Privacy Impact Assessment (PIA): FDA - INDST - QTR3 - 2024 - FDA3562153

Created Date: 8/16/2024 8:03 AM Last Updated: 8/28/2024 2:46 PM

## Copy PIA (Privacy Impact Assessment)

Do you want to copy this PIA ?

Please select the user, who would be submitting the copied PIA.

## Instructions

Review the following steps to complete this questionnaire:

**1) Answer questions.** Select the appropriate answer to each question. Question specific help text may be available via the icon. If your answer dictates an explanation, a required text box will become available for you to add further information.

**2) Add Comments.** You may add question specific comments or attach supporting evidence for your answers by clicking on the icon next to each question. Once you have saved the comment, the icon will change to the icon to show that a comment has been added.

**3) Change the Status.** You may keep the questionnaire in the "In Process" status until you are ready to submit it for review. When you have completed the assessment, change the Submission Status to "Submitted". This will route the assessment to the proper reviewer. Please note that all values list questions must be answered before submitting the questionnaire.

**4) Save/Exit the Questionnaire.** You may use any of the four buttons at the top and bottom of the screen to save or exit the questionnaire. The button allows you to complete the questionnaire. The button allows you to save your work and close the questionnaire. The button allows you to save your work and remain in the questionnaire. The button closes the questionnaire without saving your work.

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

## General Information

| | | | |
|---|---|---|---|
| **PIA Name:** | FDA - INDST - QTR3 - 2024 - FDA3562153 | **PIA ID:** | 2123702 |
| **Name of Component:** | FDA - CDER IND Smart Template | **Name of ATO Boundary:** | CDER Study Data Review Tools |
| **Overall Status:** |  | **PIA Queue:** | |
| **Submitter:** | | **# Days Open:** | 14 |
| **Submission Status:** | Submitted | **Submit Date:** | 8/15/2024 |
| **Next Assessment Date:** | N/A | **Expiration Date:** | 1/1/2100 |
| **Office:** | | **OPDIV:** | FDA |
| **Security Categorization:** | | **OpDiv PIA ID:** | FDA3562153 |
| **Legacy PIA ID:** | | **Make PIA available to Public?:** | Yes |

| | | |
|---|---|---|
| **1:** | Identify the Enterprise Performance Lifecycle Phase of the system. | Operations and Maintenance |
| **2:** | Is this a FISMA-Reportable system? | No |
| **3:** | Does the system have or is it covered by a Security Authorization to Operate (ATO)? | Yes |
| **4:** | ATO Date or Planned ATO Date. | 1/10/2023 |
| **5:** | Is the system or electronic information collection, agency or contractor operated? | Agency |

## PTA

### PTA

| | | |
|---|---|---|
| **PTA - 2:** | Indicate the following reason(s) for this PTA. Choose from the following options. | PIA Validation (PIA Refresh) |
| **PTA - 2A:** | Describe in further detail any changes to the system that have occurred since the last PIA. | Since this Privacy Threshold Analysis/Privacy Impact Assessment was last approved Food and Drug Administration (FDA) has added several new templates to the system, including Nitrosamine Review Template, Division of Hematology Oncology Toxicology (DHOT) Abbreviated Review Template, Pharmacology and Toxicology (PT) Consult Review Template, Health Hazard Evaluations (HHE) Consult Review Template, PT Consult Memorandum Template, Reportable Food Registry (RFR) Memorandum Template, Product-Specific Guidance(PSG) Consult Review Template, Controlled Correspondence Review Template, and Excipient Consult Review Template. |
| **PTA - 3:** | Is the data contained in the system owned by the agency or contractor? | Agency |

| | | |
|---|---|---|
| **PTA - 4:** | Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions. | The Center for Drug Evaluation and Research (CDER) Investigational New Drug (IND) Smart Template System is a Food and Drug Administration (FDA) internal-facing Web-based application. FDA/CDER pharmacology/toxicology IND and The Office of Generic Drugs (OGD) reviewers (FDA employees) use the system to capture their review notes along with the non-clinical study data included in commercial submissions.<br><br>The main purpose of the Center for Drug Evaluation and Research (CDER) Investigational New Drug (IND) Smart Template System is to automate the capture of findings described in a pharmacology/toxicology IND review of animal testing data. This data is related to an entity's development of a new drug and the submission of the research and trial/study information in support of the entity's request that FDA approve the subject new drug.<br><br>The system provides captured information in a searchable internal database. Captured review and findings data includes study title, study number, study duration, study duration units, Good Laboratory Practices (GLP) compliance information, target organs, key study findings, route of administration, species, strain, dedicated juvenile animal study, drug lot number and percentage purity, and drug information (code name, generic name, Chemical Abstract Service (CAS) registry number, pharmacologic class).<br><br>Some of the study data is imported from the FDA's non-clinical Janus system which contains information on animal studies.<br><br>The findings are captured in the system in a searchable database that CDER can use to inform future regulatory review and decision-making activities.<br><br>The system has also been enhanced to store data from a variety of relevant templates as listed below in Privacy Threshold Analysis (PTA)-5. This information is primarily meeting minutes and other documents than can be used for reference purposes by reviewers.<br><br>The users of the system are CDER pharmacology/toxicology reviewers who are FDA employees working in the CDER Office of New Drugs (OND) or Office of Generic Drugs (OGD). System maintenance is performed by FDA employees and direct contractors. Users of CDER IND Smart Template are provided access based on their specific roles. |
| **PTA - 5:** | List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored. | The system is designed to store commercial IND non-clinical animal testing study data along with pharmacology/toxicology review findings. Both non-clinical animal testing study data and pharmacology/toxicology review findings are |

considered non-PII data. The non-clinical animal testing study data includes administrative data about the relevant drug application, descriptive data about the drug, related pharmacology and toxicology information, and data about the relevant animal testing study, such as application number, review number, supporting document number, indication, drug information (code name, generic name, Chemical Abstract Service (CAS) registry number, pharmacologic class). The animal testing study data stored in the system includes study title, study number, study duration, study duration units, Good Laboratory Practices (GLP) compliance, target Organs, key study findings, route of administration, species, strain, dedicated juvenile animal study, drug lot no and purity (percentage). The animal testing study data does not include information that directly, or in combination, identifies or can be linked to an individual.

The ExecCAC Smart Minutes Final Study template collects the following PII: Committee member names. Also collects the following non-PII: date of meeting, application type and number, drug name, sponsor, background, Mouse Carcinogenicity Study, Rat Carcinogenicity Study, and Executive CAC conclusions.

The ExecCAC Smart Minutes Protocol template collects the following PII: FAX sender name (FDA), sending FAX number (FDA), FAX recipient name (Company), receiving FAX number (Company), FDA contact phone number, Company contact phone number, Committee member names. It also contains the following non-PII: date, company name, subject, total FAX pages, comments, date of meeting, application type and number, drug name, sponsor, background, Mouse Carcinogenicity Study Dose Selection, Rat Carcinogenicity Study Dose Selection, Executive CAC Recommendations and Conclusions.

The Final Carcinogenicity Protocol Modification template collects the following PII: reviewer name. Also collects the following non-PII: Date, Application Number, Division, Associated Applications and Divisions, Product and Indication, Pharmacology/ Drug Class, Sponsor, Study Type, Date of ECAC Dose Concurrence, Doses + Control group(s), Dose Selection Basis, Current Week of Study, Sponsor's Request (Dose Adjustment or Early Termination), Sponsor Rationale, Division's Proposed Response, Exec CAC Recommendation for Response, and Additional Comments.

The Final Carcinogenicity Risk Assessment template collects the following PII: Reviewer Name. Also collects the following non-PII: Date, Application Number, Division, Associated Applications and Divisions, Product and Indication, Pharmacology, Sponsor, Sponsor Rationale, Additional rationale/ information, Division Recommendation and Justification, Exec CAC Recommendation, Is Assessment Adequate Without a Carcinogenicity Study, and Additional Comments.

The Final PTCC Meeting Minutes template collects

the following PII: Attending Members and Guests. Also collects the following non-PII: date, topics discussed, referenced documents, and time adjourned.
The Final Subcommittee Consult template collects the following PII: Requester Name (FDA), Committee Members. Also collects the following non-PII: Subcommittee name, date, subject, question to the committee, background and relevant data, committee response, final recommendation.
The OTC Monograph template collects the following PII: Reviewer, Supervisor, Division Director, Project Manager. Also collects the following non-PII data: CDER Receipt Date, OTC Monograph, Stage of Monograph, purpose of review, reviewer completion data, GRAS category, proprietary data flag, and date of study initiation.
The Smart Memo template collects the following PII: Author name. Also collects the following non-PII: date, category, subject, and memo/summary statement.
The Nitrosamine Review Template collects the following PII: Reviewer, Supervisor/Team Leader, Project Manager. It also collects the following non-PII data: Application Number, Supporting Document Number/s, CDER Receipt Date, Sponsor, Product, Pharmacologic Class, Indication, Therapeutic area, Clinical Review Division, Pharm/Tox Division, Purpose of Review, Alternative Assays, Reviewer Completion Date, Chemical Information.
The DHOT Abbreviated Review Template collects the following PII: Reviewer, Supervisor/Team Leader, Project Manager. It also collects the following non-PII data: Application Number, Supporting Document Number/s, CDER Receipt Date, Sponsor, Product, Pharmacologic Class, Indication, Therapeutic area, Clinical Review Division, Pharm/Tox Division, Purpose of Review, Alternative Assays, Reviewer Completion Date, Clinical Relevance, and Nonclinical Summary.
The PT Consult Review Template collects the following PII: Pharmacology-Toxicology Primary Reviewer, Pharmacology-Toxicology Secondary Reviewer, Tertiary Reviewer, To (addressee). It also collects the following non-PII data: Drug Substance/Product, Applicant, DMF#/ANDA#, RLD#/Approval Date, Sponsor, Reason for Consult, Impurity Chemical Name, Date of Submission, Date Consult Received, Date of Completion, Conclusion, Deficiency Classification, and PT Consult Review.
The HHE Consult Review Template collects the following PII: Pharmacology-Toxicology Primary Reviewer, Pharmacology-Toxicology Secondary Reviewer, Tertiary Reviewer, To (addressee). It also collects the following non-PII data: Drug Substance/Product, Applicant, DMF#/ANDA#, RLD#/Approval Date, Sponsor, Reason for Consult, Impurity Chemical Name, Date of Submission, Date Consult Received, Date of Completion, Conclusion, Deficiency Classification, and Impurity Toxicology Summary.
The PT Consult Memorandum Template collects the following PII: Pharmacology-Toxicology

| | | |
|---|---|---|
| | | Primary Reviewer, Pharmacology-Toxicology Secondary Reviewer, Tertiary Reviewer, To (addressee). It also collects the following non-PII data: Drug Substance/Product, Applicant, DMF#/ANDA#, RLD#/Approval Date, Sponsor, Reason for Consult, Impurity Chemical Name, Date of Submission, Date Consult Received, Date of Completion, Conclusion, Deficiency Classification, and Consultation Review.<br>The RFR Memorandum Template collects the following PII: Pharmacology-Toxicology Primary Reviewer, Pharmacology-Toxicology Secondary Reviewer, Tertiary Reviewer, To (addressee). It also collects the following non-PII data: Drug Substance/Product, Applicant, DMF#/ANDA#, RLD#/Approval Date, Sponsor, Reason for Consult, Impurity Chemical Name, Date of RfR Submission, Date Consult Received, Date of RfR Memo Completion, Reconsideration Request, Grant or Deny Decision, and RFR Memorandum.<br>The PSG Consult Review Template collects the following PII: Pharmacology-Toxicology Primary Reviewer, Pharmacology-Toxicology Secondary Reviewer, Tertiary Reviewer, To (addressee). It also collects the following non-PII data: Drug Substance/Product, Applicant, DMF#/ANDA#, RLD#/Approval Date, Sponsor, Reason for Consult, Impurity Chemical Name, Date of Submission, Date Consult Received, Date of Completion, Conclusion, Deficiency Classification, and PSG Consult Review.<br>The Controlled Correspondence Review Template collects the following PII: Pharmacology-Toxicology Primary Reviewer, Pharmacology-Toxicology Secondary Reviewer, Tertiary Reviewer, To (addressee). It also collects the following non-PII data: Drug Substance/Product, Applicant, DMF#/ANDA#, RLD#/Approval Date, Sponsor, Reason for Consult, Impurity Chemical Name, Date of Submission, Date Consult Received, Date of Completion, Conclusion, Deficiency Classification, and Controlled Correspondence Review.<br>The Excipient Consult Review Template collects the following PII: Pharmacology-Toxicology Primary Reviewer, Pharmacology-Toxicology Secondary Reviewer, Tertiary Reviewer, To (addressee). It also collects the following non-PII data: Drug Substance/Product, Applicant, DMF#/ANDA#, RLD#/Approval Date, Sponsor, Reason for Consult, Impurity Chemical Name, Date of Submission, Date Consult Received, Date of Completion, Conclusion, Deficiency Classification, and Excipient Consult Review. |
| **PTA - 5A:** | 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. The system providing credentials is |
| **PTA - 5B:** | Please identify the type of user credentials used to access the system. | |

| | | |
|---|---|---|
| **PTA - 6:** | Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual. | The system collects the information to create a fully searchable database that can be used to support FDA's mission of consistent review process by informing future regulatory review and decision-making activities. The system allows users to download a blank smart template, enter non-clinical study data and review notes, upload the template with entered data, and perform search, query and reporting using the uploaded study data.<br>Collected non-clinical study (performed using animal testing information) data includes application number, review number, supporting document number, indication, drug information (code name, generic name, CAS registry number, pharmacologic class), and pharmacology and toxicology information. The animal testing study data stored in the system includes study title, study number, study duration, study duration units, Good Laboratory Practices (GLP) compliance, target organs, key study findings, route of administration, species, strain, dedicated juvenile animal study, drug lot number and purity. The animal testing study data is generated from the non-clinical study phase of a new drug development by a drug company. When a drug company seeks the FDA's approval for a new drug, they must conduct the non-clinical animal testing study phase which is regulated by the FDA. The drug company submits an IND submission (also known as an application), including animal testing study data, to seek FDA's approval to move into the clinical study which is the next phase of a new drug development. The FDA/CDER pharmacology/toxicology IND reviewers use the IND Smart Template system to capture their review notes along with the non-clinical study data related to commercial IND submissions.<br>User access credentials are not entered in the template. User access and system use are restricted based on the user's individual access permission.<br>System users are authenticated by FDA enterprise-wide PIV-based Single Sign-On. The system provides role-based security to restrict users' access to different system functionalities.<br>Once a user is successfully authenticated by FDA Single Sign-On, the system employs different user roles (i.e., regular users versus administrators) to control each user's permissions for performing different system functionalities. Users of CDER IND Smart Template are provided access based on their specific roles. To maintain a role-based security, the following PII information is collected and stored by CDER IND Smart Template: FDA Network Account Name, name and FDA email address. The source of the PII is FDA Active Directory which is part of another system that is the subject of a separate assessment. The system utilizes the FDA Network Account Name temporarily and does not store this data element in the system. |
| **PTA - 7:** | Does the system collect, maintain, use or share PII? | Yes |

| | | |
|---|---|---|
| **PTA - 7A:** | Does this include Sensitive PII as defined by HHS? | No |
| **PTA - 8:** | Does the system include a website or online application? | No |
| **PTA - 8A:** | Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)? | |
| **PTA - 9:** | 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. | |
| **PTA - 10:** | Does the website have a posted privacy notice? | |
| **PTA - 11:** | Does the website contain links to non-federal government websites external to HHS? | |
| **PTA - 11A:** | Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS? | |
| **PTA - 12:** | Does the website use web measurement and customization technology? | |
| **PTA - 12A:** | Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII. | |
| **PTA - 13:** | Does the website have any information or pages directed at children under the age of thirteen? | |
| **PTA - 13A:** | Does the website collect PII from children under the age thirteen? | |
| **PTA - 13B:** | Is there a unique privacy policy for the website and does the unique privacy policy address the process for obtaining parental consent if any information is collected? | |
| **PTA - 14:** | Does the system have a mobile application? | No |
| **PTA - 14A:** | Is the mobile application HHS developed and managed or a third-party application? | |
| **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. | |
| **PTA - 16:** | Does the mobile application/ have a privacy notice? | |
| **PTA - 17:** | Does the mobile application contain links to non-federal government websites external to HHS? | |
| **PTA - 17A:** | Is a disclaimer notice provided to users that follow external links to resources not owned or operated by HHS? | |
| **PTA - 18:** | Does the mobile application use measurement and customization technology? | |
| **PTA - 18A:** | Describe the type(s) of measurement and customization technologies or techniques in use and what information is collected. | |
| **PTA - 19:** | Does the mobile application have any information or pages directed at children under the age of thirteen? | |
| **PTA - 19A:** | Does the mobile application collect PII from children under the age thirteen? | |
| **PTA - 19B:** | Is there a unique privacy policy for the mobile application and does the unique privacy policy address the process for obtaining parental consent if any information is collected? | |
| **PTA - 20:** | Is there a third-party website or application (TPWA) associated with the system? | No |
| **PTA - 21:** | Does this system use artificial intelligence (AI) tools or technologies? | No |

**PIA**

**PIA**

| | | |
|---|---|---|
| **PIA - 1:** | Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share. | Name<br>Email Address<br>Phone numbers<br>Other - Free text Field - FDA Network Account Name Fax Number |
| **PIA - 2:** | Indicate the categories of individuals about whom PII is collected, maintained or shared. | Employees/ HHS Direct Contractors |
| **PIA - 3:** | Indicate the approximate number of individuals whose PII is maintained in the system. | 201 - 500 |
| **PIA - 4:** | For what primary purpose is the PII used? | The primary purpose of the PII is to restrict users' access based on their specific roles. |
| **PIA - 5:** | 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 - 6:** | Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID. | |
| **PIA - 6A:** | Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID. | |
| **PIA - 7:** | Identify legal authorities governing information use and disclosure specific to the system and program. | All information used by the system is in support of FDA drug review activities authorized by the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 301. |
| **PIA - 8:** | Are records in the system retrieved by one or more PII data elements? | No |
| **PIA - 8A:** | Please specify which PII data elements are used to retrieve records. | |
| **PIA - 8B:** | 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. | |
| **PIA - 9:** | Identify the sources of PII in the system. | Government Sources<br>Within the OPDIV |
| **PIA - 10:** | Is there an Office of Management and Budget (OMB) information collection approval number? | Yes |
| **PIA - 10A:** | Provide the information collection approval number. | OMB No. 0910-0014 |
| **PIA - 10B:** | Identify the OMB information collection approval number expiration date. | 9/30/2026 |
| **PIA - 10C:** | Explain why an OMB information collection approval number is not required. | N/A |
| **PIA - 11:** | Is the PII shared with other organizations outside the system's Operating Division? | No |
| **PIA - 11A:** | Identify with whom the PII is shared or disclosed. | |
| **PIA - 11B:** | Please provide the purpose(s) for the disclosures described in PIA - 11A. | |
| **PIA - 11C:** | List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)). | |
| **PIA - 11D:** | 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. | |
| **PIA - 12:** | Is the submission of PII by individuals voluntary or mandatory? | Voluntary |
| **PIA - 12A:** | If PII submission is mandatory, provide the specific legal requirement that requires individuals to provide information or face potential civil or criminal penalties. | |

| | | |
|---|---|---|
| **PIA - 13:** | Describe the method for notifying individuals that their information will be collected and how they can opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason. | There are no opt-out procedures specific to CDER IND Smart Template. Individuals provide their contact information as a practical requirement in order to communicate with employed by FDA and to gain access to the system. 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 personnel whose PII is captured in the system cannot perform their duties if they opt-out of providing their PII. |
| **PIA - 14:** | Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained. | If FDA changes its practices regarding the collection or handling of PII that impacts IND Smart Template system, the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include e-mail to individuals, adding or updating online notices or forms, or other available means to inform the individual. |
| **PIA - 15:** | Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not. | Individuals who suspect their PII has been inappropriately obtained, used, or disclosed in any FDA system have a number of avenues available to resolve their concerns. These individuals may contact their supervisor, the FDA Privacy Office, the FDA's Systems Management Center, use the Employee Resource Information Center (ERIC) phone and email, or contact other FDA offices via email, phone and standard mail avenues (all listed on fda.gov).<br><br>Employees may also report suspected data breaches and obtain assistance through FDA's Employee Resource Information Center (ERIC), FDA's Systems Management Center (SMC), and FDA's Privacy Office. HHS and FDA policy obligates all permanent and Direct Contractor personnel to rapidly report suspected breaches. Within FDA, all reports of suspected breaches must be reported to the SMC. |

| | | |
|---|---|---|
| **PIA - 16:** | Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not. | Individuals voluntarily provide their PII. 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. PII relevancy is supported through the design of the system and forms to require and collect only the PII elements necessary to administer the system and enable its intended use. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Integrity and availability are protected by privacy and security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on 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. CDER IND Smart Template performs annual reviews to evaluate user access. |
| **PIA - 17:** | Identify who will have access to the PII in the system. | Administrators<br>Developers<br>Contractors |
| **PIA - 17A:** | Select the type of contractor. | HHS/OpDiv Direct Contractors |
| **PIA - 17B:** | Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices? | Yes |
| **PIA - 18:** | Provide the reason why each of the groups identified in PIA - 17 needs access to PII. | Administrators-Monitor the system activities and manage system access permissions.<br><br>Developers-For the purpose of developing and managing the system.<br><br>Contractors-Direct contractors provide support to the system. |
| **PIA - 19:** | Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII. | FDA users and Direct Contractors with valid network accounts who require access to the system must obtain supervisory approval and signature before access is granted. The agency reviews the system access list on a quarterly basis to adjust users' access roles and permissions and delete unneeded accounts from the system. |
| **PIA - 20:** | Describe the technical methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job. | The relevant supervisor will indicate on the user account creation form the minimum access that is required in order for the user to complete his/her job. The scope of access is restricted based on role-based criteria. |

| | | |
|---|---|---|
| **PIA - 21:** | Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained. | All system users at FDA take annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity, and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure). The FDA Office of Information Management and Technology (OIMT) verifies that individuals successfully complete the training. |
| **PIA - 22:** | Describe the training system users receive (above and beyond general security and privacy awareness training). | Personnel are trained on the use of the system and the HHS Rules of Behavior. Additional role-based training is available via FDA's Privacy Office. |
| **PIA - 23:** | Describe the process and guidelines in place with regard to 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 PII information in the system is covered under the General Records Schedule 3.2 "Information Security Systems Records", Item 31, "Systems requiring special accountability for access." The disposition instruction is to "destroy 6 years after password is altered or user account terminated but longer retention is authorized if required for business needs." The disposition authority is under DAA-GRS-2013-0006-0004. |
| **PIA - 24:** | Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response. | 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.<br><br>Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools.<br><br>Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls.<br><br>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 & Comments

### Privacy Analyst Review

| | | | |
|---|---|---|---|
| **OpDiv Privacy Analyst Review Status:** | Approved | **Privacy Analyst Review Date:** | 8/15/2024 |
| **Privacy Analyst Comments:** | | **Privacy Analyst Days Open:** | |

### SOP Review

| | | | |
|---|---|---|---|
| **SOP Review Status:** | Approved | **SOP Signature:** | |
| **SOP 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. | **SOP Review Date:** | 8/16/2024 |
| | | **SOP Days Open:** | 1 |

### Agency Privacy Analyst Review

| | | | |
|---|---|---|---|
| **Agency Privacy Analyst Review Status:** | Approved | **Agency Privacy Analyst Review Date:** | 8/23/2024 |
| **Agency Privacy Analyst Review Comments:** | Reviewer: Shanai Shobowale<br><br>This PIA is ready for SAOP review and approval. | **Agency Privacy Analyst Days Open:** | 7 |

### SAOP Review

| | | | |
|---|---|---|---|
| **SAOP Review Status:** | Approved | **SAOP Signature:** | Archer Signature_Bridget Guenther.docx |
| **SAOP Comments:** | | **SAOP Review Date:** | 8/28/2024 |
| | | **SAOP Days Open:** | 5 |

### Supporting Document(s)

| Name | Size | Type | Upload Date | Downloads |
|---|---|---|---|---|
| No Records Found | | | | |

### Comments

| Question Name | Submitter | Date | Comment | Attachment |
|---|---|---|---|---|
| No Records Found | | | | |

## Admin Section

| | | | |
|---|---|---|---|
| **Is OpDiv Privacy Analyst Approved ?:** | 1 | **Is OpDiv Privacy Analyst Return ? :** | 0 |
| | | **Is SOP Return ?:** | 0 |
| **Is Agency Privacy Analyst Approve ?:** | 1 | **Is Agency Privacy Analyst Return ?:** | 0 |
| **Is SAOP Approved?:** | 1 | **Is SAOP Return ?:** | 0 |
| **Total Approved:** | 4 | **Total Return:** | 0 |
| **Total Approval Required:** | 4 | | |

## Miscellaneous Fields

| | | | |
|---|---|---|---|
| **Last Updated:** | 8/28/2024 2:46 PM | **History Log:** | View History Log |