

Copy PIA (Privacy Impact Assessment)

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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 - CAFPA - QTR3 - 2024 - FDA2422541	PIA ID:	2049703
Name of Component:	FDA - CVM Corporate Animal Food Program Application	Name of ATO Boundary:	OC Digital Solution Partners Appian
Overall Status:		PIA Queue:	
Submitter:		# Days Open:	20
Submission Status:	Submitted	Submit Date:	7/23/2024
Next Assessment Date:	N/A	Expiration Date:	8/7/2027
Office:		OPDIV:	FDA
Security Categorization:		OpDiv PIA ID:	FDA2422541
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)?		No
4:	ATO Date or Planned ATO Date.		9/8/2023
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.	Conversion
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, the Center for Veterinary Medicine (CVM) in the Food and Drug Administration (FDA) made the following changes to the system: CAFPA has deployed three new modules, Veterinary Feed Directive (VFD), Out-of-Specifications (OOS), and Pet Food Tracker (PFT) in the last quarter of FY2023 and first quarter of FY2024.
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 purpose(s) of the system is CAFPA is a new CVM internal browser-based data collection application to support five CVM business workflow modules. The five-module system includes: License Application Tracking System Module, Veterinary Feed Directive Distributor Notification Module (VFD), Out-of-Specification Assay Report Module, Recall, Reportable Food Registry (RFR) & Reconditioning Module, and Pet Food Tracking Module. The application will include a vocabulary management system that will manage and control the numerous vocabularies in the five modules.

The relationship of this system to other FDA systems collections is that some of the modules pull data elements from IT systems like Emergency Operations Network (EON) and Recall Enterprise System (RES).

The key functional elements of the system include each of the modules operate as a separate unique entity. The goal of this application is to house a single repository for all five modules, while also limiting information redundancy. The application will help alleviate duplication or minimize manual cross-referencing of information. The single repository application allows for information transfer, quick reference capabilities, and assist in assessing future regulatory scenarios.

System "users" consist of Subject Matter Experts (SMEs) in animal food (all modules) and animal pharmaceutical products (recalls only). Non-SMEs within CVM personnel will have read only access and reporting once development is completed in FY2025.

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 types of information collected into the system are industry-submitted medicated feed mill license requests, notifications of intent to distribute VFD feeds, out-of-specification assay reports, recall (pharma and animal food) and reconditioning information, safety reporting for pet and animal food information, and safety reporting-related sample information.

The types of data that are maintained are internal to FDA and are indicated above. The types of data shared from the system is approved non-PII information that is shared to other public-facing systems such as ADAFDA.

The amount of time the PII is stored in the system per CFR Sec. 820.180 The record retention period is relative to the period of time equivalent to the design and expected life of the document. The CAFPA system and modules will be consolidating functions and records currently captured generated in existing tracking system databases. Retention schedules will be developed for the electronic CAFPA system, as well any other unscheduled records that are captured, created, or stored in any component module of the system. Currently the following records are classified and

scheduled under the CVM File Plan as:

1. License Application Tracking System (LATS),

CVM 11600 Facility Registrations

CVM 11610 CVM Medicated Feed Mill Licensing Files.

CVM 11611 CVM Approved Licenses.

CVM 11612 CVM Revoked Applications.

CVM 11613 CVM Medicated Feed Mill License Status Tracking System.

2. Veterinary Feed Directive Distributor Module (VFD),

No file code/schedule found unless these can be classified with the records listed above under LATS. Retention schedule and file code to be determined.

3. Out-of-specification Assay reports (OOS),

FDA 4300 Laboratory Quality Assurance Records.

4. Recall, RFR, and Reconditioning module,

FDA 7110 Recall Action Files.

5. Pet food tracking module

Not enough information yet to determine the retention yet and would need to examine the regulatory and business requirements. Retention schedule and file code to be determined.

PTA - 5A: Are user credentials used to access the system?

Yes

PTA - 5B: Please identify the type of user credentials used to access the system.

HHS User Credentials

HHS Email Address

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 information about recalls (Recall Enterprise System (RES)), reportable food registry (RFR) (Emergency Operations Network (EON)), and pet food reports (EON) are collected and maintained in order to provide a way to obtain the same information reported by the recall personnel or external customer and additional data elements entered by CVM personnel.

PII from the system/component/collection about recalls and reportable food registry pet food reports are shared internally within FDA. PII from the system about stored pet food reports are shared internally within FDA and through Freedom of Information Act (FOIA) requests that is pulled and provided for redaction to CVM's FIOA staff.

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?	Yes
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	No
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.	<p>The purpose of the website is a new CVM internal browser-based data collection application to support five CVM business workflow modules. The five-module system includes: License Application Tracking System Module, Veterinary Feed Directive Distributor Notification Module (VFD), Out-of-Specification Assay Report Module, Recall, RFR & Reconditioning Module, and Pet Food Tracking Module. The application will include a vocabulary management system that will manage and control the numerous vocabularies in the five modules. Each of the modules operate as a separate unique entity. The goal of this application is to house a single repository for all five modules, while also limiting information redundancy. The application will help alleviate duplication or minimize manual cross-referencing of information. The single repository application allows for information transfer, quick reference capabilities, and assist in assessing future regulatory scenarios.</p> <p>The following categories of individuals have access to the website and is used by CVM and other authorized FDA employees. These employees require access to names and contact information in order to implement regulatory requirements.</p> <p>Users access the website via (public URL, Login, etc.) internal URL that requires the user to be listed within the system's user management log.</p>
PTA - 10:	Does the website have a posted privacy notice?	No
PTA - 11:	Does the website contain links to non-federal government websites external to HHS?	No
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?	No
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?	No
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 Email Address Phone numbers Medical records (PHI) Mailing Address Medical Records Number Legal Documents Patient ID Number
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Employees/ HHS Direct Contractors Members of the public
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system.	Above 2000
PIA - 4:	For what primary purpose is the PII used?	The FDA uses the PII for the primary purpose to enable ongoing FDA communications with industry under CVM regulation and with the reporter.
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.	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 the regulated animal food industry to register facilities and/or are subject to inspections for compliance with requirements in 21 CFR parts 558, 507, 225, and 589.
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.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Email Online Government Sources Within the OPDIV
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA - 10A:	Provide the information collection approval number.	
PIA - 10B:	Identify the OMB information collection approval number expiration date.	
PIA - 10C:	Explain why an OMB information collection approval number is not required.	An OMB information collection approval number is not required because this is not a Paperwork Reduction Act information collection. There are no forms associated with CVM CAFPA.
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.	In the case of information for a public citizen, the information was collected in the course of an FDA investigation or submitted as part of an animal food facility registration. For animal food facilities submitting information on an OMB approved form or online system, the FDA privacy policy is displayed or available via a hyperlink. Consumers reporting a pet food problem can opt to choose anonymous in a drop-down menu when reporting information into the safety reporting portal of which this information is brought into CAFPA.
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 related to the AFRA system, the Agency will employ measures to provide any required notice and obtain consent from individuals regarding the collection or use of this PII. This may include email to individuals, adding or updating online notices or forms, or other available means from 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 several options available to resolve the situation. These individuals may contact the office or division where they have determined their information is being held. Individuals may then make requests for their information to be corrected or amended. FDA considers these requests and, if appropriate, makes the requested changes.
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.	<p>An individual's PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Incorrect data is corrected during FDA/CVM's use of the system/information, e.g., updating name of the 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.</p> <p>The process in place for periodic reviews of PII to ensure data 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.</p>
PIA - 17:	Identify who will have access to the PII in the system.	<p>Users</p> <p>Contractors</p>
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.	The reason the following groups need access to PII is that this application is still under development and so we have a group of authorized contractors working to complete development of the last module. Once development is complete, the authorized contractors will be removed from access to this application. This is expected by the end of fourth quarter FY2024.
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Only authorized users will have system access. FDA processes prevent contractor / developer staff from accessing the Production database. System requirements dictate that all CVM staff have view access to all CAFPA information including PII. A CVM employed systems administrator will grant access approvals to any other FDA staff who are not in the CVM organization.
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.	<p>The following technical methods are in place to allow those with access to PII to only access the minimum amount of information necessary to perform the job:</p> <p>User access is limited to accounts created by the administrator of the application for each specific module. Business requirements limit PII access to authorized employees, who may only see PII that is explicitly shared by public industry.</p>
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 FDA system users complete annual FDA information 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 - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	Some example trainings available to all HHS personnel include Records Management Training and Dangerous Documents Data Privacy Day: Privacy 101 (Open to all HHS employees) - Avoiding Landmines in Your Records and Emails.

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).

Per CFR Sec. 820.180 The record retention period is relative to the period of time equivalent to the design and expected life of the document. The CAFPA system and modules will be consolidating functions and records currently captured generated in existing tracking system databases. Retention schedules will be developed for the electronic CAFPA system, as well any other unscheduled records that are captured, created, or stored in any component module of the system. Currently the following records are classified and scheduled under the CVM File Plan as:

1. License Application Tracking System (LATS),

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CVM 11610 CVM Medicated Feed Mill Licensing Files.

CVM 11611 CVM Approved Licenses

CVM 11612 CVM Revoked Applications

CVM 11613 CVM Medicated Feed Mill License Status Tracking System.
2. Veterinary Feed Directive Distributor Module (VFD), No file code/schedule found unless these can be classified with the records listed above under LATS. Retention schedule and file code to be determined.
3. Out-of-specification Assay reports (OOS), FDA 4300 Laboratory Quality Assurance Records.
4. Recall, RFR, and Reconditioning module, FDA 7110 Recall Action Files
5. Pet food tracking module - Not enough information yet to determine the retention yet and would need to examine the regulatory and business requirements. Retention schedule and file code to be determined.

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.

PII will be stored only in the Production Appian Cloud database that is FedRAMP certified and HIPAA compliant.

Review & Comments

Privacy Analyst Review

OpDiv Privacy Analyst Review Status:	Approved	Privacy Analyst Review Date:	7/23/2024
Privacy Analyst Comments:		Privacy Analyst Days Open:	

SOP Review

SOP Review Status:	Approved	SOP Signature:	
SOP Comments:		SOP Review Date:	7/23/2024
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	Agency Privacy Analyst Review Date:	7/25/2024
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 7/25/2024 The comments on this PIA were to spell out acronyms on the PTA and PIA. Deferred to SAOP for review and approval.	Agency Privacy Analyst Days Open:	2

SAOP Review

SAOP Review Status:	Approved	SAOP Signature:	Archer Signature_Bridget Guenther.docx
SAOP Comments:		SAOP Review Date:	8/7/2024
		SAOP Days Open:	13

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 17	Data Feed Service, piafrmihs	7/23/2024	CAFPA is used by CVM and other authorized FDA employees. These employees require access to names and contact information in order to implement regulatory requirements.	
PIA - 1	VILLAFUERTE, NESTOR	7/23/2024	The PTA states that the system has no ATO, however, the planned date inputted has passed (9/28/2023) PTA-5 Please define acronym ADAFDA PIA-1 - Please include these PII elements into your responses in PTA-5 and PTA-6 in the next iteration of the PTA.	
PIA - 14	VILLAFUERTE, NESTOR	7/23/2024	Please define acronym AFRA	
PIA - 24	VILLAFUERTE, NESTOR	7/23/2024	Please define acronym HIPAA and FedRAMP	

Admin Section

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

Miscellaneous Fields

Last Updated:	8/7/2024 11:28 AM	History Log:	View History Log
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