PTA / PIA: FDA - DMSS - QTR4 - 2025 - FDA5077649

Created Date: 11/24/2025 11:35 PM Last Updated: 12/10/2025 11:24 AM

## General Information

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| **PTA / PIA Name:** | FDA - DMSS - QTR4 - 2025 - FDA5077649 | **PTA / PIA ID:** | 4056680 |
| **Component Name:** | FDA - HFP Data Management Support Services System | **ATO Boundary Name:** | HFP Knowledge Management Applications |
| **Overall Status:** | Complete | **# of Days - Open:** | 14 |
| **Submitter:** | | **Submit Date:** | 11/25/2025 |
| **Next Assessment Date:** | 12/08/2028 | **Expiration Date:** | 12/8/2028 |
| **Office:** | | **OpDiv:** | FDA |
| **Security Categorization:** | Moderate | | |
| **Make PIA available to Public?:** | Yes | **PIA Required:** | Yes |

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| **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. | 9/9/2025 |
| **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

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| **PTA 01:** | Point of Contact (POC) Name | POC Name: Carrol Burgundy<br><br>Secondary POC: Kimberly Jones |
| **PTA 01A:** | POC Title and Organization | POC Title: HFP Privacy Officer<br><br>POC Organization: HHS/FDA/HFP/OPIE<br><br>Secondary POC Title: HFP Government Information Specialist<br><br>Secondary POC Organization: HHS/FDA/HFP/OPIE |
| **PTA 01B:** | POC Email Address | carrol.burgundy@fda.hhs.gov |

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| **PTA 01C:** | POC Phone Number | 240-402-2158 |
| **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. | In support of the Food and Drug Administration's modernization efforts, the Human Foods Program (HFP) has implemented the Data Management Support Services System (DMS3). The purpose of the HFP DMS3 system is to improve accuracy, data entry, record management, and robust reporting processes and combine all these features in a single application. Prior to the system's implementation, inefficient processes that utilized Jabber, SharePoint and Outlook, along with unreliable telecommunication connections and a lack of modern tracking and reporting tools lead to major delays that impacted the FDA/Food Facility Registration (FFR) mission.<br><br>HFP DMS3 is utilized to receive, triage, respond to, and store inquiry cases submitted by members of the public (industry professionals) about FFRs. Individuals do so via phone, email, or webform FDA 3907 (currently used by the HFP Knowledge Management System (the subject of a separate assessment). For inquiries by phone or email, FDA staff captures the first name, last name, phone number, and optional email address of the individual. This personal information is captured to verify that the person calling/emailing is associated with the FFR registration and therefore can request information about the FFR. For emailed inquiries, FDA personnel request only the email address of the individual making the inquiry, however if the individual would like to provide his/her name they can do so. Information is collected via phone by a live agent or through emailed inquiries. (Future DMS3 functionality will include webform, but they are not available at this time.) A case (or ticket) is created internally by an agent to document the inquiry, and that is how the information gets into the system.<br><br>The implementation of HFP DMS3 allows for the integration with Automated Call Distribution (ACD) so calls/emails and tickets/data can be created automatically and virtually route telephone calls and email messages to the individual FDA agents and business areas. The creation of a single ticketing system standardizes the practice of issue reporting and resolution, as well as creating a central database from which solutions can be found and adapted to new issues. A well-functioning ticketing system enables multiple specialists with the capability to monitor information and solutions already gathered to resolve these issues without duplicating work across applications. In addition, the central database is used to monitor the frequency of issues that may impact system functionality and allow specialists to determine if these issues require a more comprehensive and consistent |

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| | | resolution. Overall, the functionalities contribute to greater accuracy of data, enhanced records management and reporting, and greater operational efficacy across applications.<br><br>System "users" consist of members of the HFP DMS3 team (FDA permanent federal employees and direct contractors). |
| **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. | The HFP DMS3 system collects and stores case specific data and business contact information that consists of personally identifiable information (PII). The following PII is collected about internal users of the system: (a) name; (b) email address (business); (c) user credentials (username and password), and (d) approved internet protocol (IP) addresses (FDA licensed users).<br><br>The system also maintains the following information about members of the public (industry professionals): (a) e-mail address (business/personal); (b) mailing address (business/personal); (c) phone number (business/personal); (d) name; (e) food facility registration (FFR) number, (f) food establishment identification number (FEI), and (g) Data Universal Numbering System (DUNS) data.<br><br>Usernames and passwords for FDA DMS3 licensed users are initially generated by system administrators (Admins). By default, user accounts contain the username of the FDA employee (system user). Users receive an initial welcome email providing a uniform resource locator (URL) that must be used to setup an account password within 48 hours after receipt of the email. If a password reset is required, the user must request a password reset (to be completed by a system Admin.<br><br>PII collected and/or maintained in the system is not shared with any other system or organization. Users access the system through single sign-on (SSO) authentication and the use of personal identification verification (PIV) cards. Usernames match the user's FDA username and are standardized.<br><br>System information is retained in accordance with National Administration Records Administration (NARA) general records schedules. |
| **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<br>HHS/OpDiv PIV Card<br>HHS Username<br>Password |

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| **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. | Information is collected/maintained in the system to record case specific data and DMS3 operations information since the system's primary purpose is to support DMS3 business group efforts to automate and streamline their business workflow and allow users to locate information from one centralized repository.<br><br>PII about FDA personnel using the system is collected to allow access to the system. Contact information about members of the public (industry professionals) is collected and/or maintained for business follow up with individuals who have contacted FDA to inquire about FFRs. Individuals who have inquiries contact FDA via email, phone, or public webform. For inquiries by phone or email, the FDA staff captures first name, last name, phone number, and optional email address. This personal information is captured to verify that the person calling/emailing is listed on the FFR registration. FDA staff provides information related to the FFR to the person(s) whose name is associated with the FFR registration. For emailed inquiries, FDA staff need only email address, with name optional. Future DMS3 functionality will include webform, but they are not available at this ticket. A case (or ticket) is created internally by an agent to document the inquiry, and that is how the information gets into the system.<br><br>PII is used for verification purposes only. PII is used to retrieve FFR related data only. Records in the system are not about the individuals' submitting inquiries. FFR data consists of facility and registration related information. System data is retrieved based upon the FFR number.<br><br>PII is not shared with anyone who does not have access to DMS3. |
| **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.com/ (Internal only) |
| **PTA 08B:** | Are any of the website or online applications accessible by the public (including publicly accessible log in pages)? | No |
| **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 the website is to provide HFP DMS3 users a direct way of accessing the DMS3 Salesforce application. DMS3 business group personnel access the website via an internal, non-public URL.<br><br>Members of the public who wish to submit an inquiry via the web do so using a separate public facing URL and webform available on FDA.gov. |
| **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? | No |

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| **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

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| **PIA 22:** | Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share. | Identifying Numbers<br>DUNS<br>Biographical Information<br>Name<br>User Credentials<br>Contact Information<br>Email Address (Personal)<br>Mailing Address (Personal)<br>Phone Numbers (Personal)<br>Email Address (Business)<br>Mailing Address (Business)<br>Phone Numbers (Business)<br>Other<br>Other |
| **PIA 22A:** | Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list. | FEI number; FFR number; IP address |
| **PIA 23:** | Indicate the categories of individuals about whom PII is collected, maintained, or shared. | Employees/HHS Direct Contractors<br>Members of the public |
| **PIA 24:** | Indicate the approximate number of individuals whose PII is maintained in the system. | 500 – 4,999 |
| **PIA 25:** | For what primary purpose is the PII used? | The FDA uses the PII for the primary purpose of collecting contact information about industry professionals to follow up on business inquires. This is done using subject matter expert consultation responses, knowledgebase and frequently asked questions (FAQs) that are delivered via email, phone, or mail.<br><br>PII about users is used for system access control 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 Federal Food, Drug and Cosmetic Act (FDC&A, 21 U.S.C. 301) and 5 U.S.C. 301. |
| **PIA 29:** | Are records in the system retrieved by one or more PII data elements? | No |

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| **PIA 30:** | Identify the sources of PII in the system. | Directly from an individual about whom the information pertains<br>Hard Copy Mail/Fax<br>Phone<br>Email<br>Online<br>Other |
| **PIA 30A:** | Identify the "other" sources of PII in the system not mentioned in the above list. | Webform |
| **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. | Information is not directly collected from members of the public and forms are not used for collection purposes. Therefore, the requirements of the Paperwork Reduction Act do not apply. |
| **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. | Individuals voluntarily submit their information and have control over information they opt to provide in text fields.<br><br>There is no method for employees to opt out to submit PII. Permanent employees, Direct Contractors, and other personnel must provide their PII in order for the Agency to process administrative materials and securely administer access to agency information and property. |
| **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. | No such changes are anticipated. If the agency changes the collection, use, or sharing of PII data in this application, the affected individuals will be notified by the most efficient and effective means available and appropriate to the specific change(s). This may include a notice on relevant web sites or email notice to the individuals. |

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| **PIA 36:** | Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not. | Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have a number of avenues available to rectify the situation. Individuals may contact the office or division where they have determined that their records are held and request their information be corrected or amended. FDA considers these requests and, if appropriate, makes the requested changes. Additionally, individuals may contact FDA offices via email, telephone, and standard mail avenues (all listed on fda.gov).<br><br>Employees concerned about the use of their PII, can work with their supervisors, the Employee Resource and Information Center (ERIC), or FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC).<br><br>FDA personnel are required to immediately report any suspected incidents or breaches to the FDA CIOCC. |
| **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. | 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.<br><br>Relevancy is supported by design of the system and related processes to solicit or collect only the PII necessa4ry for the system's purpose and supporting functionality. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).<br><br>Integrity and availability are protected by privacy and security controls selected and implemented in the course of providing the system with an authority to operate (ATO).<br><br>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. |
| **PIA 38:** | Identify who will have access to the PII in the system. | Users<br><br>Administrators<br><br>Developers<br><br>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 |

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| **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.<br><br>Administrators: Administrators have access to PII to complete system and user administration as well as reporting. Some administrators are Direct Contractors.<br><br>Developers: Developers have access to PII for system development purposes. Some developers are Direct Contractors.<br><br>Contractors: Direct contractors will need access to facilitate system enhancements, operation and management, and reporting. Direct contractors support Administrator, developer, and project management roles. |
| **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 in a role-based paradigm to set access limits at the individual user level.<br><br>Access requests are reviewed one at a time and DMS3 System Administrators and/or privileged users update and maintain a list of active users, which includes DMS3 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 DMS3 to authorized roles. Information flow for DMS3 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 for the user to complete his/her job. The DMS3 information technology (IT) and business project team define roles so that each user only has the access rights necessary to perform his/her work.<br><br>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. DMS3 System Admins and/or privileged users update and maintain a list of active users with assigned IP addresses, which includes DMS3 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. | Personnel must complete FDA's mandatory Computer Security and Privacy Awareness Training on an annual basis. FDA Office of Information Management and Technology (OIMT) verifies that training has been successfully completed. |

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| **PIA 43:** | Describe the training system users receive above and beyond general security and privacy awareness training. | For additional privacy guidance, personnel may contact the HFP'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 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). | N1-088-07-2-Registration and Listing Files-Temporary-Cutoff after establishment goes out of business or product is not commercially marketed. Delete/destroy 10 years after cutoff.<br><br>N1-088-07-2-Registration and Listing Systems. Database Records-Temporary-Cutoff after establishment goes out of business or product is not commercially marketed. Delete/destroy 10 years after cutoff or when no longer needed for legal, research, historical or reference purposes, whichever is the latest. If data are migrated into a new system or replaced by a successor system, delete/destroy after the verification of successful data migration. |
| **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. | FDA secures PII in the system using the following administrative controls: 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.<br><br>FDA secures PII in the system using the following technical controls: Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools.<br><br>FDA secures PII in the system using the following physical controls: Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls.<br><br>Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199. |

## Review and Comments

### OpDiv Privacy Analyst Review

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| **Privacy Analyst Review Decision:** | Approved | **Privacy Analyst Review Date:** | 11/25/2025 |
| **Privacy Analyst Review Comments:** | Due to an Archer error, General Q 03: “Does the system have or is it covered by a Security Authorization to Operate (ATO)??" erroneously reports that no ATO is in place. The correct response should be "Yes" and ATO date is 9/9/2025. At this time, we are unable to update Archer to reflect the correct answer “Yes.” | **# of Days - PA Review:** | 0 |

### SOP Review

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| **SOP Review Decision:** | Approved | **SOP Review Date:** | 11/25/2025 |
| **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

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| **Agency Privacy Analyst Review Decision:** | Approved | **Agency Privacy Analyst Review Date:** | 11/26/2025 |
| **Agency Privacy Analyst Review Comments:** | Reviewer: Nestor Villafuerte<br><br>11/26/2025 This PIA is ready for SAOP review and approval. | **# of Days - APA Review:** | 1 |

### SAOP Review

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| **SAOP Review Decision:** | Approved | **SAOP Review Date:** | 12/9/2025 |
| **SAOP Review Comments:** | | **# of Days - SAOP Review:** | 13 |

### SAOP Signature

| Date | User | Type | Name | Original Value | New Value |
|---|---|---|---|---|---|
| 12/9/2025 2:15 PM | 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 01B | Data Feed Service, pta_pia_FDA_Release | 11/24/2025 | Secondary POC email: kimberly.jones@fda.hhs.gov | |
| PTA 01 | BLAND, CRYSTAL | 11/25/2025 | 11/25/2025 Per FDA's Email, "<br><br>The subject PIA is ready for your review. Since its last approval, it has been determined that this system is not a Privacy Act system of records and additional edits were required to ensure accuracy of content." | HFP Data Management Support Services System-FDA-DMSS-QTR4-2025-FDA5077649.pdf<br><br>HFP DMS3 DN Reviewed SOP approved 11.24.25.pdf |