

US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/29/2016

OPDIV:

FDA

Name:

Field Accomplishments and Compliance Tracking System

PIA Unique Identifier:

P-9056673-042526

The subject of this PIA is which of the following?

Major Application

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

No

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?

Existing

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

PIA Validation

Other...

Describe in further detail any changes to the system that have occurred since the last PIA.

The Field Accomplishment and Compliance Tracking System (FACTS) and Electronic States Access to FACTS (eSAF) went through minor Operations & Maintenance changes.

Additionally, eSAF was modified to synchronize with Recall Audit Check (RAC). The modification enables eSAF not only to search records in RAC concerning FDA-required recalls of products, but also to run reports on the status of recalls to offices within the FDA.

The databases supporting both FACTS and eSAF have been migrated from Oracle 10g to 11g, and the FACTS database has been migrated to the Oracle Exadata server platform.

The Oracle forms that provide the user interface for FACTS were migrated to the Oracle WebLogic 11g Exalogic server platform, and the eSAF Java application was migrated to the Oracle WebLogic 11g server platform.

Describe the purpose of the system.

The Field Accomplishments & Compliance Tracking System (FACTS) is a comprehensive, agency-wide, mission-critical information system that provides automated support for the daily activities conducted by the FDA Office of Regulatory Affairs (ORA) headquarters and field offices. As a nationwide, online, interactive system, FACTS assists ORA in conducting inspections of regulated products and facilities, reporting on its activities, and tracking progress. FACTS supports all FDA field operations. It produces reports and analyses of current and past field work assignments and results. It also provides information about levels of effort and costs.

FACTS is a central data repository and is used to: keep records about activities related to managing reviews of product applications from manufacturers and producers of regulated products; communicate with federal and state partners; manage the workload of ORA employees; conduct investigative, compliance, and analytical operations; and perform quality assurance.

The Electronic States Access to FACTS (eSAF) is an element of FACTS with an online application that allows FDA to automate the issuance of work requests to inspectors who are state employees and who execute duties under contract agreement with the FDA. eSAF allows state inspectors to enter and update inspection results and to provide "recall audit check" information, i.e., reports on the status of recalls of products. Additionally, eSAF provides state inspectors access to limited data about facilities, businesses, and other institutions maintained in FACTS. This enables states to assess information about past inspections and violations to identify high-risk institutions within their jurisdictions.

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

The FACTS system contains data about: commercial firms and products regulated by FDA; FDA actions and determinations such as inspections and product recalls; and, FDA employees, state inspectors working as direct contractors with FDA, and firm points of contact and consumers associated with these activities. The type of data collected includes firm addresses, points of contact, functions, activities, reports filed with FDA, FDA's investigatory findings about firms and their business relationships, FDA decisions concerning inspections and investigations, firm procedures, compliance and enforcement activities related to a firm, a firm's regulated products, and consumer complaints related to regulated products.

The eSAF element of the system contains data about state inspections (food and feed) as well as information needed to generate recall audit checks (reports and evaluations about efforts to recall products). eSAF also contains information regarding state inspectors as well as regulated entity points of contact (individuals).

FDA uses the data collected in FACTS and eSAF to review current and past fieldwork assignments, results, and the times and costs to accomplish assignments related to regulation, product safety surveillance, and compliance. The FACTS database is also used to provide information about FDA's performance as a Federal agency to Congress and the Office of Management and Budget (OMB). FDA action and performance information extracted from FACTS includes metrics such as the number of inspections performed and product-related consumer complaints received.

FDA employees and direct contractors (system users) request a user account for the FACTS system and in the course of doing so provide their name and work contact information.

The only individuals who can access the FACTS system are FDA employees and direct contractors who have been approved as FACTS users. Once approved, FACTS users access the system using an assigned username and a temporary password provided to them via e-mail.

Users reset their temporary password to a password of their choosing that meets complexity standards.

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

The information in FACTS about FDA employees and direct contractors (state inspectors) consists of full name, initials, work phone number, work fax number, work e-mail address, nickname, FDA district (e.g., for field offices), work address (city, state, and building), username, password, and the FDA internal employee number (used for identification in the Enterprise Administrative Support Environment (EASE) a system with its own Privacy Impact Assessment (PIA).

The information in FACTS about firm points of contact consists of work contact information including name, title, type of consignee (type of organization or individual with a responsibility for the regulated product, e.g., distributor), and telephone number.

Additionally, eSAF collects the name and work contact information of the recall consignee entity points of contact, and information from the consignee regarding injuries and complaint information associated with the product recall, as captured via FDA Form 3177 Recall Audit Check Report, this is a form that is internal to FDA and is completed/used only by FDA personnel or direct contractors.

FACTS may contain PII information provided voluntarily by members of the public filing consumer complaints via phone or e-mail to the FDA Consumer Complaint Coordinator, and as pulled from adverse event reports stored in other FDA systems. Consumer PII and product complaint information is entered directly into the FACTS system by an authorized FACTS user or FACTS database administrator. Information collected about consumers typically does not include name; FDA discourages the consumer submission of unnecessary PII, but they nevertheless may choose to include name, address, phone number, or other contact information. Consumers are normally identified by initials which are provided with a description of relevant health information (e.g., adverse effect caused by a product used by the consumer).

FDA retrieves eSAF and FACTS records using the name of a regulated product or the name of a regulated entity. FDA does not use names of individuals or other PII to retrieve records in the system.

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

Yes

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

Date of Birth

Name

E-Mail Address

Mailing Address

Phone Numbers

Medical Notes

Device Identifiers

Information about users includes username and password, as well as work contact information

Other PII that a consumer chooses to include when submitting a complaint regarding an FDA-regulated product.

Consumer submitting product complaints may choose to include age or date of birth, sex, weight, and ethnicity or race.

Information from adverse event and product problem reports stored in other FDA systems includes information about relevant products and devices, and, related adverse events, including health outcomes and relevant dates.

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

Employees

Public Citizens

Business Partner/Contacts (Federal/state/local agencies)

Employees includes permanent FDA employees and direct contractors. Public Citizens refers to firm points of contact and consumers. Business Partners is a reference to state inspectors who perform FDA work as direct contractors.

How many individuals' PII is in the system?

100,000-999,999

For what primary purpose is the PII used?

The FDA uses the PII in FACTS to: manage the process of reviewing applications for FDA approval of drugs, devices, cosmetics, and other FDA-approved items; manage federal/state partnerships; manage workloads; conduct investigations and compliance reviews; and to contact individuals employed by regulated businesses and organizations.

FDA uses the PII in eSAF to communicate with state inspectors (under FDA contract). FDA provides work requests to state inspectors, and state inspectors report inspection results and recall audit check information to the FDA.

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

FDA information extracted from FACTS may include metrics about the number of inspections performed, consumer complaints received, recalls audited, and other similar agency performance information. This information may include limited PII in FACTS about employees and direct contractors.

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

The Federal Food, Drug and Cosmetic Act (21 U.S.C. 301); see e.g., sections 415, 510 and 905, requiring registration of producers and suppliers of regulated substances.

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

No

Not applicable.

Identify the sources of PII in the system.

Government Sources

Within OpDiv

State/Local/Tribal

Identify the OMB information collection approval number and expiration date

Information collected under OMB approval is not submitted directly to FACTS. This includes adverse event reports stored in other FDA systems as submitted to FDA from external sources using FDA forms 3500/3500A under OMB approval No. 0910-0291, expiring September 30, 2018.

Is the PII shared with other organizations?

Yes

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

Within HHS

To manage work and respond to reported problems, PII in FACTS is shared internally with other FDA systems. FACTS provides consumer complaint data to FDA's Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting system (CAERS) and provides inspection assignment data to the FDA's Turbo Establishment Inspection Report (TurboEIR) system. These are restricted access internal systems and are the subject of separate assessments.

State or Local Agencies

State and local agency inspectors (direct contract employees) with access to eSAF may view inspections data that includes PII such as consignee contact information and the consignee's input on injuries/complaints associated with the product under FDA recall.

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

There are existing FDA Interconnection Security Agreements (ISA) between FDA's ORA and other FDA Centers/Organizations regarding the exchange of data via secured interfaces between their systems and FACTS, and contracts with state authorities using the electronic state access to FACTS tool (eSAF).

Describe the procedures for accounting for disclosures.

Not applicable. Information is not retrieved using a name or a unique individual identifier, FACTS and eSAF are not Privacy Act systems of records and are not subject to subsection (c) of the Act requiring certain accountings of disclosures.

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

At the time of hire, FDA personnel are given notice on forms, web pages and in orientation and consent to FDA's use of their professional information in relation to their work as a federal/FDA employee.

Contracts with states using FACTS/eSAF specify that states must share inspections data with FDA and provide state inspector name and contact information. FDA web pages and forms facilitate the submission of adverse event report information and consumer complaints, and they describe how FDA will use submitted information.

Members of the public (e.g., consumers, physicians) who voluntarily submit an adverse event report are given notice on FDA submission form 3500, which advises against the unnecessary submission of PII, describes how FDA will use their identifying information and provides them an option to specify that FDA not disclose their identity to manufacturers. FDA privacy policies are also permanently available across all fda.gov web pages and describe FDA policies and practices for information collection and sharing. Submission of PII by consumers (consumer submitted complaints) is voluntary.

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.

Submission of PII by FDA employees and direct contractors, while not "mandatory" as that term is used by the Privacy Act, is required to become a FACTS user. There is no opt-out process.

Regulated entities are required to provide the work contact information PII of a point of contact (POC); this can be the PII of any individual authorized to send and receive communications on behalf of the regulated entity and the POC can be changed.

The information is a practical requirement in order for the system to function and effectively serve its purpose.

Submission of PII by consumers (consumer submitted complaints) is voluntary.

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

If FDA practices change with regard to the PII collected in FACTS, the agency will employ appropriate notice and consent procedures. This may include email to individuals, adding or updating forms and online notices and disclaimers, or using other available technological methods for notification and consent.

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.

Personnel may raise concerns and/or submit data corrections through supervisory channels and FDA's Employee Resource and Information Center (ERIC). Individuals who are not FDA employees or direct contractors may contact FDA through numerous email, phone and standard mail avenues (all listed on fda.gov).

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

PII for FDA personnel is obtained via FDA's Employee Administrative Support Environment (EASE) system. FDA personnel and direct contractors may correct/update their information. Data discrepancies identified in the course of system use are addressed when discovered.

Consumer and entity point of contact PII is submitted by the individual and its accuracy is subject to the submitter. Data discrepancies identified in the course of system use are addressed when discovered.

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

Users:

Reviewing and processing of inspections and consumer complaints.

Administrators:

Reviewing, processing and administering the system, files and data as well as access control.

Developers:

Troubleshooting issues with the system, performance and access.

Contractors:

(Direct contractors) Supporting the IT team for administration, troubleshooting and development of the system.

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

FDA users and direct contractors with valid network accounts who require access to FACTS must have supervisory approval and signature before access is granted. The agency reviews the system access list on a quarterly basis to adjust users' access roles and permissions and delete unneeded accounts from the system.

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.

The relevant supervisor will indicate on the FACTS user account creation form the minimum access that is required in order for the user to complete his/her job. The scope of access is restricted based on role-based criteria. All users are authenticated and employ unique user ID and passwords.

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 must complete security and privacy awareness training at least once each year.

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

Informal training on functionality and system use is provided to the users at the district and field level. All users are provided guidance on adhering to HHS Rules of Behavior and may obtain additional instruction with FDA's privacy program.

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.

FACTS records and PII are included in regularly scheduled database backups and offsite storage of backups. FACTS does not contain a system-specific process or technical mechanism for the destruction of records or PII.

The records handled in FACTS are governed by a variety of records schedules specific to the nature of the records. The retention and destruction periods generally range from 10 to 30 years after an action closes, or, when a record is no longer needed for trend analysis or reference, whichever is latest. For example, FACTS program database records are maintained in accordance with the National Archives and Records Administration (NARA) approved citation N1-088-09-003 which states that records disposition is temporary, with records deleted or destroyed 10 years after the end of the fiscal year in which the subject regulatory action is final. Program management files and adverse event reports/systems fall under NARA approved citation N1-088-07-002 which provides specific record keeping timeframes.

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

Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others.

Technical safeguards include role-based access settings, firewalls, passwords and others. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls.

Other 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.