

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

Status:	Approved	PIA ID:	1324867
PIA Name:	FDA - FURLS_SCH - QTR2 - 2021 - FDA1950986	Title:	FDA - OC FDA Unified Registration and Listing System
OpDIV:	FDA		

PTA

PTA - 1A:	Identify the Enterprise Performance Lifecycle Phase of the system	Operations and Maintenance
PTA - 1B:	Is this a FISMA-Reportable system?	No
PTA - 2:	Does the system include a website or online application?	Yes

URL Details

Type of URL	List Of URL
Internet (publicly available)	https://www.access.fda.gov/
PTA - 3:	Is the system or electronic collection, agency or contractor operated? Agency
PTA - 3A:	Is the data contained in the system owned by the agency or contractor? Agency
PTA - 5:	Does the system have or is it covered by a Security Authorization to Operate (ATO)? No
PTA - 5B:	If no, Planned Date of ATO 8/22/2016
PTA - 7:	Describe in further detail any changes to the system that have occurred since the last PIA The following new modules have been added under the FDA Unified Registration and Listing System (FURLS): Dairy Listing Module (DLM) and Food Safety Modernization Act (FSMA) modules [Third-Party Program-Accreditation Body (AB) and Third-Party Program-Certification Body (CB), Systems Recognition Program (SR), Voluntary Qualified Importer Program (VQIP)], and Foreign Supplier Verification Program (FSVP).
PTA - 8:	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 Food and Drug Administration (FDA) created the FDA Industry Systems (FIS) to facilitate the making of submissions to the FDA, including

registrations, listings, and other notifications. FIS is the portal which goes through Online Account Administration (OAA) and into FURLS.

The FDA created the FIS and FDA Unified Registration, and Listing System (FURLS) modules were, in part, in response to the Bioterrorism Act of 2002, which gave high priority to improved information management to help protect the food supply. The Act requires that the FDA develop two systems: 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). Under the law, the facilities had to be registered by December 12, 2003, when the "Prior Notice" requirement went into effect. FURLS developed and maintained the OAA and FFR components, with OAA used to authenticate personnel who access to PNSI.

FURLS modules provide the capability for industry, both domestic and foreign, 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 the FURLS modules.

OAA is the FURLS user account database and user authentication module. Internal FDA users authenticate using Single Sign On (SSO). All other modules require that the external users log

PTA - 9:

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.

into the system and authenticate (via username and password) to determine which modules within FURLs the user can access per the users' access request. Users may be external (to FDA) industry users (local/foreign industry owners, operators, and agents) or state agency users under contract with the FDA. Users may also be internal (to FDA) 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), work phone number, fax number, email address, mailing address, 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: job title, 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).

All FURLS modules also collect the same PII as OAA. The FURLS modules consist of: Acidified/Low-Acid Canned Foods Registration and Process Filing (LACF), Biologics Export Certification Applications and Tracking System (BECATS), Certificate Application Process (CAP), CDER Export Certification Application and Tracking System (CDER eCATS), CDRH Export Certification Application and Tracking System (CECATS), Dairy Listing Module (DLM), Device Registration and Listing Module (DRLM), Food Facility Registration (FFR), New Dietary Ingredient Notification (NDIN), Structure/Function Claims Notification (SFCN), Shell Egg Producer Registration Module (SEPRM), Tobacco Registration and Listing System (TRLM), and Food Safety Modernization Act (FSMA) modules including Third-Party Program-Accreditation Body (AB) and Third-Party Program-Certification Body (CB), Systems Recognition Program (SR), Voluntary Qualified Importer Program (VQIP), and Foreign Supplier Verification Program (FSVP).

CECATS and BECATS also collect additional PII consisting of company taxpayer identification number (ID). The company taxpayer identification number is only associated with CECATS and BECATS external users.

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 -9A:

Are user credentials used to access the system?

Yes

PTA - 10:

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

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. FDA employees and direct contractors access FURLS via a network-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) and include:

The Center for Food Safety and Nutrition (CFNS) LACF module allows for the management and tracking of low acid canned foods and acidified canned foods. FDA regulations mandate the registration of all foreign and domestic acidified and low-acid canned food facilities, and the filing of specific product processing data to ensure the safety of these food products. The FFR module enables registration actions by food facilities that manufacture, process pack, or hold food for human/animal consumption in the United States. This includes foreign facilities that export food items to the US. The SEPRM is used to register facilities that have over 3,000 egg-laying hens. The CAP module allows CFNS to issue and manage export certifications electronically and control the submission and workflow of export certifications. The SFCN and NDIN modules support dietary supplement safety and ensure the safety of dietary ingredients in dietary supplements with 30-day post-market reviews. The DLM provides a spreadsheet of approved listings of dairy firms that are published for external users, and for FDA personnel. This spreadsheet provides its' users the ability to monitor the Firm listing status regarding publication by FDA facility listings.

The Center for Tobacco Products (CTP) TRLM provides a means for tobacco companies to register domestic and foreign facilities that manufacture tobacco products to be sold in the US.

The Center for Devices and Radiological Health (CDRH) DRLM is used to register facilities that manufacture medical devices and to list the products manufactured at these facilities. The CECATS module allows CDRH's Office of Compliance (OC) to collect, verify, track, and issue export certificates.

The Center for Biologics Evaluation and Research (CBER) BECATS module provides a means for tracking certificate requests, automating the certificate process and for FDA

personnel to monitor domestic product status.

The Center for Drug Evaluation and Research (CDER) CDER eCATS module aids the Center to electronically process and transfer export certificates approved data to the Office of Financial Management for collection of export certificate fees.

OAA is used to maintain account information. An alert module is used to send mass notifications to selected facilities. An Enterprise Service Bus (ESB) sends notifications to industry resulting from registration actions and controls the schedule of batch processes. An ESB is a set of rules and principles for integrating numerous applications together over a "bus-like" structure which allows systems to communicate without dependency on or knowledge of other systems on the bus. PNSI is integrated with OAA's user authentication and authorization capabilities. Once a user is authenticated via OAA, they are provided access to PNSI based on the user's role.

FURLS users who access or use the system do not use any personal identifiers to retrieve records held in the system.

PTA - 10A:	Are records in the system retrieved by one or more PII data elements?	No
PTA - 11:	Does the system collect, maintain, use or share PII?	Yes
PIA		
PIA - 1:	Indicate the type of PII that the system will collect or maintain	Name Mother's Maiden Name E-Mail Address Phone numbers Taxpayer ID Mailing Address Others - (a) Access credentials for external users (username/password) and (b) fax number
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared	Employees/ HHS Direct Contractors Public Citizens
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 primary purpose of the PII in FURLs is to create, manage, and communicate regarding registrations/listings/certificates and associated industry users registering through FURLs. For example: username/password is used to ensure controlled, secure access; email and mailing address are used to communicate with industry users regarding any actions taken on submissions including new account creation, account deactivation or reactivation, temporary passwords for password reset, new submissions, status changes, return for action, and other actions.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research)	None.
PIA - 7:	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: 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 - 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

Other HHS OPDIV

State/Local/Tribal

Foreign

Non-Government Sources

Members of the Public

Private Sector

PIA - 9A:

Identify the OMB information collection approval number or explain why it is not applicable.

The system uses the following OMB approved forms:

Forms 2541/2541d/2541e/2541f/2541g

OMB Approval Number 0910-0037

OMB Expiration Date 10/31/2020

FDA 3613

OMB Approval Number 0910-0498

OMB Expiration Date 04/30/2021

FDA 3972

OMB Approval Number 0910-0509

OMB Expiration Date 11/30/2020

Form 3972

OMB Approval Number 0910-0839

OMB Expiration Date 01/31/2021

FDA 3613d/3613e

OMB Approval Number 0910-0793

OMB Expiration Date 08/31/2018

Form 3733

OMB Approval Number 0910-0660

OMB Expiration Date 08/31/2019

Form 3673(03/08)

OMB Approval Number 0910-0625

OMB Expiration Date 06/30/2019

Form 3537/3537a

OMB Approval Number 0910-0502

OMB Expiration Date 08/31/2019

Form 3880

OMB Approval Number 0910-0330

OMB Expiration Date 05/31/2021

Form 3955

OMB Approval Number 0910-0331

OMB Expiration Date 06/30/2019

Form 3997

OMB Approval Number 0910-0750

OMB Expiration Date 06/30/2019

Form 4041

OMB Approval Number 0910-0840

OMB Expiration Date 07/31/2020

FDA 3741

OMB Approval Number 0910-0650

OMB Expiration Date 01/31/2019

Form 3540

OMB Approval Number 0910-0520

OMB Expiration Date 07/31/2020

Non numbered Form

OMB Approval Number 0910-0842

OMB Expiration Date 08/31/2020

PIA - 10:

Is the PII shared with other organizations outside the system's Operating Division?

Yes

PIA - 10A:

Identify with whom the PII is shared or disclosed and for what purpose

State or Local Agency/Agencies

Within HHS

PIA - 10A (Justification):	Explain why (and the purpose) PII is shared with each entity or individual.	<p>Within HHS: FDA only. FDA's Office of Regulatory Affairs (ORA): ORA personnel who operate their Firms Master List Service system (FMLS) have restricted read access to some of the tables of the Food Facility Registration Module (FFRM)/Shell Egg Registration Module.</p> <p>State or Local Agency/Agencies: Personnel of State Agencies are direct contractors with the FDA who are provided read access to Food Facility Registration (FFR) data.</p>
PIA - 10B:	List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement, Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	FDA establishes Memoranda of Understanding (MOUs) and employs Non-Disclosure Agreements to govern recipient data handling.
PIA - 11:	Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason	<p>Facility/Registrant points of contact self-submit PII (work contact information) and are aware of the purpose of the FDA's use of the data for communicating with the submitter regarding a registration submission. All submitters may view additional information on FDA's privacy policies permanently posted on FDA.gov.</p> <p>At the time of hire, FDA personnel consent to the submission and use of their information by HHS/FDA as a condition of employment. HHS and FDA representatives, and the various individuals involved with the specific personnel data collection and use (such as Human Resources staff) provide notification to the subject personnel at the time the data is requested. Information that is provided about an individual is as it relates to their role in an organization instead of their personal information.</p>
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 13:	Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason	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 HHS/FDA as a condition of employment.
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 the FDA should change 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 - 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	External submitters (e.g., registrant point of contact) may contact the FDA offices identified in the FDA's online web/privacy policy and elsewhere on FDA.gov. FDA personnel may

		raise concerns through the FDA Employee Resource and Information Center (ERIC) or contact FDA's Systems Management Center (SMC) or Privacy Office.
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	Registrants 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 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 - 17:	Identify who will have access to the PII in the system and the reason why they require access	Users Administrators Contractors Others
PIA - 17A:	Provide the reason of access for each of the groups identified in PIA -17 Users: FDA internal users and direct contractors receive, review, manage and track submissions. Administrators: Administrative purposes such as activating or re-instating a canceled facility registration and resetting passwords. Some of the administrators are direct contractors. Contractors: To view data in read only mode. Direct contractors require access to fulfill responsibilities under their FDA contract. Others: External/industry users can create their own accounts and submit data. The external users can only access their own PII data.	
PIA - 17B:	Select the type of contractor	HHS/OpDiv Direct Contractor
PIA - 18:	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 - 19:	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	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 - 20:	Identify training and awareness provided to personnel (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	All FURLS users take annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to

	maintained	<p>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.</p>
PIA - 21:	Describe training system users receive (above and beyond general security and privacy awareness training).	<p>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.</p>
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific NARA records retention schedule(s) and include the retention period(s)	<p>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. 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. From the LACF PIA: FDA file codes 7220-7225 (NARA approved citation nos. N1-88-07-2 and General Records Schedule 20-2a, 2b, 4-7, 12, 16) 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.</p>
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	<p>Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. 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.</p>

PIA - 26:	Does the website have a posted privacy notice?	Yes
PIA - 27:	Does the website use web measurement and customization technology?	No
PIA - 28:	Does the website have any information or pages directed at children under the age of thirteen?	No
PIA - 29:	Does the website contain links to non-federal government websites external to HHS?	No