PTA / PIA: FDA - FURLS - QTR3 - 2025 - FDA4949206

Created Date: 7/11/2025 4:37 PM Last Updated: 7/22/2025 8:46 AM

General Information

PTA / PIA Name:	FDA - FURLS - QTR3 - 2025 - FDA4949206	**PTA / PIA ID:**	3476586
Component Name:	FDA - OC FDA Unified Registration and Listing System	**ATO Boundary Name:**	OC FDA Unified Registration and Listing System
Overall Status:	Complete	**# of Days - Open:**	11
Submitter:		**Submit Date:**	7/21/2025
Next Assessment Date:	07/21/2028	**Expiration Date:**	7/21/2028
Office:		**OpDiv:**	FDA
Security Categorization:	High		
Make PIA available to Public?:	Yes	**PIA Required:**	Yes

General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	Yes
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	Yes
General 04:	ATO Date or Planned ATO Date.	7/28/2025
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

PTA 01:	Point of Contact (POC) Name	Chi Nguyen
PTA 01A:	POC Title and Organization	FURLS Program Manager
PTA 01B:	POC Email Address	chi.nguyen1@fda.hhs.gov
PTA 01C:	POC Phone Number	724-771-0290
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.	The Food and Drug Administration (FDA) has made no changes to this system/component since the last Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) was approved.
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 subject of this assessment is the Office of the Commissioner (OC) Unified Registration Listing System (OC FURLS), one of several modules that operate within the larger system boundary by the same name. The Bioterrorism Act of 2002 required the Food and Drug Administration (FDA) to develop two systems designed to safeguard the nation's food supply: one to support the registration of facilities that manufacture, process, pack, or hold food products intended for consumption in the United States (Food Facility Registration or FFR) and one to receive prior notice before food is imported or offered for import into the United States (Prior Notice System Interface or PNSI). FDA implemented key provisions of the Act with the creation of the FDA Industry System (FIS, assessed separately) and the FDA Unified Registration Listing System (FURLS), a portfolio of registration, listing, export certification, reporting, and user authentication applications. These systems were created, in part, to streamline and modernize how FDA manages registration and listing information for the industries it regulates. The objective of OC FURLS is to support the FDA regulations that require registration by all facilities manufacturing, processing, or holding FDA regulated products with the FDA in order to conduct business with the United States. FDA personnel can also use the application to identify facilities not in compliance with FDA laws and regulations for firm’s manufacturing medical devices in the United States. This single, unified, secure web-based platform provides users with the capability to register food, poultry, tobacco and medical facilities, request export certificates, provide product information, and apply to be added to listing programs. FDA manages these requests, communicates with industry, and approves or rejects submissions through available multi-use FURLS modules. Web-based modules include those employed by users and those used by system support (e.g., administrators, developers). The multi-layered functionality of OC FURLS enables the FDA to identify risks earlier in the submission process and take a proactive, solution-based approach to addressing challenges in a constantly evolving industry. OC FURLS is used by internal and external users. Internal users of the system are FDA permanent employees and Direct Contractors. External users are members of the public (e.g., local/foreign industry owners, operators, and agents). Access to

		the system is managed by the Online Account Administration (OAA) application (the FURLS user account database and user authentication module that is the subject of its own assessment). To make submissions to FDA, external users must first create a user account to include an account identification number (I.D.) and password. OAA uses the business rules and infrastructure implemented by FDA's Single Sign-On (SSO) process in creating and administering FDA Personnel user accounts for internal users. User accounts must be established before users can access OAA and make submissions to FURLS. Internal and external users submit through FIS (the online submission portal) and then routed to OAA before being granted access to FURLS. FURLS supports internal and external users through help desk support and is available to assist with any technical issues that users could potentially encounter.
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.	OAA is the FURLS user account database and user authentication module. Internal FDA users authenticate using SSO. All modules require that external users log into the system for authentication to determine which modules within FURLS the user can access per the users' access request. Users include external (to FDA) industry users (local/foreign industry owners, operators, and agents) or state agency users under contract with the FDA, as well as internal (to FDA) users such as permanent agency employees or FDA Direct Contractors. OAA collects the following personally identifiable information (PII) data on external users: first and last name, state liaison email address (for state access), professional/office phone number and fax number, professional/office email address, professional/office mailing address, access credentials (username/password), and job title (if combined with other unique identifiers) and access credentials (username/password). The username is assigned by the system using the facility name and a random five-digit number, and the password is encrypted and stored within FURLS. OAA also collects the following non-PII data: state agency (for state access), company uniform resource locator (URL), security questions, security question responses, and Dun & Bradstreet Data Universal Numbering System number (DUNS number, which may be potential PII when combined with other unique identifiers). Non-PII data such as facility or product information is collected in all FURLS modules as required. Registrants may voluntarily submit additional non-PII data consisting of seasonal start/end dates or establishment type.
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 Non-HHS User Credentials 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.	OC FURLS is a web-based system that allows foreign and domestic facilities to register with the FDA. It supports the implementation of FDA regulations that require facilities manufacturing, processing or holding any FDA regulated products to register with the FDA. Most FURLS users are industry account holders who utilize FURLS to register their food, medical device, tobacco or poultry facilities. The remaining FURLS users are FDA employees and Direct Contractors who use the system to access facility registration information. Industry account holders access FURLS via web-based authentication using username and password which is managed at the database level. OAA is used to maintain account information for external users of the application. FDA employees and Direct Contractors access FURLS using FDA's enterprise level SSO process using multi-factor authentication. FURLS consists of two types of modules: the web-based modules employed by users, and system support modules. The web-based modules are broken down by FDA Operating Division (OPDIV). OAA collects the following personally identifiable information (PII) data on external users: first and last name, state liaison email address (for state access), professional/office phone number and fax number, professional/office email address, professional/office mailing address, job title (if combined with other unique identifiers) and access credentials (username/password). The username is assigned by the system using the facility name and a random five-digit number, and the password is encrypted and stored within FURLS. OAA also collects the following non-PII data: state agency (for state access), company uniform resource locator (URL), security questions, security question responses, and Dun & Bradstreet Data Universal Numbering System number (DUNS number). FURLS users 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://www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1
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 objective of OC FURLS is to support the FDA regulations that require all facilities manufacturing, processing, or holding FDA regulated products be registered with the FDA in order to conduct business with the United States. FDA personnel can also identify facilities not in compliance with FDA laws and regulations for firm's manufacturing medical devices in the U.S. The website provides an additional way for external users of the system to ensure they are in compliance with the FDA registration requirements and a way for FDA personnel to monitor domestic product status. Internal and external users access the system via public URL different authentication processes. Internal users authenticate using SSO. External users authenticate using username and password.
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
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.	Identifying Numbers DUNS Biographical Information Name User Credentials Contact Information Email Address (Business) Mailing 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.	Fax Number (business); job title (where combined with other unique identifier); email addresses also include State email addresses.
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?	PII in FURLS is used to for account creation and system access. PII is also used for business communication purposes with industry regarding questions about submissions registrations, listings, and certifications.
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.	FDA issues export certificates under Sections 801(e) or 802 under the Export Reform and Enhancement Act of 1996. Sections 510 and 905 of the Food, Drug and Cosmetic Act (FD&C, codified at 21 U.S.C. 360 and 387e) require establishments (e.g., manufacturers, re-packers, and re-labelers) to register with FDA upon engaging in the manufacture, preparation, propagation, compounding, or processing of FDA regulated products including food, drugs, medical devices, poultry, tobacco and biological products, with certain exceptions. Statutory citations: 5 U.S.C. 301; 21 U.S.C. 321, 331, 342, 344, 351, 352, 355, 360, 360b, 371, 374, 381, 387e, 393; 42 U.S.C. 262, 264, 271.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No
PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Email Online Government Sources Within the OPDIV Other HHS OPDIV State/Local/Tribal Non-Government Sources Members of the Public
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA 31A:	Provide the information collection approval number(s) and expiration date(s).	0910-0625 Expiration Date: 08/31/2025
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.	There is no opt-out process for this system. Regulated entities are required by law to register and to submit information necessary to administer the registration process. FDA personnel and Direct Contractors consent to the submission and use of their information by Department of Health and Human Services (HHS)/FDA as a condition of employment.
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 FDA should changes its privacy practices or its collection, use, or sharing of PII data in FURLS, the agency will notify the individuals whose PII is in the system in the most efficient and effective form available and appropriate to the specific change(s). This may include establishing a formal process involving written and/or electronic notice. Alternatively, the FDA will notify by informal processes such as e-mail to the affected individuals and/or FDA-wide e-mail blast.
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 many avenues available for assistance. These individuals may contact FDA offices, including the Privacy Office, the Employee Resource and Information Center (ERIC-FDA personnel only), the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail avenues (all listed on fda.gov and the FDA intranet). FDA personnel are required to rapidly report any suspected incidents or breaches to the FDA CIOCC. Contractors are required to safeguard all information and to report potential data breaches to the FDA.
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.	Registrant point of contact PII is self-submitted and registrants/facilities certify accuracy of information. Registrant points of contact may correct or update their information using FURLS, the contact information provided on fda.gov and/or the specific fda.gov web pages associated with the FURLS program. Accuracy is ensured by individual review at the time of reporting. Users may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. 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 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 Administrators Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	Users: require access PII about themselves and other users to make proper annual updates. The PII is self-submitted and registrants/facilities certify accuracy of information. Administrators: require access to PII about users to make proper annual updates. Contractors: some administrators are Direct Contracto
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Personnel who have access to PII are provided the information based on the need for access required to perform their duties. Personnel who require access to the system must obtain supervisor approval and sign off before access is granted.
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.	The requesting user's supervisor will indicate on the account creation form the minimum information system access that is required for the user according to their role. The agency reviews the system access list on a quarterly basis and adjusts users' access permissions and removes unneeded accounts from the system.
PIA 42:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) to make them aware of their responsibilities for protecting the information being collected and maintained.	All FURLS users 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 Management and Technology (OIMT) verifies that training has been successfully completed and maintains a record of certificates of training on all FDA employees and direct contractors.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	FDA personnel who use FURLS receive FURLS-specific training on how to use the system and adhere to agency security, privacy and other relevant policies. Privacy program materials are also available to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA. Privacy guidance is also available via the FDA's 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).	The agency continuously reviews the retention and destruction process associated with the information contained within FURLS to ensure it complies with FDA and NARA regulations. Applicable records control schedule: FDA file code 7210 and 7222 for Registration and Listing files and system database records; NARA approved citation N1-88-07-2, Item 6.1. Disposition: Temporary - Cutoff after establishment goes out of business or product is not commercially marketed. The certificate modules delete/destroy after 5 years. All other modules 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 it after the verification of successful data migration. FDA file codes 7220-7225 (NARA approved citation no. N1-88-07-2, Item 6.1) cover FDA's Registration and Listing Systems. These files are temporary and are destroyed when no longer needed, the establishment goes out of business, the product is no longer marketed, destroyed 10 years after cutoff.
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 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:**	7/21/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	7/21/2025
SOP Review Comments:	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	**# of Days - SOP Review:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	7/22/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 7/22/2025 All comments addressed. 7/15/2025 Please see comments and update accordingly. PIA-22: Please select "User Credentials" and "DUNS. PIA-37: Please verify whether retention and disposal schedule N1-88-07-2 has been rescinded or superseded. It does not appear in the current or newly approved NARA schedules, and it is not listed in the Records Control Schedule (RCS) repository or recent Federal Register notices—indicating it may no longer be in effect. If no longer in effect then please update your response accordingly	**# of Days - APA Review:**	1

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	7/22/2025
SAOP Review Comments:	Approved on behalf of the SAOP.	**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
7/22/2025 6:33 AM	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 05A	Data Feed Service, pta_pia_FDA_Release	7/11/2025	Internal Users: Active Directory External users: OAA	
PTA 01	BLAND, CRYSTAL	7/14/2025	Per FDA's Email, Attached a copy of PIA.	OC FURLS AOB SOP 7.11.25.df.pdf
PIA 37	BLAND, CRYSTAL	7/15/2025	Please verify whether retention and disposal schedule N1-88-07-2 has been rescinded or superseded. It does not appear in the current or newly approved NARA schedules, and it is not listed in the Records Control Schedule (RCS) repository or recent Federal Register notices—indicating it may no longer be in effect. If no longer in effect then please update your response accordingly.	
PIA 22	BLAND, CRYSTAL	7/15/2025	Please select "User Credentials" and "DUNS."	
PTA 01	BLAND, CRYSTAL	7/22/2025	FDA's Email, attached	7-21-2025 EMAIL_RESUBMISSION_ FDA - FURLS - QTR3 - 2025 - FDA4949206 PIA.pdf