PTA / PIA: FDA - SERIO - QTR3 - 2025 - FDA4949165

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General Information

PTA / PIA Name:	FDA - SERIO - QTR3 - 2025 - FDA4949165	**PTA / PIA ID:**	3494713
Component Name:	FDA - OII System for Entry Review and Imports Operations	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	11
Submitter:		**Submit Date:**	7/17/2025
Next Assessment Date:	07/20/2028	**Expiration Date:**	7/20/2028
Office:		**OpDiv:**	FDA
Security Categorization:	High		
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	POC Title: Information System Owner POC Organization: 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.	U.S. Food and Drug Administration (FDA) has made no changes to System for Entry Review and Imports Operations (SERIO) 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 purpose of the U.S. Food and Drug Administration's (FDA's) Office of Inspections and Investigations (OII) Case and Workload Management (OCWM) systems/applications is to support the Food and Drug Administration's (FDA) surveillance and regulatory enforcement processes in making informed admissibility determinations regarding FDA regulated products offered for import into the United States (U.S.) and its territories. Individuals and organizations that import goods regulated by the FDA into the U.S. must provide the FDA with information related to their intent to import these goods. The FDA may inspect the shipments bound for the U.S. If goods are found to be adulterated, unsafe, or incorrectly identified, penalties range from fines to banning the shipment from import. Under certain circumstances, the FDA may delay or refuse importation of products unless and until FDA agents confirm that these products are safe, uncontaminated, and correctly identified. FDA uses System for Entry Review and Imports Operations (SERIO) to assist FDA field staff with making admissibility decisions for imported commodities. PII is collected by this component of OCWM.
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.	The data maintained in SERIO include Personally Identifiable Information (PII) in the form of business contact information, including: name (first and last), email, address, and phone numbers for authorized/designated personnel at registered entities (importers, consignees, and manufacturers involved in Prior Notice Filing). Data also include non-PII (firm name and firm address) about firms holding the shipment of an imported product. SERIO contains FDA and Direct Contractor employees' PII data including name (first and last), work phone number, work e-mail address, and system username. In addition, SERIO also collects non-PII including job title and FDA organization/center. These data are necessary for management work activities such as assessing the compliance activities of regulated institutions and collecting samples or regulated products to assess them for purity and accurate labelling.
PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS/OpDiv PIV Card

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.	SERIO is used to review entries/shipments of food, drugs, and other products regulated by the FDA. OCWM automates agency business processes used to determine: (1) the admissibility to the United States of foreign-origin products regulated by FDA, and (2) compliance with Prior Notice requirements. These admissibility and compliance determinations serve to ensure the safety, efficacy, and quality of the foreign-origin products for which FDA has regulatory responsibility under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301). The information about FDA employees and contractors is collected and/or maintained in order to facilitate workload management and tracking of completed work. The information about consignees and firm details is collected and/or maintained in order to allow for tracking of entry reviews done by FDA personnel. PII from the system/component/collection is shared internally within the FDA only in order to facilitate any reporting compliance requirements as necessary.
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://serio.fda.gov/serioApp
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 following categories of individuals have access to the website: Entry Reviewer, Entry Manager, Contractor Developers, and Testers. Users access the website via SSO using their FDA provisioned PIV card. Their credentials are checked against Active Directory and once authenticated given the appropriate roles to perform their work (following the principle of least privilege).
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?	Yes
PTA 14A:	Is the mobile application HHS developed and managed or a third-party application?	HHS

PTA 15:	Describe the purpose of the mobile application, who has access to it, and how users access it. Please address each element in your response.	The purpose of the mobile application is to provide the capability to users to conduct a field exam on a government issued mobile device especially when there is no internet connection. The following users have access to the mobile application: the field users who perform investigation work and FDA OII employees working at International Mail Facilities. These users are provided with a FDA issued iPads and are added to SERIO system admin group. Users can access the mobile application by Single Sign On using their certificate issued on the iPad.
PTA 16:	Does the mobile application have a privacy notice?	Yes
PTA 17:	Does the mobile application contain links to non-federal government websites external to HHS?	No
PTA 18:	Does the mobile application use measurement and customization technology?	No
PTA 19:	Does the mobile application have any information directed at children under the age of thirteen?	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.	Biographical Information Name User Credentials 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.	Job title, FDA organization or center name and the firm name. All the data mentioned, whether considered non-PII or not, is linked to authorized personnel, FDA employees, or direct contractors, and it is all stored within the system.
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Business Partners/Contacts (Federal state, local agencies) Employees/HHS Direct Contractors Members of the public 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.	100,000 – 999,999
PIA 25:	For what primary purpose is the PII used?	FDA uses the personally identifiable information in Imports in support of the processing, management, admissibility determinations, and tracking of FDA-regulated products offered for admission into the U.S. Information about FDA employees is also used to restrict system access and authenticate users. Name (first and last) and work contact information (email address, phone number, fax number, office address) is required for contact purposes and to document product origin and destination. Names and other PII (email and phone numbers) about individuals suspected of criminal or terrorist activity are used as one metric FDA assesses to identify shipments that present a high risk of contamination, which may be selected for a prior notice hold and/or inspection.
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 legal authorities that govern information use and disclosures specific to the system and program are: The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, as amended by the Food Safety Modernization Act, 21 U.S.C. 220. Relevant provisions can be found at 21 U.S.C. 331 and 350-387. Also, the agency collects and shares information pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), 42 U.S.C. 201.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No
PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Online Government Sources Within the OPDIV Other Federal Entities Non-Government Sources Members of the Public 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.	The information collected for SERIO does not meet the definition of "information collection request" as defined by the Paperwork Reduction Act.

PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	Yes
PIA 32A:	Identify with whom the PII is shared or disclosed.	Other Federal Agency/Agencies
PIA 32B:	For each disclosure, name the organizations/systems the system shares PII with and the purpose(s) of the disclosure.	The PII is shared and disclosed with because: FDA received the PII data from the other government agencies such as U.S. Customs and Border Protection (CBP) and United States Postal Service (USPS).
PIA 32C:	List any agreements in place that authorize the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	An Interconnection Security Agreement between FDA and CBP is currently in place. It was renewed on 5/26/2022 and is good for three years. The title of this agreement is: ISA-2022-03-0133 ISA-2022-03-0133: Interconnection Security Agreement between the U.S. Department of Homeland Security (DHS) U.S. Customs and Border Protection (CBP) and the U.S. Food and Drug Administration (FDA) via the Homeland Security Enterprise Network (HSEN) Automated Commercial Environment (ACE) and FDA Office of Regulatory Affairs (ORA) Imports Interoperability Web Services (IWS). ISA-2024-06-0361: Interconnection Security Agreement (Renewal) between CBP ACE-C and FDA OII OSSIE IWS by way of the HSEN Extranet Infrastructure is currently under renewal.
PIA 32D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	This system is not a Privacy Act system of records subject to the disclosure accounting requirement of the Act. If Privacy Act records are disclosed through the use of the system, the disclosing office will maintain an accounting. The Privacy Office makes available to agency programs guidance on how to create and maintain an accounting of disclosures in accordance with the Privacy Act of 1974.
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.	Individuals provide their contact information as a practical requirement in order to communicate with FDA and where appropriate to have system access. There are no opt-out procedures specific to Imports. While FDA requires that regulated entities supply the PII of a point of contact, that person can be anyone who is authorized to send and receive communications on behalf of the regulated entity. FDA employees and Direct Contractors must provide their PII to receive access to the system. There is no opt-out procedure, Refusal to provide PII for system access may impact the employees' ability to complete their FDA-specific duties.

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.	No such changes are anticipated. If the FDA changes its practices with regard to the collection or handling of PII related to the Imports 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, revising this PIA or other available means to inform the individual.
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.	Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have a number of avenues available to resolve the situation including FDA's Employee Resource and Information Center (ERIC) and FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). These individuals may also contact the FDA Privacy Office via email, phone and standard mail avenues (all listed on fda.gov).
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.	Users' PII is required. 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). Design of forms and webpages to collect/solicit only necessary PII ensure data relevancy. Integrity and availability are protected by security and privacy controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on 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. ORA performs annual reviews to evaluate user access.
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: FDA Users have access in order to review, process, and manage data submissions. Administrators: Review, processing, and administering the system, files and data, and access control. Developers: Troubleshooting issues with the system, performance, and access. Contractors: Supporting the IT team for administration, troubleshooting, and development of the system. This includes both Direct Contractors, as well as FDA employees. Direct Contractors can be users, administrators, and developers with regard to the Imports system.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FDA users (employees and Direct Contractors) with valid network accounts who require access to OII SERIO system must obtain formal supervisor 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 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.	Technical methods include requiring FDA users' supervisors to indicate on user account creation forms the minimum access that is required in order for users to complete their jobs. The scope of access is restricted based on role-based criteria.
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 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 individuals successfully complete the training.
PIA 43:	Describe the 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 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).	The records handled in Imports 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. Imports program 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 45:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	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 use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at 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.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	7/17/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	7/17/2025
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:**	7/21/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 7/21/2025 All comments have been addressed. This PIA is ready for SAOP review and approval. 7/17/2025 Please see comment and update accordingly. PIA-22: Per PTA-5, Please select "Mailing Address (Business)," "User Credentials," and "Other: job title, FDA organization or center name and the firm name." All the data mentioned, whether considered non-PII or not, is linked to authorized personnel, FDA employees, or direct contractors, and it is all stored within the system.	**# of Days - APA Review:**	4

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	7/21/2025
SAOP Review Comments:	Approved on behalf of the SAOP	**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
7/21/2025 8:41 AM	BLAND, CRYSTAL	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	7/15/2025	Per FDA's Email: Exported copy of PIA attached.	
PIA 22	BLAND, CRYSTAL	7/17/2025	Per PTA-5, select "Mailing Address (Business)," "User Credentials," and "Other: job title, FDA organization or center name and the firm name." You mention that some of the data is non-PII but all the data mention above is tied to the data of the authorized or designed personnel or they're tied to the FDA employee or direct contractors. All data is stored in the system.	