PTA / PIA: FDA - IERS - QTR4 - 2025 - FDA4995275

Created Date: 10/21/2025 4:37 PM Last Updated: 11/20/2025 3:32 PM

General Information

PTA / PIA Name:	FDA - IERS - QTR4 - 2025 - FDA4995275	**PTA / PIA ID:**	3927100
Component Name:	FDA - CVM Information Exchange Repository Service	**ATO Boundary Name:**	CVM Pharmacovigilance Workflow Manager
Overall Status:	Complete	**# of Days - Open:**	30
Submitter:		**Submit Date:**	10/21/2025
Next Assessment Date:	11/19/2028	**Expiration Date:**	11/19/2028
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.	3/6/2023
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	System Owner FDA/CVM
PTA 01B:	POC Email Address	Sabrina.Mosley@fda.hhs.gov
PTA 01C:	POC Phone Number	240-402-5237
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

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 United States Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) Information Exchange Repository Service (IERS) validates electronically submitted eXtensible Markup Language (XML) files to verify they adhere to Health Level Seven (HL7) format standards for Adverse Drug Events. IERS, as part of the CVM Pharmacovigilance Workflow Manager (PV Works) System) (the subject of a separate assessment), will provide an acknowledgement message back to the submitter whether their submission is accepted or rejected (and why).
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.	Manufacturers, veterinarians, and individuals submit forms FDA Form 1932 (Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report) or Form 1932a (Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report - for voluntary reporting) to CVM to report an adverse event with a veterinary drug experienced by an animal. Information provided to FDA in these forms includes the contact information of the person making the report (reporter) who will most often be a veterinarian or other health care professional but who may also be an animal owner or other member of the public. Contact information will include first and last name, phone number (work/professional or personal), email address (work/professional or personal) and mailing address (work/professional or personal). Submissions also include a description of the adverse event, an adverse event identification number, and any information regarding the animal that suffered the adverse event (e.g., description of the animal, medical and drug information). The information received is contact information from the persons submitting the adverse event reports (adverse events to animal drugs). The contact information is not for our CVM safety reviewers. The adverse event reports could come directly from consumers (pet owners, veterinarians), or the reports could be from industry pharmacovigilance representatives. The personally identifiable information (PII) data is retained indefinitely. CVM IERS validates the electronically submitted forms to verify they adhere to HL7 format standards for Adverse Drug Events. IERS will provide an acknowledgement message back to the submitter whether their submission is accepted/rejected and why. The only individuals who can access CVM PV Works are FDA employees or Direct Contractors who have been approved as PV Works (Vet) users. They must submit their name, work email address and work phone number in order to have their account created. FDA employees and Direct Contractors use the Single Sign-On on option to access the system after their account is created.

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.	CVM IERS is a component of the PV Works system, which is a data repository and analytical tool suite. CVM veterinarian safety reviewers use this system to evaluate the safety of animal drugs based on reported adverse events and the related information submitted to the agency in forms FDA 1932 and 1932a. The agency receives these reports electronically through the FDA Electronic Submissions Gateway (ESG), (the subject of a separate assessment) and by mail. The information received is contact information from the persons submitting the adverse event reports (adverse events to animal drugs). The contact information is not for the CVM safety reviewers. The adverse event reports could come directly from consumers (pet owners, veterinarians), or the reports could be from industry pharmacovigilance representatives. Because PV Works (Vet) tracks adverse events in animals, the system organizes data primarily according to the active ingredient or the name of the manufacturer. FDA uses the collected data to generate monthly reports that are provided to the public via OpenFDA. These reports list adverse events according to the active ingredient and the animal species. CVM IERS or PV Works (Vet) does not use any personal identifiers to retrieve records.
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 (Personal) Mailing Address (Personal) Phone Numbers (Personal) 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.	100,000 – 999,999
PIA 25:	For what primary purpose is the PII used?	The personally identifiable information (PII) collected in the system is used to contact the manufacturer, the veterinarian, or the individual who submitted the report. CVM may contact these individuals to follow up on their submission, clarify information, or request additional information regarding the adverse event. The CVM reviewer name and contact information is collected for internal workflow management purposes.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA makes no secondary use of the PII.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The legal authorities that govern information use and disclosures specific to the system and program are Federal Food, Drug, and Cosmetic Act: 21 U.S.C. 301, see e.g., section 360b.
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 Email 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).	For both forms FDA 1932 and 1932a, the OMB information collection approval number is OMB 0910-0284. Expiration date: 8/31/2026
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.	Private Sector
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 reporters who receive a notice on the Confidentiality Statement on the form for self-reporters informing them that the reporter's identity, including the identity of self-reporter, may be shared with the manufacturer unless requested otherwise. Manufacturers may contact reporters to ask questions and follow up on their submission.

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
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.	All external requests for copies of individual adverse drug event reports from CVM's adverse event database are routed to CVM Freedom of Information (FOI) staff for processing. CVM FOI staff review the reports and redact PII.
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.	Manufacturers are required to submit form FDA 1932 to report an adverse event. Individuals (e.g., manufacturer point of contact) cannot opt-out of this collection. The PII is necessary for monitoring and analyzing adverse event reports and product complaints. Veterinarians or members of the public who would report using form FDA 1932a, provide PII voluntarily. They may decline to report or to include PII in a report. CVM safety reviewers may not opt-out of the system's use of their name as the assigned reviewer. This information is necessary to monitor and manage event reports and product complaints.
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 PV Works 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 email 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 may contact FDA or CVM by phone, mail or email using the contact information provided on fda.gov and the specific fda.gov web pages associated with the adverse event reporting program. CVM safety reviewers who have a concern may contact their management, the FDA Privacy Office or seek assistance via FDA's Employee Resource Information Center (ERIC).

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.	Reporter's PII is provided voluntarily by the individual. 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). Integrity and availability are protected by security controls selected and implemented in the course of providing the system with an authorization 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, track and analyze adverse event data as part of their safety reviews. Some of the users may be Direct Contractors. Administrators monitor the system and database. Direct Contractors may see adverse data as part of their contractual responsibilities in resolving system and data related problems.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	System access requests are reviewed and approved by the system/business owner along with the PV Works management team. System accounts are reviewed regularly to determine if access is still required for each user. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).
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.	Supervisors apply least privilege access and role-based access control to ensure the minimum information system access that is required in order for the user to complete his/her job. The access list for the information system is reviewed on a quarterly basis and 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 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 Digital Transformation (ODT) verifies that training has been successfully completed.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	The Users are provided with a User's Guide for PV Works.
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 specific National Archives and Records Administration (NARA) records schedule is FDA-wide records schedules: file codes 6100-6135 regarding Adverse Event/Experience and Product Defect Reports Records in these files are covered by either NARA Citation No. N1-88-07-2 or General Records Schedules 3.1, 4.1, 5.4, 5.5, and 5.6. Most records are temporary with destruction schedules between 10 and 30 years, or when no longer needed.
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.	The FDA secures PII in the system as follows: Administrative safeguards include user training, system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	10/21/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	10/21/2025
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:**	11/17/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 11/17/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	27

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	11/20/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	3

SAOP Signature

Date	User	Type	Name	Original Value	New Value
11/20/2025 11:05 AM	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	VILLAFUERTE, NESTOR	11/3/2025	Archer sync issue with ATO. Q3 is stating "No" although the ATO date stated is valid.	
PTA 01	BLAND, CRYSTAL	11/17/2025	11/17/2025 Per FDA email on 10/21/2025 **The ATO date is 3/6/2023.**	10-21-2025 EMAIL_IERS_RE_ PIA ready for Privacy Analyst Review.pdf