PTA / PIA: FDA - FACTS - QTR2 - 2026 - FDA5271781

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General Information

PTA / PIA Name:	FDA - FACTS - QTR2 - 2026 - FDA5271781	**PTA / PIA ID:**	4620307
Component Name:	FDA - OII Field Accomplishments and Compliance Tracking System	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	11
Submitter:		**Submit Date:**	7/6/2026
Next Assessment Date:	07/09/2029	**Expiration Date:**	7/9/2029
Office:		**OpDiv:**	FDA
Security Categorization:	Moderate		
Make PIA available to Public?:	Yes	**PIA Required:**	Yes

General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	No
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	Yes
General 04:	ATO Date or Planned ATO Date.	3/4/2025
General 05:	Is the system or electronic information collection, agency or contractor operated?	Agency
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	Sabrina Mosley
PTA 01A:	POC Title and Organization	Information System Owner Office of Inspections and Investigations (OII)
PTA 01B:	POC Email Address	sabrina.mosley@fda.hhs.gov
PTA 01C:	POC Phone Number	240-731-8624
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)

PTA 02A:	Describe in further detail any changes to the system that have occurred since the last PIA.	The Food and Drug Administration (FDA) has made no major changes to the Field Accomplishments and Compliance Tracking System (FACTS) system since the last Privacy Threshold Analysis/Privacy Impact Assessment was approved.
PTA 03:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA 04:	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	The Field Accomplishments and Compliance Tracking System (FACTS) is an internal-facing, agency-wide, mission-critical information system operated by the Office of Inspections and Investigations (OII) within the Food and Drug Administration (FDA). It provides comprehensive automated support for the daily activities conducted by OII headquarters and field offices across the nation, serving as a central data repository for workload management, sample collections, investigative operations, and compliance operations. FACTS carries out its mission through several core functions. The system records, tracks, and manages both domestic and foreign inspections, domestic field exams, and audits of state officials, enabling consistent and uniform enforcement activities across all FDA field locations. It also captures and manages sample collection data, analysis workflows, and results, providing field staff and reviewers with accurate scientific information to support regulatory decisions. In addition, FACTS supports investigative and compliance activities, including the tracking of consumer complaints and adverse events, helping OII staff identify and respond to potential public health risks. The system further records work assignments and accomplishment hours, allowing headquarters and field management to monitor productivity, allocate resources effectively, and analyze activity metrics. FACTS also plays an important role in information sharing and interoperability. It provides data in support of Congressional and Government Accountability Office (GAO) inquiries, Freedom of Information Act (FOIA) requests, press requests, budget justifications, and Advisory Committee on Regulatory Activities (ACRA) requests. The system exchanges data with multiple FDA Center systems, such as sharing Inspection Assignment Requests (IARs) data with the Center for Drug Evaluation and Research (CDER) Establishment Evaluation System (EES), directly supporting the evaluation of new drug applications. In support of the Department of Health and Human Services (HHS) mission, FACTS enables the FDA to enforce the safety of regulated products through inspections, reporting, and tracking. As a nationwide, online, interactive system, it provides rapid review of current and past field work assignments, results, and time information, maximizing staff productivity and enhancing decision-making through a fast, accurate flow of

		scientific and management information among inspectors, reviewers, regulators, and other program personnel. FACTS users include FDA employees, such as regulatory and compliance personnel, system administrators, and development staff, as well as HHS Direct Contractors who support the application through helpdesk and development activities. Access to FACTS is restricted to internal FDA users only and is not publicly accessible. Users access the system via an intranet Uniform Resource Locator (URL) (https://OII.fda.gov/forms/frmservlet?config=facts) using secure login credentials through the FDA's Single Sign-On (SSO) capability, which is integrated with the FDA Enterprise Active Directory (AD). Access is granted on a role-based basis, with permissions reviewed on a quarterly basis to ensure that only authorized personnel retain access appropriate to their individual duties.
PTA 05:	List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.	FACTS collects, maintains, and manages several categories of information in support of OII's regulatory and compliance mission. The primary types of information collected into the system include workload management data, sample collections, investigative operations data, and compliance operations data. These broad categories encompass the full range of field activities conducted by FDA investigators and compliance personnel on a daily basis. With respect to Personally Identifiable Information (PII), FACTS collects and maintains business contact information for points of contact at FDA-regulated firms. This includes business email addresses, business mailing addresses, business phone numbers, business fax numbers, job titles, employee ID numbers, Dun & Bradstreet's Data Universal Numbering System (DUNS) information, the FDA Establishment Identifier (FEI), and firm names. Firm names and FEI are considered a form of PII in cases where the name of the business directly identifies an individual, such as a sole proprietorship (e.g., "John Smith Hamburgers"). In addition to PII, the system maintains non-PII firm data, including firm aliases and firm addresses (physical business location is separate from the business mailing address). It is important to note that Social Security Numbers (SSNs), truncated SSNs, and Taxpayer Identification Numbers (TINs) are not collected, used, processed, or transmitted by FACTS. The system also captures information related to inspections and investigations, including domestic and foreign inspection records, field examination results, sample collection and analysis data, consumer complaints, adverse events, work assignments, and accomplishment hours. This information is used to support regulatory decision-making, enforcement activities, and reporting

		obligations across FDA field operations. FACTS exchanges data with other FDA Center systems, such as IARs data with the CDER EES. PII within the system is not shared with organizations outside of HHS's Operating Division. Before any PII can be shared, non-disclosure agreements, Memoranda of Understanding (MOUs), and Information Sharing Agreements (ISAs) must be documented and in place. With respect to retention, records handled in FACTS are governed by a variety of National Archives and Records Administration (NARA)-approved records schedules specific to the nature of the records. Retention and destruction periods generally range from 10 to 30 years after an action closes or when a record is no longer needed. Specifically, FACTS database records are maintained in accordance with NARA-approved citation N1-088-09-3, which designates records as temporary and requires that they be 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.
PTA 05A:	Are user credentials used to access the system?	Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system.
PTA 05C:	Please identify the system that maintains the user credentials or controls access to this system.	FDA Active Directory
PTA 06:	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	FACTS collects, maintains, and shares information to support the FDA's core regulatory mission of enforcing the safety of FDA-regulated products. The information collected serves distinct purposes depending on the category of individuals or entities involved. For FDA-regulated firms and their employees, FACTS collects and maintains business contact PII — specifically the firm's main point of contact's job title, employee ID number, work address, work phone number, work fax number, and work email address. Related firm data is also collected, including the FEI, firm name, firm alias, firm address, and DUNS information. This information is collected to enable FDA investigators and compliance personnel to identify regulated establishments, communicate with vendors and firm representatives, and support the management of inspections, investigations, and compliance reviews. Accuracy of this information is maintained by allowing firms to update their firm name through registration, through the FEI portal, and through inspections. For FDA employees and HHS Direct Contractors, the system collects and maintains work assignment data, accomplishment hours, employee ID numbers, and other workload management information. This information is collected and maintained to allow OII headquarters and field

		management to monitor and manage field operations, allocate resources effectively, analyze activity metrics, and ensure accountability across the organization. More broadly, FACTS collects and maintains inspection records, sample collection and analysis data, consumer complaints, and adverse event information to support the FDA's ability to conduct regulatory surveillance, enforce compliance, and respond to public health concerns. This information is used to manage the process of reviewing applications for FDA approval of drugs, devices, cosmetics, and other FDA-regulated items; manage federal and state partnerships; conduct investigations and compliance reviews; and contact individuals employed by regulated businesses and organizations. Information is shared with other FDA Center systems — such as the exchange of IARs data with the CDER EES — to support coordinated regulatory decision-making, including the evaluation of new drug applications. This sharing is carried out to maximize the flow of scientific and management information among inspectors, reviewers, regulators, and other program personnel, ultimately in support of FDA's mission in the areas of regulation, surveillance, and compliance. It is noted that all FDA Center systems with which FACTS exchanges data, including CDER EES, are within the same FDA Operating Division, and therefore this data exchange does not constitute sharing PII outside of the Operating Division. The FDA makes no secondary use of PII collected within FACTS, and all information sharing outside the system is governed by appropriate agreements such as MOUs and ISAs.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	https://oii.fda.gov/forms/frmservlet?config=facts
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No

PTA 09:	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	The purpose of the FACTS website is to provide a central data repository for workload management, sample collections, investigative operations, and compliance operations. It serves as the primary online interface through which OII headquarters and field office personnel conduct and document the daily regulatory and enforcement activities of the FDA, including inspections, investigations, sample collections, and compliance reviews. The website supports rapid review of current and past field work assignments, results, and time information, enabling effective decision-making and resource management across FDA field operations nationwide. Access to the FACTS website is restricted to internal FDA users only — it is not accessible to the general public. The following categories of individuals have access to the system: FDA employees, including regulatory and compliance personnel, system administrators, and developers, as well as HHS direct contractors supporting the application through helpdesk and development activities. Access is granted on a role-based basis, meaning each user is provided only the minimum level of access necessary to perform their individual job duties. User access permissions are reviewed on a quarterly basis, and accounts that are no longer needed are purged from the system to ensure that only authorized personnel retain access. Users access the FACTS website via an intranet URL, meaning the system is accessible only within the FDA's internal network and is not reachable through a public-facing web address. Upon navigating to the site, users log in using secure credentials through the FDA's SSO capability, which is integrated with the FDA Enterprise Active Directory. This authentication mechanism ensures that only verified FDA personnel and authorized contractors are able to gain entry to the system.
PTA 10:	Does the website have a posted privacy notice?	Yes
PTA 11:	Does the website contain links to non-federal government websites external to HHS?	No
PTA 12:	Does the website use web measurement and customization technology?	Yes
PTA 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	Session Cookies- Does Not Collect PII
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA 14:	Does the system have a mobile application?	No
PTA 20:	Are any third-party websites or applications (TPWA) associated with the system?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment		
PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Identifying Numbers Employee ID Number DUNS Contact Information Email Address (Business) Mailing Address (Business) Phone Numbers (Business) Other Other
PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Fax Number (Business) FDA Establishment Identifier (FEI) Firm Name Job Title
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors Vendors/Suppliers/Third-Party Contractors (Contractors other than HHS Direct Contractors)
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	The FDA uses the PII maintained in FACTS primarily to support its core regulatory and enforcement mission. Specifically, the PII is used to manage the process of reviewing applications for FDA approval of drugs, devices, cosmetics, and other FDA-regulated items; to manage federal and state partnerships; to manage workloads and analyze activity metrics; to conduct investigations and compliance reviews; and to contact individuals employed by regulated businesses and organizations.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA makes no secondary use of the PII.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The following legal authorities govern information use and disclosure specific to FACTS: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374 Public Health Service Act, 42 U.S.C. 262–264 These legal authorities provide the basis under which all PII is collected and gathered within FACTS as part of regulated inspections and investigations.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	Yes

PIA 29A:	Please specify which PII data elements are used to retrieve records.	The PII data elements that are used to retrieve records in the system/system component/information collection are name, phone number, email address and mailing address.
PIA 29B:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	SORN 1: 09-10-0002, Regulated Industry Employee Enforcement Records SORN 2: 09-10-0010, Bioresearch Monitoring Information System
PIA 30:	Identify the sources of PII in the system.	Government Sources Within the OPDIV Non-Government Sources Private Sector
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA 31B:	Explain why an OMB information collection approval number is not required.	An Office of Management and Budget (OMB) information collection approval number is not required for FACTS because the system does not collect any information from the general public. As an internal-facing system accessible only to FDA employees and authorized HHS contractors, FACTS is not subject to the Paperwork Reduction Act (PRA) requirements that would necessitate an OMB information collection approval number. The PRA generally applies to federal agencies when they collect information from the public, and since FACTS exclusively supports internal FDA field operations and collects information only in the context of regulated inspections and investigations — rather than through public-facing data collection activities — the requirement for an OMB approval number is not applicable.
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary

PIA 34:	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	FACTS collects business contact PII voluntarily provided by representatives of FDA-regulated firms in the course of regulated inspections and investigations conducted under the authority of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374, and the Public Health Service Act, 42 U.S.C. 262–264. As such, individuals are made aware that their business contact information is being collected as part of the regulatory inspection or investigation process at the time of the interaction with FDA field personnel. Should FDA practices change regarding the collection or use of PII within FACTS, the agency will provide any required notice and obtain consent from individuals through one or more of the following methods: Federal Register notices, hard copy mail to individuals, adding or updating online notices and disclaimers, or using other available technological means for notification and consent. The agency's privacy notices, which are posted on the FACTS website, also serve to inform users of the system's data collection practices and their rights with respect to their PII.
PIA 35:	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). If they cannot be notified or have their consent obtained, explain why.	When major changes occur to FACTS that affect the collection or use of PII — such as changes to disclosure practices or data uses — the FDA will provide any required notice and obtain consent from affected individuals through appropriate channels. Personnel may raise concerns and/or submit data corrections through supervisory channels and FDA's Employee Resource and Information Center (ERIC). Should FDA practices change regarding the collection or use of PII within FACTS, the agency will provide any required notice and obtain consent from individuals through one or more of the following methods: Federal Register notices, hard copy mail to individuals, adding or updating online notices and disclaimers, or using other available technological means for notification and consent. These procedures ensure that individuals whose PII is maintained in the system are informed of any material changes to how their information is collected, used, or disclosed, and that their consent is obtained where required.

PIA 36:	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.	FACTS maintains several processes to address and resolve concerns raised by individuals who believe their PII has been inappropriately obtained, used, or disclosed, or that their PII is inaccurate. All PII collected within FACTS is relevant to the system's regulatory mission, as point of contact information is necessary to communicate with vendors and regulated firm representatives. PII, specifically name and work contact data, is provided voluntarily by the vendors themselves, and accuracy is initially ensured through individual review of purchase orders. In the event that an individual believes their PII has been inappropriately obtained, used, or disclosed, or that the information maintained in the system is inaccurate, personnel may raise concerns and submit data corrections through supervisory channels and FDA's Employee Resource and Information Center (ERIC). Additionally, accuracy of firm-related PII is maintained on an ongoing basis by allowing firms to update their firm name and contact information through registration, through the FEI portal, and through inspections, providing a practical mechanism for individuals to ensure their information remains current and correct. Before any PII can be shared outside of the system, non-disclosure agreements, MOUs, and ISAs must be documented and in place, providing an additional layer of protection against inappropriate disclosure. All PII is gathered under the authority of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374, and the Public Health Service Act, 42 U.S.C. 262–264, ensuring that its collection and use are grounded in established legal authority.

PIA 37:	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	FACTS has several processes in place for the periodic review of PII to ensure data integrity, availability, accuracy, and relevancy. Each element is addressed as follows: Data Integrity: Regular testing of backup systems and data recovery procedures confirms that PII can be restored without corruption or loss of information. Periodic assessment of user permissions and system access logs ensures that only authorized personnel can modify PII records, maintaining the authenticity and completeness of the data. Additionally, access to the system is reviewed on a quarterly basis, and user accounts that are no longer needed are purged from the system to prevent unauthorized modifications to PII records. Data Availability: Continuous monitoring of system uptime, response times, and accessibility ensures that PII is available to authorized users when needed for legitimate business purposes. As a nationwide, online, interactive system, FACTS is designed to support the 24/7 operational needs of OII headquarters and field offices, ensuring that authorized personnel have reliable and timely access to the information necessary to carry out their regulatory and enforcement responsibilities. Data Accuracy: Accuracy of PII is maintained by allowing firms to update their firm name and contact information through registration, through the FEI portal, and through inspections. This ensures that the business contact information maintained in FACTS remains current and reflective of the most up-to-date information provided by regulated firms and their representatives. Data Relevancy: Regular evaluation is conducted to ensure that the PII collected within FACTS remains necessary for the specific business purposes for which it was originally collected. Access to PII is granted on a need-to-know and minimum necessary basis, and user access permissions are reviewed and adjusted on a quarterly basis to ensure that only personnel with a legitimate business need retain access to PII records. This ongoing review process helps to ensure that PII is not retained beyond its useful purpose and that the information maintained in the system remains relevant to FDA's regulatory and enforcement mission.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors

PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	**Users** — Require access to PII in order to perform and document FDA inspections. As the primary operational users of the system, FDA investigators and compliance personnel must be able to access firm contact information and related PII to carry out their regulatory and enforcement responsibilities, including conducting inspections, recording results, and communicating with regulated firm representatives. **Administrators** — Require access to PII in the course of performing analysis of historical activities and to review work in process. Administrators need visibility into PII records to effectively manage and oversee system operations, ensure data quality, and support the overall integrity of the information maintained within FACTS. **Developers** — Require access to PII to perform Level 3 helpdesk support. This highest tier of technical support necessitates direct access to system data, including PII, in order to diagnose and resolve complex technical issues that cannot be addressed at lower support levels. **Contractors** — Helpdesk Direct Contractors require access to PII to perform Level 1 and Level 2 helpdesk support activities. These lower tiers of technical support involve assisting users with system access issues and other routine technical matters that may require limited visibility into PII records in order to effectively resolve user-reported problems.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FACTS has several administrative procedures in place to determine which system users may access PII. System access requests are reviewed and approved by the system and business owner along with the OII Case and Workload Management (OCWM) management team prior to access being granted. This review process ensures that only individuals with a legitimate business need are permitted to access the system and the PII contained within it. Access is granted and restricted at the individual level as appropriate to each individual's duties through role-based access controls, implementing the principles of need-to-know and minimum necessary access. This means that each user is provided only the minimum level of access required to perform their specific job functions, limiting unnecessary exposure to PII across the system. System accounts are reviewed on a regular basis to determine whether access is still required for each user. Specifically, user access permissions are reviewed and adjusted on a quarterly basis, and accounts that are no longer needed are purged from the system to ensure that only currently authorized personnel retain access to PII. Supervisors indicate the appropriate level of access when accounts are created, ensuring that role-based access controls are applied correctly from the outset and that the minimum necessary principle is upheld throughout the lifecycle of each user account.

PIA 41:	Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.	FACTS employs several technical methods to ensure that those with access to PII are limited to only the minimum amount of information necessary to perform their job duties. These technical controls work in conjunction with the administrative procedures described previously to enforce the principles of need-to-know and minimum necessary access throughout the system. When user accounts are created, supervisors indicate the minimum level of information system access required for the user to complete their job responsibilities. This ensures that role-based access controls are applied correctly from the outset, limiting each user's visibility into PII records to only those that are directly relevant to their assigned duties. The access list for the information system is reviewed on a quarterly basis, during which users' access permissions are reviewed and adjusted as necessary, and unneeded accounts are purged from the system to prevent unauthorized or unnecessary access to PII. At the database level, FACTS implements Oracle system-level security controls, including the use of defined database roles that restrict access to system functions and data. Two primary roles are utilized — a read-only role that provides select access to all system tables, and a user role that provides select, update, delete, and insert access to all system tables. These roles are assigned based on each user's specific job requirements, ensuring that users can only interact with PII records in the manner necessary to perform their duties. Additionally, a login audit trail is maintained that records detailed information about user access, including login and logout times and workstation identifiers, providing an additional layer of accountability and oversight over access to PII within the system. Automatic disconnection occurs after three failed login attempts, and sessions are terminated after 60 minutes of inactivity, further limiting the risk of unauthorized access to PII.
PIA 42:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) to make them aware of their responsibilities for protecting the information being collected and maintained.	All FDA personnel who use FACTS, including system owners, managers, operators, contractors, and program managers, are required to complete mandatory security and privacy awareness training at a minimum of once per year. This annual training is designed to ensure that all personnel who interact with the system are aware of their responsibilities for protecting the information being collected and maintained within FACTS, including PII and other sensitive data.

PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	In addition to the general annual security and privacy awareness training, users of FACTS receive system-specific training to ensure they understand the particular security and privacy requirements associated with the system. Users are also required to review and adhere to the Rules of Behavior governing the use of FACTS, which outline the specific responsibilities and expectations for protecting the information maintained within the system. Furthermore, users may obtain additional privacy guidance from the agency's privacy officials as needed to address specific questions or concerns related to the protection of PII within the system.
PIA 44:	Describe the process and guidelines in place for the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	FACTS has established processes and guidelines in place for the retention and destruction of PII in accordance with NARA-approved records retention schedules. The records handled in FACTS are governed by a variety of records schedules specific to the nature of the records, with retention and destruction periods generally ranging from 10 to 30 years after an action closes or when a record is no longer needed. Specifically, FACTS database records are maintained in accordance with NARA-approved citation N1-088-09-3, which designates records as temporary in nature. Under this schedule, records are deleted or destroyed 10 years after the end of the fiscal year in which the subject regulatory action is final. This schedule governs the primary operational records maintained within the FACTS database, including inspection records, sample collection data, compliance operations data, and other information collected in support of FDA's regulatory and enforcement mission. Program management files maintained within FACTS are governed by a separate NARA-approved citation, N1-88-07-2. Program management files within FACTS are considered temporary records requiring a 10-year retention period after the fiscal or calendar year cutoff. These records are to be securely destroyed upon expiration of this 10-year period. Upon reaching the end of their applicable retention period, records are deleted or destroyed in accordance with the relevant NARA-approved schedule, ensuring that PII is not retained beyond the period necessary to fulfill the purposes for which it was originally collected and maintained.
PIA 45:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	FACTS employs a comprehensive set of administrative, technical, and physical controls to secure the PII maintained within the system. Each element is addressed as follows: Administrative Controls: Administrative safeguards include mandatory security and privacy awareness training for all FDA personnel at a minimum of once per year, ensuring that all system users are

aware of their responsibilities for protecting PII. System documentation advises on the proper use of the system, and the principles of need-to-know and minimum necessary access are implemented when awarding access to the system. System access requests are reviewed and approved by the system and business owner along with the OCWM management team, and access is granted and restricted at the individual level as appropriate to each individual's duties through role-based access controls. User access permissions are reviewed and adjusted on a quarterly basis, and accounts that are no longer needed are purged from the system. Users are also required to review and adhere to the Rules of Behavior governing the use of FACTS and may obtain additional privacy guidance from the agency's privacy officials as needed.

Technical Controls: Technical safeguards include the use of firewalls and access controls such as usernames, passwords, and multi-factor authentication (MFA) to prevent unauthorized access to the system and the PII contained within it. Regular testing of information technology systems is conducted to ensure the continued effectiveness of technical controls. At the database level, Oracle system-level security controls are implemented, including defined database roles that restrict access to system functions and data based on each user's specific job requirements. A login audit trail is maintained that records detailed information about user access, including login and logout times and workstation identifiers, providing accountability and oversight over access to PII. Automatic disconnection occurs after three failed login attempts, and sessions are terminated after 60 minutes of inactivity to further limit the risk of unauthorized access. The system is also SSO-enabled and integrated with the FDA Enterprise Active Directory, ensuring that only verified and authenticated personnel are able to access the system. Static code analysis is completed via SonarQube to identify and address potential security vulnerabilities in the application code. Security controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication (SP) 800-53 as determined using Federal Information Processing Standard (FIPS) 199.

Physical Controls: Physical safeguards include the location of all system servers at FDA facilities that are protected by security guards, locked facility doors, and climate controls. These physical security measures ensure that the hardware infrastructure supporting FACTS and the PII maintained within it is protected against unauthorized physical access, environmental hazards, and other physical threats. Access to server facilities is restricted to authorized personnel only, providing an additional layer of protection for the PII stored within the system.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	7/6/2026
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	7/6/2026
SOP Review Comments:	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	**# of Days - SOP Review:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	7/8/2026
Agency Privacy Analyst Review Comments:	Reviewer: Godisgreat Peters 7/8/2026 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	2

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	7/10/2026
SAOP Review Comments:		**# of Days - SAOP Review:**	2

SAOP Signature

Date	User	Type	Name	Original Value	New Value
7/10/2026 4:50 PM	BAUR, VANESSA	Signature	SAOP (Email PIN)		Content Signed

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PTA 01	BLAND, CRYSTAL	7/8/2026	Per FDA: EMail and PIA attached	PTA _ PIA 5271781 OII Field Accomplishments and Compliance Tracking System - SOP Approved.pdf OII Field Accomplishments and Compliance Traking System (FACTS)_SOP Approved.pdf