

Date Signed: 10/7/2021

Acronyms

ATO - Authorization to Operate
 CAC - Common Access Card
 FISMA - Federal Information Security Management Act
 ISA - Information Sharing Agreement
 HHS - Department of Health and Human Services
 MOU - Memorandum of Understanding
 NARA - National Archives and Record Administration
 OMB - Office of Management and Budget
 PIA - Privacy Impact Assessment
 PII - Personally Identifiable Information
 POC - Point of Contact
 PTA - Privacy Threshold Assessment
 SORN - System of Records Notice
 SSN - Social Security Number
 URL - Uniform Resource Locator

General Information

Status:	Approved	PIA ID:	1341655
PIA Name:	FDA - FWFPS - QTR2 - 2021 - FDA1956194	Title:	FDA - ORA Systems for Inspections, Recall, Compliance and Enforcement
OpDIV:	FDA		

PTA

PTA - 1A:	Identify the Enterprise Performance Lifecycle Phase of the system	Operations and Maintenance
PTA - 1B:	Is this a FISMA-Reportable system?	No
PTA - 2:	Does the system include a website or online application?	No
PTA - 3:	Is the system or electronic collection, agency or contractor operated?	Agency
PTA - 3A:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA - 5:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
PTA - 5B:	If no, Planned Date of ATO	7/15/2019
PTA - 7:	Describe in further detail any changes to the system that have occurred since the last PIA	Since the last Privacy Impact Assessment (PIA) approval, changes and updates to the Field Accomplishments and Compliance Tracking System (FACTS) and to the Electronic States Access to FACTS (eSAF) have included updates and bug fixes as well as platform upgrades to improve the functionality, performance, usage, and reliability of the application. Otherwise, there have been no additions, updates, or changes to existing personally identifiable information (PII) data elements or their use, processing, and storage by FACTS or eSAF.
PTA - 8:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions?	The purpose of Field Accomplishments and Compliance Tracking System (FACTS) is to provide automated support for the daily

regulatory activities conducted by the FDA Office of Regulatory Affairs (ORA) headquarters and field offices. This includes supporting business processes for: managed product application reviews; federal/state partnership activities; workload management; investigative compliance, and analytical operations; and quality assurance and other critical initiatives. FACTS provides a central data repository for workload management, sample collections, investigative operations, and compliance operations. As a nationwide, online, interactive system, FACTS provides the ORA the ability to enforce the safety of FDA-regulated products through inspections, reporting, and tracking. FACTS effectively supports all FDA field operations including inspections, investigations, sample collections and collection of consumer complaints.

The Electronic States Access to FACTS (eSAF) application is an element of FACTS that allows FDA to automate the issuance of work requests to inspectors who are state employees and who execute duties under contract agreements 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 product recalls. 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.

PTA - 9:

List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.

The primary functions of FACTS include the collection, maintenance and sharing of several

types of data.

For workload management, the PII used includes assignment requester first and last name, FDA point of contact (POC) first and last name, POC work/FDA phone and fax numbers. Non-PII used for workload management includes FDA assignment organization, assignment date, assignment subject, assignment status, FDA operations, review remarks, products reviewed/sample collected.

For inspections and field operations, the PII used includes FDA inspector first and last name, FDA division decision maker first and last name as well as Direct Contractor state inspector first and last name. The non-PII used in inspections and field operations includes inspections results, processes/conclusions, division decisions, product description, investigation reason, findings and recommendations, adverse inspectional observations, inspection summary, products covered/description, inspection refusals, and operation remarks.

For sample collections and lab analysis, the PII employed includes FDA sample collector first and last name and FDA lab analyst first and last name. Non-PII used in this context includes sample description, collection reason and remarks, firm FEI and firm name, firm type, product name and description, analyzing organization, analysis performed, and lab conclusion.

For consumer complaints, the PII that is involved includes Complaint submitter's (e.g., consumer, physician) information (first name, last name, home address, home phone, work phone and date of birth (when included in medical notes provided as relevant to a submission)), and FDA complaint receiver first and last name. Non-PII data includes complaint description, adverse event (event, result, date, injury/illness, FDA remarks, complainant's symptoms and age).

For FDA-regulated firms, the PII used in FACTS is the firm's main POC's information (first name, last name, job title, work address, work phone, work fax and work email). Related non-PII includes firm establishment identifier (FEI), firm name, firm alias, firm address, and Dun & Bradstreet's data universal number system (DUNS) information.

eSAF contains data about state inspections (food and feed). The workflow of eSAF begins with the request inspection process whereby an inspector submits a request to conduct a specific inspection) involving the creation, update and issuance of an inspection assignment. The PII handled in this context includes FDA assignment requester first name and last name, FDA assignment POC first name, last name, work email, work address, and work phone. Non-PII used includes

assignment subject, state agency, assignment status, assignment remarks, assignment background.

The workflow continues with the record results process. The PII handled in this process includes state investigator first name, last name, work phone, and state agency. Non-PII data includes adverse inspectional observations issued to the firm, inspection summary, inspection refusals, sample collected, consumer complaints, reason for investigation, operation findings/recommendations, State Contract Monitor (SCM) remarks for state inspection, the inspection summary, and conclusions.

Finally, the workflow concludes with the review results process which involves reviewing inspection results, checklists and forms encompassing all aforementioned data in leading to acceptance (or rejection) and finalization of the inspection by the FDA.

FDA employees and Direct Contractors (system users) request a user account for FACTS and/or eSAF and provide PII data including their first name, last name, work phone, work fax, work email and work address along with their internal employee number (used for identification in the Enterprise Administrative Support Environment (EASE), an FDA system with its own PIA).

PTA -9A:	Are user credentials used to access the system?	Yes
PTA - 10:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual	FACTS provides the ORA the ability to enforce the safety of FDA-regulated products through inspections, reporting, and tracking. Key

functionality includes access to information and FDA business processes for developing, managing, tracking, and reporting field operations at the Headquarters and local level. FACTS also supports documenting and tracking work requirements linked to specific assignments to capture the time/work performed and providing data to ORA's reporting systems. These reporting systems enable the Division of Planning and Evaluation (DPE) to demonstrate how FDA meets its performance goals.

FACTS collects information about samples and provides a rudimentary chain of custody between the inspection/investigation/field exam and the laboratory. FACTS also collects and maintains information about the activities performed, the results of the event and the evidence collected. It enables FDA to create and track work assignments from single assignments to multi-district projects and provides an interface to collect and share information with certified state inspectors, allowing FDA to share the investigatory workload with the states. The system allows for issuing laboratory assignments, laboratory analytical data reporting, laboratory recommendations and accomplishments that are captured by FACTS. FDA uses FACTS functions to track samples collected and sent to the FDA laboratories and facilitate the core of ORA's performance management processes. The data maintained in FACTS provides information regarding product defects, consumer complaints, illness/injury reports, food borne illnesses, and other product problem data.

The eSAF system element implements the overall business processes supporting the life cycle of processing states' inspection data. eSAF inspection management capabilities include the following:

- a) FDA SCMs can create and issue an inspection assignment to a state in their home district;
- b) FDA SCMs can upload a specified Excel file template with assignment and operation data used to create assignments and operations in batches and issue them to the appropriate state agencies within their division;
- c) State reviewers affiliated with the state agency/state to which an FDA assignment was issued can accept the assignment and the State Data Entry person can record inspection results, and States can also record ad hoc inspection results;
- d) State users can upload an unlimited number of documents about an inspection or investigation;
- e) FDA and state users can view detailed information related to firms;
- f) State users can record investigations and enter operation accomplishments when the firm is out of business;
- g) State users can enter inspection data in the Bovine Spongiform Encephalopathy (BSE) Checklist and the Hazard Analysis and Critical

Control Point (HACCP) Form 3501 electronically;

h) State users can record Animal Food Risk Data forms as part of inspection data;

i) FDA SCMs can review inspection results and electronically sign the inspection assignment (using FACTS electronic signature which is a 10-digit number ID that serves as an internal key for an "FDA personnel table"); and

j) State users can provide Recall Audit Check information about recalled products as captured via FDA Form 3177 and further completed by FDA personnel.

FDA restricts access to FACTS and eSAF to FDA employees and Direct Contractors who have been approved as FACTS users. Once approved, users access FACTS and/or eSAF using an assigned username and a temporary password provided to them via e-mail that is then updated by the user upon first access to a permanent password meeting the agency's password standards.

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.

PTA - 10A:	Are records in the system retrieved by one or more PII data elements?	No
PTA - 11:	Does the system collect, maintain, use or share PII?	Yes
PIA		
PIA - 1:	Indicate the type of PII that the system will collect or maintain	<p>Name</p> <p>E-Mail Address</p> <p>Phone numbers</p> <p>Medical records (PHI)</p> <p>Date of Birth</p> <p>Mailing Address</p> <p>Devices Identifiers</p> <p>User Credentials</p> <p>Others - Consumers submitting product complaints may choose to include age or, sex, weight, and ethnicity or race. Information about users includes username and password. Likewise, contact information PII in the system is primarily work/professional context but may include home address and phone number for consumers in some instances.</p>
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared	<p>Employees/HHS Direct Contractors</p> <p>Public Citizens</p> <p>Vendors/Suppliers/Third-Party Contractors (Contractors other than HHS Direct Contractors)</p>
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system	Above 2000
PIA - 4:	For what primary purpose is the PII used?	<p>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 and analyze activity metrics; conduct investigations and compliance reviews; and to contact individuals employed by regulated businesses and organizations.</p> <p>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.</p>
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research)	FDA makes no secondary uses of PII for training, testing or research.
PIA - 7:	Identify legal authorities, governing information use and disclosure specific to the system and program	FDA uses this system to protect and promote the health and safety of consumers under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301), the Federal Records Act, and 5 U.S.C. 301.
PIA - 9:	Identify the sources of PII in the system	Directly from an individual about whom the information pertains

		<p>In-person</p> <p>Hard Copy Mail/Fax</p> <p>Email</p> <p>Online</p> <p>Government Sources</p> <p> Within the OPDIV</p> <p> State/Local/Tribal</p> <p>Non-Government Sources</p> <p> Private Sector</p>
PIA - 9A:	Identify the OMB information collection approval number or explain why it is not applicable.	Not applicable. Information collected under OMB approval is not submitted directly to FACTS. However, data from OMB approved information collections maintained in other agency systems is used to inform actions managed in FACTS. This data includes, for example, 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, 2021.
PIA - 9B:	Identify the OMB information collection expiration date.	9/30/2021
PIA - 10:	Is the PII shared with other organizations outside the system's Operating Division?	Yes
PIA - 10A:	Identify with whom the PII is shared or disclosed and for what purpose	State or Local Agency/Agencies
PIA - 10B:	List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement, Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	There are existing contracts with state authorities using eSAF, and there are Interconnection Security Agreements (ISA) in place between FDA's ORA and other FDA Centers/Organizations regarding the exchange of data via secured interfaces between their systems and FACTS.
PIA - 10C:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII	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.
PIA - 11:	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 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.

PIA - 12: Is the submission of PII by individuals voluntary or mandatory?

Voluntary

PIA - 13: 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 of a 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 as needed.

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; they may opt not to submit a report/complaint or may limit the PII they include.

PIA - 14: Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained

No such changes are anticipated. If FDA changes its practices with regard to the collection or handling of PII related to the FACTS system, the agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include e-mail to individuals, adding or updating online notices or forms, or other available means to inform the individual.

PIA - 15: 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. If no process exists, explain why not

External individuals may contact FDA by e-mail to resolve any issues regarding their PII and may resubmit information or corrections to their PII. They may also contact FDA's Privacy

		Office using information provided on FDA.gov.
		Employees may submit concerns to their supervisor, the FDA Privacy Office, a 24-hour technical assistance line, and FDA's Systems Management Center.
PIA - 16:	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not	<p>Reporter's PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting. FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).</p> <p>PII integrity and availability are protected by privacy and security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on National Institute of Standards and Technology (NIST) guidance concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199. FACTS administrators perform annual reviews to evaluate and adjust user access.</p>
PIA - 17:	Identify who will have access to the PII in the system and the reason why they require access	<p>Users</p> <p>Administrators</p> <p>Developers</p> <p>Contractors</p>
PIA - 17A:	Provide the reason of access for each of the groups identified in PIA -17	
	Users: Authorized FDA users responsible for the process and management of data submission of inspections.	
	Administrators: Direct Contractors supporting OIMT with the review, process and administering of the system, files and data as well as access control.	
	Developers: FDA Direct Contractors support OIMT with the design, development, and testing of the system.	
	Contractors: FDA Direct Contractors support the OIMT for administration, troubleshooting and development of the system.	
PIA - 17B:	Select the type of contractor	HHS/OpDiv Direct Contractor
PIA - 18:	Describe the administrative 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.
PIA - 19:	Describe the technical 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 request 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.
PIA - 20:	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 system users at FDA take annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity, and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure). The FDA Office of Information Management and Technology (OIMT) verifies that training has been successfully completed.
PIA - 21:	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 office level. All users are provided guidance on adhering to the Health and Human Services (HHS) Rules of Behavior and may obtain additional instruction via FDA's privacy program.
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific NARA records retention schedule(s) and include the retention period(s)	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. FACTS database records are maintained in accordance with National Archives and Records Administration (NARA) approved citation N1-088-09-3 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 fall under NARA approved citation N1-88-07-2.
PIA - 24:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response	<p>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.</p> <p>Technical safeguards include role-based access settings, firewalls, passwords, and others.</p> <p>Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls.</p> <p>Other appropriate controls have been selected from the NIST's Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.</p>