


| General Information | | |
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| PTA / PIA Name: | FDA - OASIS - QTR3 - 2025 - FDA4949170 | PTA / PIA ID: 3494712 |
| Component Name: | FDA - OII Operational and Administrative System for Import Support | ATO Boundary Name: CDRH Scientific and Research General Support Systems |
| Overall Status: | Complete  | # of Days - Open: 7 |
| Submitter: | | Submit Date: 7/16/2025 |
| Next Assessment Date: | 07/16/2028 | Expiration Date: 7/16/2028 |
| 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 | | |
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| 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. | New |
| PTA 03: | Is the data contained in the system owned by the agency or contractor? | Agency |

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| 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. | Operational and Administrative System for Import Support (OASIS) is an internal facing single sign on (SSO) component. OASIS is a 24/7/365 system that supports the US Food and Drug Administration's (FDA) surveillance and regulatory enforcement of import products into the nation. FDA uses OASIS to assist FDA field staff with making admissibility decisions for imported commodities. |
| 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. | FDA Employees - first name, last name, email, phone number, fax number, office assigned. Members of the public - firm name, firm location, firm email, firm phone number Entry data - port of entry, date of arrival, date received, product code, product code description, quantity, value of goods, shipper, country of origin. |
| 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. | Yes, but the user credentials are maintained in a separate system: Active Directory (AD). |
| 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. | Personally Identifiable Information (PII) could be contained in a firm name (Bob Murphy's Burgers for example) and contact information from the firm could be tied back to Bob Murphy. This information is collected to identify the entries that come into the US. Entries that come into the US will be tracked and vetted before being allowed to enter the country. FDA employee PII is collected for employees to perform their duties in the system. |
| 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/forms |
| PTA 08B: | Are any of the website or online applications accessible by the public (including publicly accessible log in pages)? | No |

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| 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. | <p>OASIS (Operational and Administrative System for Import Support) is an agency-wide information system that provides automated support for the daily operations of the Office of Inspections and Investigations (OII) Field Offices and Headquarters. OASIS is a comprehensive online information system that is integrated with other strategic systems at the FDA. It supports the reengineered business processes for managed application reviews, federal/state partnerships, workload management, investigative, compliance, analytical operations, quality assurance, and other critical initiatives. OASIS is an automated FDA system for processing and making admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter domestic commerce. OASIS, in combination with a screening tool called Predictive Risk Based Evaluation for Dynamic Import Compliance Targeting (PREDICT), expedite the import review process by helping FDA reviewers evaluate the declared information. When submitting an import entry to FDA, providing accurate and complete information is critical. Doing so can expedite an admissibility decision, to the benefit of both FDA and the import community.</p> <p>Users are provided a user interface to complete this work. Users can only access the website when connected to the FDA VPN. Any FDA user can visit the site, however, to be authenticated and access OASIS, they must have the correct roles associated with their SSO account.</p> |
| 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

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| PIA 22: | Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share. | <p>Biographical Information</p> <ul style="list-style-type: none"> Name User Credentials <p>Contact Information</p> <ul style="list-style-type: none"> Email Address (Business) Mailing Address (Business) <p>Other</p> <ul style="list-style-type: none"> Other |
| PIA 22A: | Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list. | Office assigned, firm name and location. |
| PIA 23: | Indicate the categories of individuals about whom PII is collected, maintained, or shared. | <p>Employees/HHS Direct Contractors</p> <p>Members of the public</p> |
| 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? | <p>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.</p> <p>Information about FDA employees is also used to restrict system access and authenticate users.</p> <p>Name (first and last) and work contact information (email address, phone number, office address) is required for contact purposes and to document product origin and destination.</p> <p>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.</p> |
| 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. | <p>The legal authorities that govern information use and disclosures specific to the system and program are:</p> <p>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.</p> |
| PIA 29: | Are records in the system retrieved by one or more PII data elements? | No |

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| PIA 30: | Identify the sources of PII in the system. | <p>Directly from an individual about whom the information pertains</p> <ul style="list-style-type: none"> Hard Copy Mail/Fax <p>Government Sources</p> <ul style="list-style-type: none"> Within the OPDIV State/Local/Tribal Foreign <p>Non-Government Sources</p> <ul style="list-style-type: none"> Members of the Public |
| PIA 31: | Is there an Office of Management and Budget (OMB) information collection approval number? | Yes |
| PIA 31A: | Provide the information collection approval number(s) and expiration date(s). | <p>OMB Information Collection Approve Number: 0910-0520</p> <p>Expiration Date: 8/8/2026</p> |
| 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 because FDA coordinates with other government agencies such as The United States (US) Customs and Border Protection (CBP) and The US 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)). | <p>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).</p> <p>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.</p> |
| 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 |

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| <p>PIA 34:</p> | <p>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.</p> | <p>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.</p> <p>FDA employees who provide their PII for system access cannot opt-out. If an employee chooses not to provide their PII, this could impact their ability to do their job duties.</p> |
| <p>PIA 35:</p> | <p>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.</p> | <p>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.</p> |
| <p>PIA 36:</p> | <p>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.</p> | <p>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 Systems Management Center. These individuals may also contact the FDA Privacy Office via email, phone and standard mail avenues (all listed on fda.gov).</p> |
| <p>PIA 37:</p> | <p>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.</p> | <p>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).</p> <p>Design of forms and webpages to collect/solicit only necessary PII ensure data relevancy.</p> <p>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.</p> |

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| 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. | <p>Users: FDA Users have access in order to review, process, and manage data submissions.</p> <p>Administrators: Review, processing, and administering the system, files and data, and access control.</p> <p>Developers: Troubleshooting issues with the system, performance, and access.</p> <p>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.</p> |
| 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 OASIS 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. | FDA users' supervisor will 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

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| Privacy Analyst Review Decision: | Approved | Privacy Analyst Review Date: | 7/16/2025 |
| Privacy Analyst Review Comments: | | # of Days - PA Review: | 0 |

SOP Review

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| 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: | 1 |

Agency Privacy Analyst Review

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| Agency Privacy Analyst Review Decision: | Approved | Agency Privacy Analyst Review Date: | 7/17/2025 |
| Agency Privacy Analyst Review Comments: | Reviewer: Nestor Villafuerte 7/17/2025 All comment have been updated. 7/16/2025 Please see comments and update accordingly. PIA-22: Per PTA-5 and PIA-25: Please select "Mailing Address (Business), and select "Other" and include "office assigned, firm name and location" in the text box. | # of Days - APA Review: | 0 |

SAOP Review

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| SAOP Review Decision: | Approved | SAOP Review Date: | 7/17/2025 |
| SAOP Review Comments: | 7/17/2025 Approved on behalf of the SAOP | # of Days - SAOP Review: | 0 |

SAOP Signature

| Date | User | Type | Name | Original Value | New Value |
|-------------------|----------------|-----------|------------------|----------------|----------------|
| 7/17/2025 8:54 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. | OII Operational and Administrative System for Import Support (OASIS).pdf |
| PIA 22 | BLAND, CRYSTAL | 7/16/2025 | Per PTA-5 and PIA-25: Please select "Mailing Address (Business), and select "Other" and include "office assigned, firm name and location" in the text box. | |