PTA / PIA: FDA - PREDICT - QTR2 - 2026 - FDA5271613

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General Information

PTA / PIA Name:	FDA - PREDICT - QTR2 - 2026 - FDA5271613	**PTA / PIA ID:**	4608662
Component Name:	FDA - OII Predictive Risk-based Evaluation for Dynamic Import Compliance Tracking	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	17
Submitter:		**Submit Date:**	6/24/2026
Next Assessment Date:	07/09/2029	**Expiration Date:**	7/9/2029
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	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 changes to Predictive Risk-based Evaluation for Dynamic Import Compliance Tracking (PREDICT) since the last Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) 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 Office of Inspections and Investigations (OII) Predictive Risk-Based Evaluation for Dynamic Import Compliance Tracking (PREDICT) system is an internal-facing system operated by the Food and Drug Administration's (FDA's) OII. Its primary purpose is to screen imported products and provide risk-based recommendations to FDA Entry Reviewers regarding whether those products should be manually inspected before entering the United States, thereby supporting the Department of Health and Human Services' (HHS's) mission of protecting public health. PREDICT carries out its functions through a rules engine that evaluates each import product line and generates a risk estimate. Import entry lines assessed as relatively low risk are released without further review, while those flagged as higher risk are routed to Entry Reviewers through the Entry Review (ER) system for manual examination. This tiered approach allows FDA personnel to focus their inspection resources on shipments that present the greatest potential concern. To support these risk assessments, PREDICT collects and analyzes a broad range of data, including shipment and entry identification details, product classification and ingredient information, country of origin, and firm data such as FDA Establishment Identifier (FEI) numbers, registration details, and compliance histories. The system also tracks import alerts, recall information, laboratory results, and violation records, all of which inform its algorithmic scoring and risk prioritization. Additionally, PREDICT provides the OII's Import Systems Compliance Branch (ISCB) with the ability to manage the rules that govern the system's business logic, ensuring that screening criteria remain aligned with current FDA compliance priorities. Access to the system is restricted to authorized FDA personnel — including Entry Reviewers, District Office staff, System Administrators, and Compliance Program Staff — who authenticate via Single Sign-On (SSO) integrated with FDA's Active Directory (AD) system (covered in separate PIA).

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.	PREDICT collects and maintains extensive information to fulfill its core mission of risk-based screening of imported products entering the United States, enabling FDA Entry Reviewers to make informed decisions about which imports require manual inspection to protect public health. The system gathers entry and shipment data (identification numbers, dates, ports, transportation details), detailed product information (classification codes, descriptions, ingredients, country of origin), and extensive firm data including FEI numbers, names, addresses, and registration details for all parties involved in import transactions: manufacturers, importers, shippers, consignees, filers, and storage facilities. The system maintains critical compliance and enforcement history data to inform current screening decisions based on past performance, including import alert information, recall data, facility inspection records, laboratory analysis results, refusal history, and violation records with associated charge codes and problem area flags. Risk assessment data, including risk scores, percentile rankings, weighted scores, and detailed scoring breakdowns, quantifies import risks using algorithmic analysis of multiple factors, allowing entries to be prioritized by risk level. Rule and targeting information encodes FDA's compliance priorities into screening logic, defining the conditions under which entries should be examined, detained, or released based on product, firm, country, and historical risk factor combinations. Information about individuals, including names, business phone numbers, business email addresses, and business physical addresses, is collected specifically to enable necessary communication with responsible parties regarding entry status, documentation issues, sample collection coordination, and inspection scheduling. This PII is not used to retrieve records in the system; records are retrieved using entry and shipment identification numbers and other non-PII transactional identifiers. This information is collected about members of the public and regulated entity representatives involved in import transactions. Employee ID numbers and associated contact information are collected about internal FDA employees and HHS Direct Contractors to manage system access and support operational workflow. All data collection serves the integrated purposes of automated risk assessment, informed human decision-making, regulatory compliance tracking, operational workflow management, and continuous improvement of targeting effectiveness through analysis of compliance trends and screening outcomes.
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.	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.	PREDICT collects and maintains extensive information to fulfill its core mission of risk-based screening of imported products entering the United States, enabling FDA Entry Reviewers to make informed decisions about which imports require manual inspection to protect public health. The system gathers entry and shipment data (identification numbers, dates, ports, transportation details), detailed product information (classification codes, descriptions, ingredients, country of origin), and extensive firm data including FEI numbers, names, addresses, and registration details for all parties involved in import transactions: manufacturers, importers, shippers, consignees, filers, and storage facilities. The system maintains critical compliance and enforcement history data to inform current screening decisions based on past performance, including import alert information, recall data, facility inspection records, laboratory analysis results, refusal history, and violation records with associated charge codes and problem area flags. Risk assessment data, including risk scores, percentile rankings, weighted scores, and detailed scoring breakdowns, quantifies import risks using algorithmic analysis of multiple factors, allowing entries to be prioritized by risk level. Rule and targeting information encodes FDA's compliance priorities into screening logic, defining the conditions under which entries should be examined, detained, or released based on product, firm, country, and historical risk factor combinations. Information about individuals, including names, business phone numbers, business email addresses, and business physical addresses, is collected specifically to enable necessary communication with responsible parties regarding entry status, documentation issues, sample collection coordination, and inspection scheduling. This PII is not used to retrieve records in the system; records are retrieved using entry and shipment identification numbers and other non-PII transactional identifiers. This information is collected about members of the public and regulated entity representatives involved in import transactions. Employee ID numbers and associated contact information are collected about internal FDA employees and HHS Direct Contractors to manage system access and support operational workflow. All data collection serves the integrated purposes of automated risk assessment, informed human decision-making, regulatory compliance tracking, operational workflow management, and continuous improvement of targeting effectiveness through analysis of compliance trends and screening outcomes.
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://ora.fda.gov/predict
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.	PREDICT is an internal-facing FDA system designed exclusively to screen imported products and provide risk-based recommendations to FDA Entry Reviewers regarding whether products should be manually inspected before entering the United States. The system evaluates entries against comprehensive screening rules, generates risk scores and percentile rankings, analyzes multiple risk factors including firm track records and compliance history, and provides automated recommendations to support entry review decisions. Access to PREDICT is restricted to authorized FDA personnel only and is not available to the general public. Authorized users include Entry Reviewers, District Office staff, System Administrators, and Compliance Program Staff. Permissions are managed through a role-based access control (RBAC) system that assigns specific organizational affiliations and role codes to each user, ensuring that individuals can only access the minimum amount of information necessary to perform their job functions. FDA users — both employees and Direct Contractors — must obtain formal supervisor approval and signature before access is granted, and the agency reviews the system access list on a quarterly basis to adjust user roles, permissions, and account statuses as needed. Users access PREDICT through Single Sign-On (SSO) authentication integrated with FDA's Active Directory (AD) system, using a Health and Human Services (HHS) Personal Identity Verification (PIV) card for multi-factor authentication. The system is accessible only through the internal FDA network via the Uniform Resource Locator (URL) https://ora.fda.gov/predict and is not available through any public-facing URL. This restricted access is consistent with the system's function of supporting sensitive import screening decisions and its storage of confidential business information, compliance data, and enforcement-related details.
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 Biographical Information Name Contact Information Email 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.	Physical Address (Business)
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	1,000,000 or more

PIA 25:	For what primary purpose is the PII used?	The PII maintained in PREDICT is used solely for operational communication and coordination related to import compliance activities, and does not serve as a retrieval key for records in the system. Records are retrieved using entry and shipment identification numbers and other non-PII transactional identifiers. Specifically, the PII - consisting of names, business phone numbers, business email addresses, and business physical addresses - enables FDA Entry Reviewers and field staff to contact responsible parties such as filers, importers, manufacturers, and facility contacts regarding entry status, documentation deficiencies, or required actions. It also allows staff to coordinate sample collection and physical inspections by reaching individuals at storage or hold locations who can provide access to goods and ensure sample availability. Additionally, PII is used to send official correspondence - including notices of detention, refusal notifications, and requests for additional information - to the appropriate individuals and addresses. Finally, PII supports compliance resolution by enabling communication with firm representatives about regulatory requirements, affirmations of compliance, or corrective actions needed to bring imported products into conformance with FDA standards.
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 maintained in PREDICT. The PII collected and maintained by the system is used solely for the primary operational communication and coordination purposes described above, and is not used for testing, training, research, or any other secondary purpose.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The legal authorities governing information use and disclosure in PREDICT are rooted in federal food and drug law. Specifically, the system operates under the authority of the Federal Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 301, as amended by the Food Safety Modernization Act (FSMA), 21 U.S.C. 220. Relevant provisions governing the use and disclosure of information in the system can be found at 21 U.S.C. 331 and 350-387.
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.	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.	PREDICT does not have its own Office of Management and Budget (OMB) information collection approval number, as the system is intended for use by FDA internal users only and does not directly collect PII from the public. However, the system does receive information that was collected under existing OMB-approved information collections. Specifically, Prior Notice Submissions employ FDA Form 3540 under OMB approval number 0910-0520, expiring September 30, 2026. Additionally, information is received in the system after collection approved under OMB number 0910-0046, which expires August 31, 2026.
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.	The submission of PII by individuals is voluntary. Individuals provide their contact information as a practical requirement to communicate with FDA, and where appropriate, to obtain system access. While FDA requires that regulated entities supply the PII of a point of contact, that individual can be anyone who is authorized to send and receive communications on behalf of the regulated entity. There are no opt-out procedures specific to imports, though the designation of which individual serves as the point of contact remains flexible, provided that person is duly authorized to act on behalf of the regulated entity.
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 major changes to the system's PII collection or handling practices are currently anticipated. However, in the event that the FDA does change its practices regarding the collection or handling of PII related to PREDICT, the agency has outlined a general framework for providing notice and obtaining consent from affected individuals. Should such changes occur, FDA will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of their PII. These measures may include direct email communication to affected individuals, adding or updating online notices or forms, revising the Privacy Impact Assessment (PIA) for the system, or employing other available means to inform individuals of the changes. The specific approach taken would depend on the nature and scope of the changes involved, with the goal of ensuring that individuals are appropriately informed and that any required consent is obtained in a timely manner.

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 PREDICT — or who believe their PII is inaccurate — have several avenues available to resolve their concerns. The specific resources available depend on whether the individual is an FDA employee or a member of the public. FDA personnel have access to two dedicated internal resources for addressing PII concerns. The first is FDA's Employee Resource and Information Center (ERIC), which serves as an internal support channel for FDA employees and Direct Contractors. The second is the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC), which handles cybersecurity and data-related incidents for FDA personnel. For all individuals, regardless of whether they are FDA personnel or members of the public, concerns regarding the inappropriate obtaining, use, or disclosure of PII — or the accuracy of PII maintained in the system — may also be directed to the FDA Privacy Office. The FDA Privacy Office is accessible through multiple contact channels, including email, phone, and standard mail, all of which are listed on fda.gov. This ensures that all affected individuals, including members of the public and regulated entity representatives whose contact information is maintained in PREDICT, have a clear and accessible pathway to raise and resolve privacy-related concerns.

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.	The accuracy of PII maintained in PREDICT is primarily ensured through individual review at the time of reporting. Individuals are responsible for providing accurate information when it is initially submitted, and FDA personnel have the ability to correct or update their own PII as needed to ensure it remains current and correct. Data relevancy is ensured through the deliberate design of forms and webpages used to collect PII, which are structured to solicit only the information that is necessary for the system's operational purposes. Additionally, access to the system is granted and restricted at the individual level based on role-based criteria, ensuring that PII is only accessible to those whose job functions require it. OII performs annual reviews to evaluate user access, further ensuring that only relevant and necessary PII remains active in the system. The integrity of PII in PREDICT is protected through security and privacy controls selected and implemented as part of the system's Authorization to Operate (ATO) process. These controls are selected based on National Institute of Standards and Technology (NIST) guidance and are appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standard (FIPS) 199, ensuring that PII remains protected from unauthorized modification or corruption. Similarly, the availability of PII in PREDICT is safeguarded through the same ATO-based security and privacy controls, ensuring that PII remains accessible to authorized users when needed and is protected from loss or disruption. Together, these integrity and availability controls reflect a comprehensive approach to maintaining the reliability and accessibility of PII throughout the system's operational lifecycle.
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 (employees and Direct Contractors) — have access to PII in order to review, process, and manage data submissions related to import compliance activities. This access enables Entry Reviewers and field staff to perform their core responsibilities, including contacting responsible parties, coordinating inspections, and issuing official correspondence. Administrators: Administrators have access to PII for the purposes of reviewing, processing, and administering the system, its files and data, and access control functions. This access is necessary to ensure the system operates correctly and that user accounts and permissions are managed appropriately. Developers: Developers have access to PII for the purpose of troubleshooting issues related to system performance and access. This access enables developers to identify and resolve technical problems that may affect the system's functionality or the integrity of the data it maintains. Contractors: HHS/Operating Division (OpDiv) Direct Contractors have access to PII to support system administration, troubleshooting, and development activities. Direct Contractors may serve in the capacity of users, administrators, or developers with respect to the PREDICT system, and their access to PII is scoped accordingly to the specific role they perform in support of PREDICT's operational and technical functions. All contractor access to PII is governed by the same Need to Know and Minimum Necessary principles that apply to FDA employees, and applicable contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FDA users — including both employees and Direct Contractors — who require access to PREDICT must first obtain formal supervisor approval and signature before access is granted. This approval process ensures that access to PII is extended only to individuals whose job functions genuinely require it, in keeping with the Need to Know and Minimum Necessary principles that govern the system's access control framework. Once access is granted, the agency conducts ongoing oversight to ensure that user access remains appropriate over time. Specifically, the system access list is reviewed on a quarterly basis to adjust users' access roles and permissions and to delete unneeded accounts from the system. This regular review process helps ensure that individuals who no longer require access to PII — due to changes in job responsibilities, organizational reassignments, or separation from the agency — are promptly removed from the system, reducing the risk of unauthorized access to sensitive information. Additionally, OII performs annual reviews to evaluate user access, providing a further layer of oversight to ensure that access privileges remain aligned with current operational needs and organizational roles.
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.	PREDICT employs a role-based access control system to ensure that users can only access the minimum amount of PII necessary to perform their job functions. When a new user account is created, the individual's supervisor indicates on the account creation form the minimum level of access required for that user to complete their assigned responsibilities. The scope of access is then configured and restricted based on these role-based criteria, ensuring that each user's permissions are tailored to their specific organizational affiliation and job function rather than providing broad or unrestricted access to all PII maintained in the system. This role-based approach is complemented by additional technical safeguards, including multi-factor authentication, firewalls, and network monitoring and intrusion detection tools, which together help ensure that access to PII is limited to authorized users operating within their designated access parameters. Collectively, these technical methods reflect FDA's commitment to implementing the Minimum Necessary principle in the design and operation of PREDICT, ensuring that PII is accessible only to those who genuinely need it to carry out their official duties.

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 — including system owners, managers, operators, contractors, and program managers — are required to complete annual mandatory computer security and privacy awareness training. This training covers Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity, and availability, as well as the proper handling of data, including any special restrictions on data use and/or disclosure. Successful completion of this training is verified by the FDA Office of Digital Transformation (ODT), ensuring that all personnel with access to PREDICT are aware of their responsibilities for protecting the PII and other sensitive information collected and maintained by the system.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	In addition to the mandatory annual computer security and privacy awareness training required of all FDA system users, PREDICT users receive informal training on system functionality and use at the district and field office level. All users are also provided guidance on adhering to the HHS Rules of Behavior and may obtain additional instruction via FDA's privacy program as needed to supplement their understanding of their responsibilities regarding the handling of PII and other sensitive information maintained in 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).	The records handled in PREDICT are governed by a variety of records schedules specific to the nature of the records involved, with retention and destruction periods generally ranging from 10 to 30 years after an action closes or when a record is no longer needed. Database records are maintained in accordance with National Archives and Records Administration (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. Program management files are governed by a separate NARA-approved citation, N1-88-07-2, which establishes the retention and destruction guidelines applicable to that category of records. Together, these NARA-approved retention schedules ensure that PII maintained in PREDICT is retained only for as long as necessary to fulfill the system's operational and regulatory purposes, and that records are disposed of in a systematic and compliant manner once the applicable retention period has elapsed.

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 Controls: Administrative safeguards for PII in PREDICT include mandatory user training to ensure that all personnel with access to the system are aware of their responsibilities for protecting sensitive information. System documentation advises users on proper system use, and access is governed by the Need to Know and Minimum Necessary principles, ensuring that PII is accessible only to those whose job functions require it. Additional administrative controls have been selected from National Institute of Standards and Technology (NIST's) Special Publication (SP) 800-53, as determined using Federal Information Processing Standards (FIPS) 199, to ensure that the overall administrative security posture of the system is appropriate to its level of risk. Technical Controls: Technical safeguards include the use of multi-factor authentication to verify the identity of users accessing the system, ensuring that only authorized personnel can gain entry. Firewalls are employed to protect the system from unauthorized external access, and network monitoring and intrusion detection tools are in place to identify and respond to potential security threats in a timely manner. These technical controls work in concert to protect the confidentiality, integrity, and availability of PII maintained in PREDICT. Physical Controls: All system servers are located at facilities protected by a combination of physical security measures, including security guards, locked facility doors, and climate controls to safeguard the hardware infrastructure on which PREDICT operates. These physical safeguards ensure that unauthorized individuals cannot gain physical access to the servers and storage systems that house PII and other sensitive data maintained by PREDICT.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	6/24/2026
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	6/29/2026
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:**	5

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	7/6/2026
Agency Privacy Analyst Review Comments:	Reviewer: Godisgreat Peters 7/6/2026 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	7

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	7/10/2026
SAOP Review Comments:		**# of Days - SAOP Review:**	4

SAOP Signature

Date	User	Type	Name	Original Value	New Value
7/10/2026 4:47 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	6/30/2026	6/30/2026 FDA's email and PIA attached.	FW_ PTA _ PIA 5271613 is ready for APA Review.pdf OII Predictive Risk Based Evaluation for Dynamic Import Compliance Tracking SOP approved.pdf