PTA / PIA: FDA - Activity Time Reporting - QTR2 - 2025 - FDA4915790

Created Date: 4/8/2025 12:27 PM Last Updated: 4/9/2025 12:28 PM

General Information

PTA / PIA Name:	FDA - Activity Time Reporting - QTR2 - 2025 - FDA4915790	**PTA / PIA ID:**	2984560
Component Name:	FDA - CVM Activity Time Reporting	**ATO Boundary Name:**	CVM Corporate Database Portal
Overall Status:	Complete	**# of Days - Open:**	1
Submitter:		**Submit Date:**	4/8/2025
Next Assessment Date:	04/08/2028	**Expiration Date:**	4/8/2028
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)?	No
General 04:	ATO Date or Planned ATO Date.	8/26/2022
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	Margaret Zabriski
PTA 01A:	POC Title and Organization	POC Title: Business Process Improvement Manager POC Organization: DHHS/FDA/CVM/OM
PTA 01B:	POC Email Address	Margaret.Zabriski@fda.hhs.gov
PTA 01C:	POC Phone Number	240-402-0561
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.	There have been no privacy related changes to the system since the last Privacy Impact Assessment (PIA) was completed.
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 Corporate Database Portal system (CDP) is a web-based application consisting of several integrated modules sharing a common database used by Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) employees to track and report on their work. CDP uses web services to share data and integrate with other FDA/CVM systems. The system supports activities related to pre-market approval of animal drugs and animal food additives, post-market animal drug safety surveillance activities, compliance activities, export certificate activities, animal drug listings and establishment registrations, bioresearch monitoring of animal drug studies, time reporting tracking, and minor use/minor species drug index files.
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.	CDP contains information on pre-market animal drugs and feeds such as research sponsor name (corporate owner), active drug ingredients, indications for use, and relevant species; post-market safety of animal drugs and feeds (such as adverse drug events and drug experience reports); animal drug products and related establishments (i.e., manufacturers and distributors); employees' daily activities and times worked, animal drug research monitoring (clinical investigators, contract research labs, manufacturing sites). correspondence contacts; export certificates; regulatory actions; and similar FDA programs administered by CVM. The system collects this information to track the drug approval process and other administrative functions performed by CVM in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act). The personally identifiable information (PII) in this system consists of name and professional contact information, such as office address, email address and phone number of clinical investigators and research sponsor personnel serving as the sponsoring entity’s point of contact for interaction with FDA and animal owners. Additionally, the system collects and maintains name and office phone number of CVM personnel who use CDP. PII about CVM personnel using CDP is collected for activity time reporting and other administrative purposes. Submission of this information is required in order to comply with the FD&C Act. The only individuals who can access the CDP system are CVM employees including direct contractors who have been approved as CDP users. Once approved, CDP users access the system via a single sign-on (SSO) process using multi-factor authentication. CDP does not require, use, collect or maintain system-specific user logon

PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS/OpDiv PIV Card
PTA 06:	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	CDP is the CVM's main transactional database that supports various data applications for CVM divisions such as CVM's Office of New Animal Drug Evaluation (ONADE), Office of Surveillance and Compliance (OSC), Office of Research (OR), Office of Minor Use, Minor Species (OMUMS), and Office of Management (OM). It is comprised of three application systems: CDP, CDP-Web, and the Compliance Log system (LOG). It is a relational database system consisting of several subsystems. CDP supports common data tables with, and provides a link to, CVM's Corporate Document Management System (CDMS). CDP is the entry portal for six modules for data entry, data storage, data tracking and reporting throughout CVM: Submission Tracking and Reporting System (STARS), Drug Experience Reporting System (DERS), Drug Product Listing (DPL), Bioresearch Information Monitoring (BIMO), Minor Use/Minor Species (MUMS) Index File System (MIFS), and Activity Time reporting (ATR). These CDP modules support pre-market and post-market business processes related to safety, product quality, administrative, food safety, drug indexing, bioresearch monitoring, and compliance. They enable FDA to administer and manage the review and processing of data necessary to ensure the quality and safety of animal drugs. This includes processing animal drug application submissions, maintaining post-market animal drug and feed safety reporting information, and performing internal accounting tasks. CDP-Web is the Java-based version of the user interface, currently providing access exclusively to STARS. The Compliance Log System (LOG) used by the Division of Compliance consists of three modules: (1) The Correspondence Tracking module that tracks correspondence received by the division with regard to animal drugs and provides various internal reports; (2) The Regulatory Action module that tracks regulatory actions taken against a company or person subject to animal drug regulations (various types of reports are available for management use); and (3) The Export Certificate Logging module that tracks information related to requests for animal drug and animal food/feed export certificates. Information from this module is sent to the Office of Financial Management (OFM) to invoice those external customers requesting certificates for billing purposes.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	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.	Biographical Information Name Contact Information Email Address (Business) Mailing Address (Business) Phone Numbers (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.	50,000 – 99,999
PIA 25:	For what primary purpose is the PII used?	PII about FDA is used for time reporting. PII about members of the public is used as professional contact information, namely regulatory contacts for external stakeholders doing business with FDA.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	N/A-FDA has no secondary use for PII.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	Information in this system is collected, used and disclosed pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301. Provisions of the FFDCA require regulated entities to maintain records and submit reports to FDA and CVM, e.g., sections 360b (1), 360cc and 379.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No
PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Online Government Sources Within the OPDIV Non-Government Sources Members of the Public Private Sector
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).	0910-0284, 08/31/2026 0910-0032, 08/31/2025 0910-0645, 08/31/2026 0910-0498, 06/30/2027
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.	Within HHS

PIA 32B:	For each disclosure, name the organizations/systems the system shares PII with and the purpose(s) of the disclosure.	The PII is shared and disclosed with FDA's Office of Financial Management (OFM). Sharing is restricted to need-to-know for the performance of authorized agency activities.
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)).	None. Disclosures are within FDA and restricted to need-to-know for the performance authorized agency activities.
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.	FDA does not expect or plan to disclose records in this system to any individuals or entities outside of FDA. This is not a Privacy Act system of records, and the Act does not require that FDA/CVM maintain an accounting of disclosures.
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.	In many cases, submission of information to this system is required in order to conduct business related to animal feed and drugs in the United States. Clinical investigators, veterinarians, animal owners and other external submitters receive notice as displayed on the submission forms; on fda.gov where the various submission processes are described and where a link to the FDA privacy policy is permanently displayed; and within the relevant statute, regulations and related Federal Register notices. In addition, certain submission forms provide for submitter confidentiality or allow the submitter to choose whether his/her identity is disclosed to the manufacturer of a drug about which an adverse event or problem report is submitted. For employees, there is not a notice/consent or optout process specific to the CDP system. At the time of hire, CVM personnel are given notice of and consent to FDA's use of their professional information in relation to their work as a federal/FDA employee. They can update and correct the information at any time through existing procedures.
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.	If FDA changes its practices with regard to the collection or handling of PII related to the CDP system, the Agency will employ 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 36:	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have several options available to resolve the situation. These individuals may contact the office or division where they have determined that their information is held. Individuals may then make further requests for their information to be corrected or amended. FDA considers these requests and, if appropriate, makes the requested changes. Employees with such concerns can additionally work with their supervisors, the Privacy Office, a 24-hour technical assistance line, FDA's Systems Management Center, and other channels. Contact information for these offices and resources is available across FDA's internet and intranet pages.
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.	An individual's PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Incorrect data is corrected in the course of FDA/CVM's use of the system/information, e.g., updating name and phone number for entity point of contact. Accuracy is ensured by individual review at the time of submission. FDA personnel may correct/update their information themselves. Individuals external to the FDA, may contact the FDA through phone or email to correct their PII. PII relevancy is ensured by the design of forms, web pages and other data collection methods to allow only for the submission of PII that is essential for necessary and authorized uses. Access to PII 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 National Institute of Standards and Technology (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. CVM performs annual reviews to evaluate user access.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators 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 - Receive, review, manage and track submissions. Some of the users are Direct Contractors. Administrators - Monitor the system, manage the workflow and system access. Contractors - refers to FDA Direct Contractors who receive, review, manage and track submissions.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Users who require access to the information system must obtain written supervisor approval and sign off before access is granted. The user's supervisor will indicate on the account creation form the minimum information system access that is required in order for the user to complete his/her job.
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.	All users of the system may require access to any and all PII in the system. While access requires authorization, all users need and have access to all PII. The access list for the information system is reviewed on a semi-annual basis during which time users' access permissions are reviewed/adjusted, and unneeded accounts are purged from the system.
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 complete 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 training has been successfully completed.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	No additional system-specific training is received by users; however, users are provided with user guides and manuals, and privacy guidance is available on the FDA intranet and from Privacy staff.
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).	There is currently no records schedule in place. A job request seeking an approved retention schedule is in development for submission to the National Archives for approval. Records are kept indefinitely until a NARA approve retention schedule has been established. Once the Agency has received notice from the National Archives, CVM will update the PIA with the appropriate records schedule.

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 multifactor 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 NIST's Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	4/8/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	4/8/2025
SOP Review Comments:	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	**# of Days - SOP Review:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	4/9/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 4/9/2025 External PIA was Approved 4/3/2025. PIA is now in Archer ready for approval.	**# of Days - APA Review:**	1

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	4/9/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
4/9/2025 11:22 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
No Records Found				