PTA / PIA: FDA - HFP KMS - QTR3 - 2025 - FDA4949089

Created Date: 7/8/2025 8:37 PM Last Updated: 7/15/2025 4:40 PM

General Information

PTA / PIA Name:	FDA - HFP KMS - QTR3 - 2025 - FDA4949089	**PTA / PIA ID:**	3463430
Component Name:	FDA - HFP Knowledge Management System	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	7
Submitter:		**Submit Date:**	7/15/2025
Next Assessment Date:	07/14/2028	**Expiration Date:**	7/14/2028
Office:		**OpDiv:**	FDA
Security Categorization:	Moderate		
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?	Yes
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.	9/9/2022
General 05:	Is the system or electronic information collection, agency or contractor operated?	Contractor
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	Wenmin Chen
PTA 01A:	POC Title and Organization	Project Manager, ODT/OIMT/OTD/DAS/ORCFB
PTA 01B:	POC Email Address	wenmin.chen@fda.hhs.gov
PTA 01C:	POC Phone Number	(240) 402-0730
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.	Since the last Human Foods Program (HFP) Knowledge Management System (KMS) Privacy Impact Assessment (PIA) in 2022, additional changes that do not impact personally identifiable information (PII) have continued to enhance system functionality and user experience. These include the implementation of Salesforce Omni-Channel Web Chat as a new communication method, supplementing existing channels such as phone, webform, email, and Agency Information Management System (AIMS) letters. Workflow updates have also been made to enable the routing of product complaint inquiries from Food and Cosmetics Information Center (FCIC) to the Safety Reporting Portal (SRP) and MedWatch portals. Further enhancements involve the creation of customized reports to support analysis of web chat activity and product complaint intake metrics. Email validation has been introduced on the FCIC webform to help reduce errors and ensure accurate delivery of case responses. Country listings in Salesforce have been updated in accordance with Geopolitical Entities, Names, and Codes (GENC) standards to maintain consistency in international data entries. Additional updates include the development of a real-time dashboard displaying key application metrics for internal monitoring, as well as continued interface improvements such as removing redundant fields and updating dropdown values for case management. Office names, contact emails, and associated documentation have also been revised to align with structural changes following the 2024 reorganization. These changes reflect the ongoing evolution of the KMS to support more efficient operations, improve public engagement, and enhance internal reporting and triage capabilities.
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 Human Foods Program (HFP) Knowledge Management System (KMS) is an FDA-owned Software-as-a-Service (SaaS) cloud solution built on the FedRAMP authorized Salesforce Platform-as-a-Service (PaaS) environment. The system's purpose is to receive, triage, respond, and store public inquiries. KMS is utilized by the HFP Office of Analytics and Outreach (HFP OAO) Food and Cosmetics Information Center (FCIC) and the FDA Food Safety Modernization Act Technical Assistance Network (FSMA TAN) which includes some members of the FDA Center for Veterinary Medicine (CVM). The system receives a wide array of inquiries related to food, dietary supplements, cosmetics, FSMA regulations, HFP related Covid-19 inquiries, and a survey for industry to report farm

and food facility temporary closure/reduction due to Covid-19 outbreak as well requesting assistance.

Many different members of the public utilize KMS to submit inquiries. The categories of public inquirers include: members of academia, consumers, media, medical personnel, industry/business (domestic and international), other domestic government officials (FDA compliance staff, FDA investigator (regulator/inspector)), state inspectors and international government officials. The FCIC receives inquiries through a variety of avenues including a public facing web form (FDA Form 3907), telephone, traditional mail and, internally, letters maintained in FDA's Agency Information Management System (AIMS, addressed in a separate privacy assessment).

The HFP KMS Salesforce application is integrated with the FDA's enterprise Voice over Internet Protocol (VOIP) computerized telephone integration solution, the Genesys Customer Interaction Center (CIC). The integration enhances customer interaction for those submitting inquiries via phone and improves response efficiency for support staff. It also provides management with real-time reporting and visibility capabilities for managing staff and phone inquiry quality.

The HFP KMS application enables the public to submit questions, automates processes for FDA licensed users to route and answer cases, and provides FDA users the ability to search the knowledge base and execute analytics. KMS routes the questions received to the appropriate FDA resources and keeps track of the resolution of the questions, time frame of resolution and other customer satisfaction metrics.

KMS consists of the following types of users: Administrators (FDA employee and Direct Contractor), Developers (Direct Contractors), Food Safety Modernization Act Technical Assistance Network (FSMA TAN, FDA employees), FCIC Support Specialist Staff Licensed Users (FDA employees) and non-licensed public inquirers (general public). Users are defined via a role based access control (RBAC) approach that ensures agency users have only the access rights needed to perform their duties. The concepts of 'least privilege' and 'need-to-know' are both enforced through RBAC.

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.	KMS collects correspondence/inquiry and work management information including the following personally identifiable information (PII): (a) name; (b) email address; (c) phone number; (d) mailing address, (e) listing of approved IP addresses (FDA licensed user), (f) food facility registration number, (g) food establishment identification number (FEI), and (h) access credentials (username/ and password) for FDA licensed users. Usernames and passwords for FDA KMS licensed users are initially created by the system administrators. Users receive an initial welcome email where they are given a URL to setup a password within 48 hours. If a password reset is required the user must request the administrator perform a password reset. The PII is retained for a period of five years. The PII is not shared with any other system or organization. KMS also collects the following non-PII: (a) inquirer category; (b) FSMA and FCIC inquiry/response information (information related to FSMA regulations, food, cosmetics, and dietary supplement questions submitted); (c) inquirer country; and (d) inquirer zip code. FDA user IP address is captured in system sign-in logs and retained for six months.
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 HHS Username Password
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.	The information about public consumers, industry, regulators and other parties from the public is collected and/or maintained in order to facilitate collaboration via contact information (E-mail address, phone number, or mailing address) and provides the means for public consumers, industry, regulators and other parties from the public to ask questions, raise issues, and obtain assistance from the FDA. PII collected in KMS is not shared outside of the application and is used only to facilitate communication with individuals submitting inquiries. HFP KMS specialists who access or use the system do not use any personal identifiers to retrieve records held in the system.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes

PTA 08A:	Provide the URL(s).	https://hfpinfo.my.salesforce-sites.com/Inquirypage Webform Customer Satisfaction Survey: https://hfpinfo.my.salesforce-sites.com/Inquirypage/SurveyPage Response Customer Satisfaction Survey: https://hfpinfo.my.salesforce-sites.com/Responsesurvey FSMA TAN knowledge base page for non-licensed FDA KMS users hosted on FDA intranet: https://hfpinfo.my.site.com/FSMATANDatabase/s/
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	Yes
PTA 09:	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.	The purpose of this website is to host a webform for individuals from the public (consumer and industry) to submit inquiries to HFP. Username and password are not required to submit an inquiry. Inquirers will only receive information related to their inquiry submission. Surveys are utilized to gather information about customer satisfaction with the website, and customer satisfaction with the inquiry response. The FSMA TAN knowledge base is utilized by FDA subject matter experts (SMEs) who are non-licensed KMS users to read frequently asked questions (FAQs) prior to providing inquiry consultation.
PTA 10:	Does the website have a posted privacy notice?	Yes
PTA 11:	Does the website contain links to non-federal government websites external to HHS?	Yes
PTA 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	Yes
PTA 12:	Does the website use web measurement and customization technology?	No
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	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 User Credentials Contact Information Mailing Address (Personal) Email Address (Business) Phone Numbers (Business) Other Other
PIA 22A:	Identify the "other" type(s) of personally identifiable information (PII) not mentioned in the above list.	(a) Listing of approved IP addresses (FDA licensed users) (b) Food Establishment Identification number (FEI) (c) Food Facility Registration number
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Business Partners/Contacts (Federal state, local agencies) 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 contact information collected by the KMS system is used solely to contact external users or to respond to general questions external users submit regarding food, cosmetics, dietary supplements, and FSMA regulations. This is done using subject matter expert consultation responses, knowledgebase and FAQs that are delivered via email, phone or mail.
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: The Food Safety Modernization Act (FSMA) 21 U.S.C. 301 et seq. 5 U.S.C. 301. The Federal Information Security Management Act of 2002 (FISMA), 44 U.S.C. 3541.
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 Phone Email Online Government Sources Within the OPDIV State/Local/Tribal Foreign Other Federal Entities Non-Government Sources Members of the Public Public Media/Internet Other
PIA 30A:	Identify the "other" sources of PII in the system not mentioned in the above list.	Industry personnel, academia, and medical
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA 31B:	Explain why an OMB information collection approval number is not required.	Food and Cosmetics Information Center (FCIC) Inquiry Form (FDA form # 3907) Form FDA 3907 does not have an OMB control number because the HFP PRA Team opined that the FCIC form is exempt from the PRA. The information the form collects does not fit within the PRA's definition of "information" thus we did not seek PRA approval. 5 CFR 1320.3(h)(4)
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
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.	Submission is voluntary, no method for consent needed.
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 the agency changes the collection, use, or sharing of PII in this system, the agency will notify affected individuals by the most efficient and effective means available and appropriate to the specific change(s). This may include a notice on the website, or email notice to the individuals.

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.	External submitters have the ability to notify and seek assistance from FDA and HFP by phone and/or email. This information is available on FDA.gov. They may also contact the FDA Privacy Office directly via email provided on FDA.gov. FDA personnel may resolve concerns by contacting the appropriate system administrator, FDA's Employee Resources and Information Center (ERIC) or the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). Privacy risks are mitigated by collecting the information directly from the external user, indicating the purpose of the collection is to enable responses to their inquiry, and sharing only aggregate non-PII regarding inquiry topics.
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.	Inquirer'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 submission with functionalities like an automated receipt email containing all information submitted on the webform. FDA personnel may correct/update their information themselves to ensure accuracy. Data 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 National Institute for 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. HFP performs annual reviews to evaluate user access. One of the controls includes information system backups reflecting the requirements in contingency plans as well as other agency requirements for backing up information. Data discrepancies identified in the course of system use are addressed when discovered. Data relevancy is maintained through web form design limiting the data submission fields to that which is necessary for system functionality and effectiveness.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators Developers 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: Only internal HFP Information Center users will have access to triage and respond to case inquiries from the public. Administrators: Administrators have access to PII to complete system and user administration as well as reporting. Some administrators are Direct Contractors. Developers: Developers have access to PII for system development purposes. Some developers are Direct Contractors. Contractors: Direct contractors will need access to facilitate system enhancements, Operations & Maintenance, and reporting. Direct contractors support Administrator, developer, and project management roles. Contractors require access to complete Salesforce development work, application administration, and analytics.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	HFP establishes differing levels of permissions using a role-based paradigm to set access limits at the individual user level. Access requests are reviewed one at a time and KMS System Administrators and/or privileged users update and maintain a list of active users, which includes KMS staff, innovators and key stakeholders. All users are granted access via role-based access controls (RBAC) and the concept of least privilege is applied. All internal FDA support staff users (FDA employees and Direct Contractors) are granted a username and password and access the site through a secure web browser. Role-based access controls are implemented to restrict access for KMS to authorized roles. Information flow for KMS data loading processes is carried out and monitored by system administrators in support of appropriate 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 indicate on the account creation form the minimum information system access that is required in order for the user to complete his/her job. The KMS Information Technology and business project team define roles so that each user only has the access rights necessary to perform his/her work. 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. KMS System Administrators and/or privileged users update and maintain a list of active users with assigned IP addresses, which includes KMS Staff, Innovators and Key Stakeholders.

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 personnel/users are required to complete FDA's IT Security and Privacy Awareness training annually. Completion of annual awareness training is tracked by the Office of Digital Transformation (ODT). For additional privacy guidance, personnel may contact the agency's Privacy Office. Privacy program materials are provided to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	No additional training is mandated for user completion other than initial KMS onboarding and Salesforce training. Users may access general system user guidance and may arrange tailored privacy training with the Privacy Office.
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).	Currently no records are being deleted or archived as we're working with records management to find the appropriate record 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 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:**	7/15/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	7/15/2025
SOP Review Comments:		**# of Days - SOP Review:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	7/15/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 7/25/2025 All comments have been addressed. 7/15/2025 Please see comments and update accordingly. PIA-31B: The response provided doesn't explain why there no OMB. This is the response that should be here: Food and Cosmetics Information Center (FCIC) Inquiry Form (FDA form # 3907) Form FDA 3907 does not have an OMB control number because the HFP PRA Team opined that the FCIC form is exempt from the PRA. The information the form collects does not fit within the PRA's definition of "information" thus we did not seek PRA approval. 5 CFR 1320.3(h)(4) 7/10/2025 Please see comments and update accordingly. PIA-31: Per PIA-31A, this response should be marked "No." PIA-31A: The response for PIA-31A should be removed and place in PIA-31B, which will populate once PIA-31 is marked "No." Also remove the personnel name from the response "- Michael Ellison, J.D. Senior Policy Analyst/ARCO for HFP (PRA)," as PIA are published and available to the public.	**# of Days - APA Review:**	0

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	7/15/2025
SAOP Review Comments:	Approved on behalf of the SAOP.	**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
7/15/2025 1:15 PM	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
PTA 01	BLAND, CRYSTAL	7/9/2025	7/9/2025 Per FDA's Email: The PIA is experiencing an Archer error with Question #3 of the general information (Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. The ATO date is 9/9/2022. At this time, we are unable to update Archer to reflect the correct answer “Yes.”	7-9-2025 EMAIL_HFP Knowledge Management System FDA- (HFP KMS - QTR3 - 2025 - FDA4949089).pdf HFP Knowledge Management System PIA.pdf
PIA 31	BLAND, CRYSTAL	7/10/2025	Per PIA-31A, this response should be marked "No."	
PIA 31A	BLAND, CRYSTAL	7/10/2025	The response for PIA-31A should be removed and place in PIA-31B, which will populate once PIA-31 is marked "No." Also remove the personnel name from the response "- Michael Ellison, J.D. Senior Policy Analyst/ARCO for HFP (PRA)," as PIA are published and available to the public.	
PIA 31B	BLAND, CRYSTAL	7/15/2025	This is the response that should be here: Food and Cosmetics Information Center (FCIC) Inquiry Form (FDA form # 3907) Form FDA 3907 does not have an OMB control number because the HFP PRA Team opined that the FCIC form is exempt from the PRA. The information the form collects does not fit within the PRA’s definition of “information” thus we did not seek PRA approval. 5 CFR 1320.3(h)(4)	