

## 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

<b>PIA Name:</b>	FDA - PVWorks - QTR1 - 2024 - FDA2125117	<b>PIA ID:</b>	1752134
<b>Name of Component:</b>	FDA - CVM Pharmacovigilance Workflow Manager	<b>Name of ATO Boundary:</b>	CVM Pharmacovigilance Workflow Manager
<b>Overall Status:</b>		<b>PIA Queue:</b>	
<b>Submitter:</b>		<b># Days Open:</b>	59
<b>Submission Status:</b>	Submitted	<b>Submit Date:</b>	1/4/2024
<b>Next Assessment Date:</b>	N/A	<b>Expiration Date:</b>	3/1/2027
<b>Office:</b>		<b>OPDIV:</b>	FDA
<b>Security Categorization:</b>		<b>OpDiv PIA ID:</b>	FDA2125117
<b>Legacy PIA ID:</b>		<b>Make PIA available to Public?:</b>	Yes
<b>1:</b>	Identify the Enterprise Performance Lifecycle Phase of the system.		Operations and Maintenance
<b>2:</b>	Is this a FISMA-Reportable system?		Yes
<b>3:</b>	Does the system have or is it covered by a Security Authorization to Operate (ATO)?		Yes
<b>4:</b>	ATO Date or Planned ATO Date.		2/22/2023
<b>5:</b>	Is the system or electronic information collection, agency or contractor operated?		Agency

## PTA

### PTA

<b>PTA - 2:</b>	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)
<b>PTA - 2A:</b>	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, there have been no privacy related changes to the system. However, it has been clarified in the PIA that both personal and professional contact information may be collected.
<b>PTA - 3:</b>	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 Pharmacovigilance Workflow Manager (PV Works (Vet)) system is a consumer off-the-shelf suite of tools that consists of five modules (PV Works, PV analyzer, PV agent, PV importer, and PV admin) the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) uses as a database repository and analytical tool for adverse event reports. FDA and CVM receive these reports from external stakeholders such as animal drug manufacturers, veterinarians, and animal owners. CVM employs the system to maintain data regarding reports of drugs that have displayed Adverse Drug Events (ADE) in animals, and to track post-market use of animal drugs to ensure they are safe and effective.

<p><b>PTA - 5:</b></p>	<p>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.</p>	<p>Manufacturers, veterinarians, and individuals submit forms FDA 1932 or 1932a 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, email address and mailing address.</p> <p>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).</p> <p>The only individuals who can access the PV Works system are FDA employees 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. Once approved, PV Works users access the system using an assigned username and a temporary password. Users reset their temporary password to a password of their choosing that meets complexity standards.</p> <p>PV Works (Vet) also maintains the name of the CVM safety reviewer assigned to each adverse event report as well as any comments the reviewer may make while evaluating the report.</p> <p>CVM PV Works collects the following PII data: Name (personal), email address (work/professional or personal), telephone (work/professional or personal), and mailing address (work/professional or personal). The PII data is retained indefinitely. The information received is contact information from the persons submitting the adverse event reports (adverse events to animal drugs). The contact info 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.</p> <p>CVM PV Works collects the following non-PII data: Description of the event, adverse event Identification number, and any information regarding the animal that suffered the adverse event (description of animal, medical and drug information).</p>
<p><b>PTA - 5A:</b></p>	<p>Are user credentials used to access the system?</p>	<p>Yes</p>
<p><b>PTA - 5B:</b></p>	<p>Please identify the type of user credentials used to access the system.</p>	<p>HHS User Credentials</p> <p>HHS Username</p> <p>Password</p>

<b>PTA - 6:</b>	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.	<p>PV Works is a data repository and analytical tool suite used by CVM veterinarian safety reviewers 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 info 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.</p> <p>In addition to PV Works module there are five other modules under the PV Works (Vet) system. PV Analyzer is a signal detection and data analysis tool. PV Importer is a tool used to upload validated reports into the database. PV Agent is a module that executes scheduled system jobs to run as background processes. And, PV Admin allows for configuration of the system to meet individual FDA office/user requirements.</p> <p>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.</p> <p>PV Works (Vet) does not use any personal identifiers to retrieve records.</p>
<b>PTA - 7:</b>	Does the system collect, maintain, use or share PII?	Yes
<b>PTA - 7A:</b>	Does this include Sensitive PII as defined by HHS?	No
<b>PTA - 8:</b>	Does the system include a website or online application?	No
<b>PTA - 8A:</b>	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	
<b>PTA - 9:</b>	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.	
<b>PTA - 10:</b>	Does the website have a posted privacy notice?	
<b>PTA - 11:</b>	Does the website contain links to non-federal government websites external to HHS?	
<b>PTA - 11A:</b>	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	
<b>PTA - 12:</b>	Does the website use web measurement and customization technology?	
<b>PTA - 12A:</b>	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	
<b>PTA - 13:</b>	Does the website have any information or pages directed at children under the age of thirteen?	

<b>PTA - 13A:</b>	Does the website collect PII from children under the age thirteen?	
<b>PTA - 13B:</b>	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?	
<b>PTA - 14:</b>	Does the system have a mobile application?	No
<b>PTA - 14A:</b>	Is the mobile application HHS developed and managed or a third-party application?	
<b>PTA - 15:</b>	Describe the purpose of the mobile application, who has access to it, and how users access it. Please address each element in your response.	
<b>PTA - 16:</b>	Does the mobile application/ have a privacy notice?	
<b>PTA - 17:</b>	Does the mobile application contain links to non-federal government websites external to HHS?	
<b>PTA - 17A:</b>	Is a disclaimer notice provided to users that follow external links to resources not owned or operated by HHS?	
<b>PTA - 18:</b>	Does the mobile application use measurement and customization technology?	
<b>PTA - 18A:</b>	Describe the type(s) of measurement and customization technologies or techniques in use and what information is collected.	
<b>PTA - 19:</b>	Does the mobile application have any information or pages directed at children under the age of thirteen?	
<b>PTA - 19A:</b>	Does the mobile application collect PII from children under the age thirteen?	
<b>PTA - 19B:</b>	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?	
<b>PTA - 20:</b>	Is there a third-party website or application (TPWA) associated with the system?	No
<b>PTA - 21:</b>	Does this system use artificial intelligence (AI) tools or technologies?	No

<b>PIA</b>		
<b>PIA</b>		
<b>PIA - 1:</b>	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Name Email Address Phone numbers Mailing Address
<b>PIA - 2:</b>	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Employees/ HHS Direct Contractors Members of the public
<b>PIA - 3:</b>	Indicate the approximate number of individuals whose PII is maintained in the system.	Above 2000
<b>PIA - 4:</b>	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.

<b>PIA - 5:</b>	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	None.
<b>PIA - 6:</b>	Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID.	
<b>PIA - 6A:</b>	Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID.	
<b>PIA - 7:</b>	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., section360b.
<b>PIA - 8:</b>	Are records in the system retrieved by one or more PII data elements?	No
<b>PIA - 8A:</b>	Please specify which PII data elements are used to retrieve records.	
<b>PIA - 8B:</b>	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.	
<b>PIA - 9:</b>	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
<b>PIA - 10:</b>	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
<b>PIA - 10A:</b>	Provide the information collection approval number.	For both forms FDA 1932 and 1932a, the OMB information collection approval number is OMB 0910-0284.
<b>PIA - 10B:</b>	Identify the OMB information collection approval number expiration date.	8/31/2026
<b>PIA - 10C:</b>	Explain why an OMB information collection approval number is not required.	N/A
<b>PIA - 11:</b>	Is the PII shared with other organizations outside the system's Operating Division?	Yes
<b>PIA - 11A:</b>	Identify with whom the PII is shared or disclosed.	Private Sector
<b>PIA - 11B:</b>	Please provide the purpose(s) for the disclosures described in PIA - 11A.	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.
<b>PIA - 11C:</b>	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)).	None.

<b>PIA - 11D:</b>	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 FOI staff for processing. CVM FOI staff review the reports and redact PII.
<b>PIA - 12:</b>	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
<b>PIA - 12A:</b>	If PII submission is mandatory, provide the specific legal requirement that requires individuals to provide information or face potential civil or criminal penalties.	
<b>PIA - 13:</b>	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.	<p>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.</p> <p>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.</p> <p>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.</p>
<b>PIA - 14:</b>	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 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 e-mail to individuals, adding or updating online notices or forms, or other available means to inform the individual.
<b>PIA - 15:</b>	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 <a href="http://fda.gov">fda.gov</a> and the specific <a href="http://fda.gov">fda.gov</a> 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).

<b>PIA - 16:</b>	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.	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 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. CVM performs annual reviews to evaluate user access.
<b>PIA - 17:</b>	Identify who will have access to the PII in the system.	Users Administrators Contractors
<b>PIA - 17A:</b>	Select the type of contractor.	HHS/OpDiv Direct Contractors
<b>PIA - 17B:</b>	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
<b>PIA - 18:</b>	Provide the reason why each of the groups identified in PIA - 17 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.
<b>PIA - 19:</b>	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).
<b>PIA - 20:</b>	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.	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.

<p><b>PIA - 21:</b></p>	<p>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.</p>	<p>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 Security (OIS) verifies that training has been successfully completed.</p>
<p><b>PIA - 22:</b></p>	<p>Describe the training system users receive (above and beyond general security and privacy awareness training).</p>	<p>The Users are provided with a User's Guide for PV Works.</p>
<p><b>PIA - 23:</b></p>	<p>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).</p>	<p>The specific 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 National Archives and Records Administration (NARA) Citation No. N1-88-07-2 or General Records Schedules 20-2a, 2b, 4-7, 11a(1), 12, and 16. Most records are temporary with destruction schedules between 10 and 30 years, or when no longer needed.</p>
<p><b>PIA - 24:</b></p>	<p>Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.</p>	<p>The FDA secures PII in the system as follows:</p> <p>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.</p> <p>Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools.</p> <p>Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls.</p> <p>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.</p>

## Review & Comments

### Privacy Analyst Review

<b>OpDiv Privacy Analyst Review Status:</b>	Approved	<b>Privacy Analyst Review Date:</b>	1/4/2024
<b>Privacy Analyst Comments:</b>		<b>Privacy Analyst Days Open:</b>	

### SOP Review

<b>SOP Review Status:</b>	Approved	<b>SOP Signature:</b>	
<b>SOP Comments:</b>		<b>SOP Review Date:</b>	1/4/2024
		<b>SOP Days Open:</b>	0

### Agency Privacy Analyst Review

<b>Agency Privacy Analyst Review Status:</b>	Approved	<b>Agency Privacy Analyst Review Date:</b>	1/5/2024
<b>Agency Privacy Analyst Review Comments:</b>	Reviewer: Nestor Villafuerte All comments have been addressed. This PIA is ready for SAOP review and approval.	<b>Agency Privacy Analyst Days Open:</b>	1

### SAOP Review

<b>SAOP Review Status:</b>	Approved	<b>SAOP Signature:</b>	Signature.docx
<b>SAOP Comments:</b>	Approved on behalf of Bridget Guenther	<b>SAOP Review Date:</b>	3/1/2024
		<b>SAOP Days Open:</b>	56

### Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
CVM Pharmacovigilance Workflow Manager_SOP Approved.pdf	220459	.pdf	1/4/2024 11:44 AM	1
Email_RE PIA in queue (CVM Pharmacovigilance Workflow Manager)_1_5_2024.msg	199680	.msg	1/5/2024 2:31 PM	0

### Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 11D	VILLAFUERTE, NESTOR	1/4/2024	Please define acronym "FOI" at first instance.	

### 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:	3/1/2024 3:23 PM	History Log:	<a href="#">View History Log</a>
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