Privacy Impact Assessment (PIA): FDA - IFTRACK II - QTR1 - 2023 - FDA2077735

Date Signed: 1/27/2023

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:**	1601608
PIA Name:	FDA - IFTRACK II - QTR1 - 2023 - FDA2077735	**Title:**	CFSAN Food Safety & Nutrition Submission Applications
OpDiv:	FDA		

PTA

PTA - 2:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	Since the last privacy impact assessment (PIA) FDA made minor updates to the system. All are bug fixes and minor enhancements to the system including submission verification, email notification, and advanced search. These changes do not include personally identifying information (PII) and does not increase or create the privacy risk associated with the system.
PTA - 3:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA - 4:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions.	The CFSAN Infant Formula Track II (IFTRACK II) system is a web-based application that replaces the predecessor IFTRACK system ("system" and

		"application" are used interchangeably in this assessment). The FDA's Center for Food Safety and Nutrition (CFSAN) Office of Nutrition and Food Labeling (ONFL) uses IFTRACK II in their work developing policy and regulations regarding nutrition labeling and food standards, infant formula and medical foods and for scientifically evaluating these products. Within ONFL, the Infant Formula and Medical Foods staff (IFMFS) is a primary internal user of the system. IFMFS is responsible for the regulation of infant formula. IFMFS responds to data submissions and notifications from manufacturers of all new or modified infant formulas and provides counsel and review in the areas of nutritional science and medical science. The office receives, reviews, and responds to pre-market (not available or marketed to the public) infant formula submissions required of manufacturers under section 412 of Federal Food, Drug, and Cosmetic Act. FDA must review and respond to infant formula (IF) manufacturer submissions within 90 calendar days of submission. IFTRACK II supports the following functions: Timely, effective, consistent, collaborative, and thorough scientific review and assessment of submissions; Communications/collaboration within FDA and with submitters; Access to records and knowledge of past reviews, responses, policy, and product history; and Providing a repository for all infant formula submissions, responses, and the details of the review process for each submission will be saved in the database.
PTA - 5:	List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.	IFTRACK II collects and maintains Infant Formula submission information submitted by manufacturers. The submissions contain mandatory information such as the product name,

manufacturer's name and address of the place of business, address for each location where the product is manufactured, complete quantitative formulations, detailed description of reformulations and/or processing changes, rationale for reformulations, detailed description of the medical conditions with which an infant formula may be associated, ingredients and labeling information and exemption requests which include details regarding the reason(s) a manufacturer requests an exemption from regulatory requirements.

IFTRACK II also maintains submission review data such as submission review reports produced by the FDA's different reviewer groups, consultants, FDA Consumer Safety Officers (CSO), Team Lead comments, internal and external communications during the review process, interim and final memos and signed CSO letters to manufacturers. The FDA reviewer groups include the CFSAN Infant Formula and Medical Food staff (IFMFS), which is responsible for the regulation and review of the infant formula submissions and is the primary reviewer group for the infant formula submission.

Internal (FDA) users access the system using a secure single sign-on (SSO) approach employing multi-factor authentication that does not require system-specific usernames or passwords.

IFTRACK II collects and maintains Infant Formula submission information submitted by manufacturers and also maintains submission review data by the FDA's different reviewer groups.

IFTRACK II collects the following personally identifying information (PII): (a) industry manufacturer/external users' login credentials (i.e., username, password); (b) information about the points of contact (POCs) regarding the infant formula submissions of the manufacturer including the work/professional-context first and last name, email address, phone number and mailing address; and (c) FDA internal users' email addresses.

For external users (submitting manufacturers), the IFTRACK II System Administrator provides them a username and an auto-generated temporary password when they register to make submissions. The industry manufacturer must then meet FDA security standards (i.e., change the temporary password during the initial login and thereafter change it every 60 days).

The PII is not shared with any other system or organization.

IFTRACK II also collects the following non-PII data: (a) new or modified infant formula information submitted for FDA to review/approve including infant formula manufacturer/product/formulation info, ingredients/labeling/nutritional data and packaging/processing information; (b) FDA

reviewers' review comments/questions to manufacturers, and the non-PII content of final letters; and (c) the status of a submission.

PTA - 5A:	Are user credentials used to access the system?	Yes
PTA - 6:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual.	IFTRACK II collects and maintains Infant Formula submission information submitted by manufacturers. The submissions contain

mandatory information such as the product name, manufacturer's name and address of the place of business, address for each location where the product is manufactured, complete quantitative formulations, detailed description of reformulations and/or processing changes, rationale for reformulations, detailed description of the medical conditions with which an infant formula may be associated, ingredients and labeling information and exemption requests which include details regarding the reason(s) a manufacturer requests an exemption from regulatory requirements.

IFTRACK II also maintains submission review data such as submission review reports produced by the FDA's different reviewer groups, consultants, FDA Consumer Safety Officers (CSO), Team Lead comments, internal and external communications during the review process, interim and final memos and signed CSO letters to manufacturers. The FDA reviewer groups include the CFSAN Infant Formula and Medical Food staff (IFMFS), which is responsible for the regulation and review of the infant formula submissions and is the primary reviewer group for the infant formula submission.

Internal (FDA) users access the system using a secure single sign-on (SSO) approach employing multi-factor authentication that does not require system-specific usernames or passwords.

IFTRACK II collects and maintains Infant Formula submission information submitted by manufacturers and also maintains submission review data by the FDA's different reviewer groups.

IFTRACK II collects the following personally identifying information (PII): (a) industry manufacturer/external users' login credentials (i.e., username, password); (b) information about the points of contact (POCs) regarding the infant formula submissions of the manufacturer including the work/professional-context first and last name, email address, phone number and mailing address; and (c) FDA internal users' email addresses.

For external users (submitting manufacturers), the IFTRACK II System Administrator provides them a username and an auto-generated temporary password when they register to make submissions. The industry manufacturer must then meet FDA security standards (i.e., change the temporary password during the initial login and thereafter change it every 60 days).

The PII is not shared with any other system or organization.

IFTRACK II also collects the following non-PII data: (a) new or modified infant formula information submitted for FDA to review/approve including infant formula manufacturer/product/formulation information, ingredients/labeling/nutritional data and

packaging/processing information; (b) FDA reviewers' review comments/questions to manufacturers, and the non-PII content of final letters; and (c) the status of a submission.

PTA - 7:	Does the system collect, maintain, use or share PII?	Yes
PTA - 7A:	Does this include Sensitive PII as defined by HHS?	No
PTA - 8:	Does the system include a website or online application?	Yes
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	Yes
PTA - 9:	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	This website allows infant formula manufacturers (external users) to submit new or updated infant formula submissions to FDA/CFSAN for review and approval. The IFTRACK II System Administrator provides the authorized external user a username and password when they register to make submissions. The external users must log in using their valid 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?	Yes
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:	Is there a third-party website or application (TPWA) associated with the system?	No
PTA - 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

PIA

PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Email Address Mailing Address Name Phone numbers
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Employees/ HHS Direct Contractors Members of the public
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system.	51 - 200
PIA - 4:	For what primary purpose is the PII used?	The FDA uses the PII in the system to administer access and communicate with manufacturers, ask questions regarding their submissions, and respond back with the final FDA response to the submission.
PIA - 7:	Identify legal authorities governing information use and disclosure specific to the system and program.	Section 412(c)(1) of the Federal Food, Drug, and Cosmetic Act requires persons responsible for

		the manufacture or distribution of a new infant formula, including infant formula for export only, to register with FDA before a new infant formula may be introduced or delivered for introduction into interstate commerce. The requirements for registration can be found in 21 CFR 106.110 and include: the name of the new infant formula, the name of the manufacturer, the street address of the place of business of the manufacturer, and the name and street address of each establishment at which the manufacturer intends to manufacture the new infant formula. Manufacturers may register at any time before introducing a new formula into interstate commerce. However, FDA requests that they do so while they submit notice of their intent to market a new infant formula in accordance with section 412(c)(1)(B) and (d)(1) of the Act.
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	No
PIA - 9:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Email Non-Government Sources Private Sector
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA - 10A:	Provide the information collection approval number.	OMB Control No. 0910-0256,
PIA - 10B:	Identify the OMB information collection approval number expiration date.	3/31/2023
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	No
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	Submission of PII is voluntary as that term is used by the Privacy Act. However, the submission of PII is necessary for users to

		access and use the system. Manufacturer contact name, address, phone, and email are needed for communications in the case of any questions during a submission review and will be used to inform manufacturers when FDA sends final review letters. Login username and password are also needed to authenticate users outside the FDA such as industry manufacturers. There is no option to object to the information collection if a manufacturer needs a submission reviewed and approved by FDA.
PIA - 14:	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained.	If FDA changes its practices regarding the collection or handling of PII related to the website, the agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include email to individuals, adding or updating online notices or forms, or other available means to inform the individual.
PIA - 15:	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	Individuals who suspect their PII has been inappropriately obtained, used, or disclosed in any FDA system have many avenues available for assistance. These individuals may contact FDA offices, including the Privacy Office, the Employee Resource and Information Center (ERIC), the 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).
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.	Individuals voluntarily provide their PII. 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. PII relevancy is supported through the design of the system to require and collect only the PII elements necessary to administer the system and enable its intended use. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). 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). Controls are selected based on the 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. CFSAN performs quarterly reviews to evaluate and adjust user access.
PIA - 17:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA - 17A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA - 17B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA - 18:	Provide the reason why each of the groups identified in PIA - 17 needs access to PII.	Users: The system users which include FDA internal reviewers and manufacturers who submit their own information. Administrators: System administrators will grant access to the system. Developers: Development contractors (Direct Contractors) to test the system. Contractors: Direct Contractors are the developers of the system
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	All access to the system for users and administrators requires approval prior to the user gaining access. System access requires business

		owner approval, is reviewed on a quarterly basis to identify and remove unnecessary accounts. Internal users must obtain supervisory confirmation and approval of their need to access the system via the single sign-on/PIV card. Only the System Administrators and FDA internal users have the accesses to the PII. For the manufacturer/external users, the IFTRACK II System Administrator provides the authorized external user a username and password when they register to make submissions. The external users must log in using their valid username and password.
PIA - 20:	Describe the technical methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.	For internal users, the user's supervisor will indicate on the account creation form the minimum information system access that is required for the user to complete his/her job. The access list for the information system is regularly reviewed to adjust users' access permissions and remove unnecessary accounts. For external users, the level of access is uniform; each account holder has access only to the materials they submit and related FDA materials.
PIA - 21:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.	All system users at FDA 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 Digital Transformation (ODT) verifies that training has been successfully completed.
PIA - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	CFSAN provides internal users with a user security policy and FDA Staff Manual Guide (SMG). For the external users, IFTRACK II Business Owner conducts system-specific training when onboarding the new users.
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	General Records Schedule (GRS) 4.2, item 15a (DAA-GRS-2013-0007-0012). Disposition is temporary, destroy when 90 days old or no longer needed pursuant to supervisory authorization,

		whichever is appropriate. CFSAN retains IF submissions and their PII content as long as needed. They are typically needed at least through the duration of the submission review process which often exceeds 90 days.
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.	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.