is contained in this application communicate it to application users through e-mail, phone, and other media, but do not submit that PII directly into this system. Use of their PII is evident to them because it is used in the course of their ongoing work-related activities.

**Is the submission of PII by individuals voluntary or mandatory?**

Voluntary

**Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.**

Employment at the FDA is voluntary, but employees that are required to travel to foreign countries as part of their duties must supply PII pursuant to federal law and agreements with foreign governments.

**Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.**

If the agency changes the collection, use, or sharing of PII data in this application, the affected individuals will be notified by the most efficient and effective means available and appropriate to the specific change(s), to include a notice on the web site, or e-mail notice to the individuals. However, no such changes that would affect the rights or interests of the individuals are anticipated.

**Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.**

Individuals who are the subject of records in this application may exercise the rights available to them under the Privacy Act. The Privacy Act permits information subjects whose records are retained in systems of records may request notification of the existence of, access to, and amendment of records about themselves.

Individuals have many other avenues available to address these concerns. They may for example work through their supervisors, human resources officials, the FDA Privacy Office, information system security officers, the information system owner, the Computer Security Incident Response Team, or the employee help line to address any concerns about inaccuracies or incidents. Any changes to an individual's name or address would need to be updated using a Standard Form 50 or 52, just as would be the case with other FDA employees, and the data would be updated in HHS's human resources information system.

**Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.**

Basic employee information (contact and identifying information) is provided by EASE. EASE receives electronic updates nightly from HHS' Enterprise Human Resource Processing system (EHRP) with official data on all active FDA civilian personnel and receives similar updates nightly from the Commissioned Corps personnel system. This nightly update ensures that all employee information has as much integrity and accuracy as possible (as updates include information on any new employees and any updates or corrections). Availability is protected by the security controls as described in this document. Relevancy is determined by collecting only such information as is needed to conduct the business practice of planning travel for FDA employees, and is periodically reconsidered as part of application updates and refinements.

For all PII, availability is protected by security controls selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined to be appropriate based on risk level using Federal Information Processing Standard (FIPS) 199.

**Identify who will have access to the PII in the system and the reason why they require access.**

**Users:**

Users are FDA staff who use the PII to perform administrative tasks, not the data subjects. Users require full access to this application in order to conduct activities. Data subjects can request passports via the application but have no access to the information retained in the application

**Administrators:**

There are three users with the Office of Information Management that have full administrative access to conduct management and oversight of the application.

**Developers:**

Developers will not normally have access to PII, but may in the course of maintaining the systems or providing technical assistance.

**Contractors:**

Some developers may be direct contractors and will have access under the same circumstances as developers.

**Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.**

Users who require access to the application need to have supervisor approval and sign off before access is granted. The user's supervisor will use an account creation form to specify the minimum application access that is required in order for the user to complete his/her job. The agency reviews the access list for the application on a quarterly basis to review and adjust users' access permissions, and to remove unnecessary accounts from the application.

**Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.**

Management establishes roles for individual personnel, with role-based restrictions permitting access only to information that is required for each individual to perform his/her job.

**Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.**

All personnel/users are required to complete FDA's IT Security and Privacy Awareness training at least annually.

**Describe training system users receive (above and beyond general security and privacy awareness training).**

A user manual is available that walks the user through each step and functionality of each application. Also, all users are instructed on adhering to the HHS Rules of Behavior in the context of their work involving this application. For additional privacy guidance, personnel may contact the agency's privacy office. Privacy program materials are provided to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.

**Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?**

Yes

**Describe the process and guidelines in place with regard to the retention and destruction of PII.**

All records from this application is retained under FDA File Code 9371c, Issuing office copies of transportation related records, which includes "travel authorizations and supporting documents." Records are retained for six years after the period of the account. NARA citation is General Records Schedule 9-1c.

**Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.**

Administrative Safeguards include training and awareness provided for all users; system manuals that advise on the proper use of the applications; implementation of Need to Know and minimum necessary principles when awarding access, and others. The application resides behind the FDA firewall. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls. More broadly, appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.