US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/24/2013

OPDIV:

FDA

Name:

Food Applications Regulatory Management

PIA Unique Identifier:

P-7967597-810413

The subject of this PIA is which of the following?

Major Application

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

Yes

Does the system include a Website or online application available to and for the use of the general public?

No

Identify the operator.

Agency

Is this a new or existing system?

Existing

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

PIA Validation

Describe in further detail any changes to the system that have occurred since the last PIA.

N/A (no system changes; annual PIA review)

Describe the purpose of the system.

The Food Applications Regulatory Management (FARM) project's electronic information management system is designed to support electronic processing, review, maintenance, and reporting for food ingredient submissions. This includes management of food and color additive petitions, Food Contact Notifications (FCNs), Generally Recognized as Safe Notices (GRNs) and Biotechnology Consultations, by providing modern electronic information management tools necessary for FDA food ingredient reviewers and managers to maximize their productivity. FARM allows reviewers to spend more time reviewing submissions and less time searching for, processing, and circulating information. FARM also allows reviewers to utilize state-of-the art analytical and search tools to support safety reviews, evaluations, and decisions.

Describe the type of information the system will collect, maintain (store), or share.

The FARM system contains information submitted by the food industry regarding ingredients that are added to or will come in contact with food. All petitions, notices, and notifications must contain appropriate and sufficient scientific data and information to support the safety review process.

The FARM system contains a minimal amount of PII which is required in order to contact industry business personnel. The names and business phone numbers collected are not used to retrieve information from the FARM system. The agency collects only the information provided for under the Federal Food, Drug and Cosmetic Act (FFDCA) and corresponding regulations (21 CFR 71-199), the Dietary Supplement and Health Education Act (DSHEA), and the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

Provide an overview of the system and describe the information it will collect, maintain (store), or share,

The FARM System is an end-to-end electronic information management system that manages and validates the receipt, processing, storage, routing, tracking, and reporting of food ingredient information collected from the food industry. It manages information regarding food ingredients that are added to or will come in contact with food for human consumption and ingredients that are consumed as dietary supplements.

The information that industry submits to the agency contains chemistry, toxicology, environmental, nutritional, microbiological, and other relevant safety-related data. Information collected by the FARM system consists of data required to perform the safety review of food ingredients under the Federal Food Drug and Cosmetic Act, the Dietary Supplement and Health Education Act (DSHEA), the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), and related FDA regulations set out in the Code of Federal Regulations at 21 CFR 71 and 170-190. These legal authorities describe the data required from industry submitters of Food and Color Additive Petitions, Food Contact Notifications (FCN), Generally Recognized as Safe Notices (GRN), New Protein Consultations, Bioengineered Foods Consultations (BNF) for the Office of Food Additive Safety, New Dietary Ingredient 75 Day Notices, and 30 Day Structure Function Label Notices for the Office of Nutrition, Labeling and Dietary Supplements (ONLDS).

Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Name

Mailing Address

Phone Numbers

The specified PII is all work contact information.

Indicate the categories of individuals about whom PII is collected, maintained or shared.

Public Citizens

Vendor/Suppliers/Contractors

No

How many individuals' PII is in the system?

5,000-9,999

For what primary purpose is the PII used?

Industry points of contact self submit PII (work contact information) for use in communicating with FDA regarding food additive petitions and similar regulatory submissions.

Describe the secondary uses for which the PII will be used.

None.

Identify legal authorities governing information use and disclosure specific to the system and program.

The Federal Food, Drug and Cosmetic Act (FFDCA, 21 U.S.C. 301) and corresponding regulations (21 CFR 71-199), the Dietary Supplement and Health Education Act (DSHEA), and the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

Are records on the system retrieved by one or more PII data elements?

No

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

Hardcopy

Online

Government Sources

Non-Governmental Sources

Private Sector

Identify the OMB information collection approval number and expiration date

OMB No. 0910-0016; Expiration date June 30, 2014.

Is the PII shared with other organizations?

No

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.

Information is provided under the initiative of the submitting company. Submission forms and instructions describe the information that must be submitted and reference online resources where individuals may also review FDA's privacy policy.

Is the submission of PII by individuals voluntary or mandatory?

Mandatory

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 not a unique notice and consent process incorporated in this system. Industry self submits point(s) of contact PII (work contact information) for use in communicating with FDA regarding food additive petitions and similar regulatory submissions, and can view additional information on FDA's privacy policies permanently displayed on FDA.gov.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

Regulated firms submit point(s) of contact PII (work contact information) for the purpose of communicating with FDA regarding a regulatory submission and can view additional information on FDA's privacy policies permanently linked on FDA.gov. If the agency makes a major change to the system related to PII, FDA will update online notices and FARM submission forms and instructions.

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.

There is not a PII complaint process dedicated to this system. Individuals may contact FDA or CFSAN by phone, mail or email using the contact information provided on fda.gov and the specific fda.gov web pages associated with the food ingredient regulation program.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

PII (work contact data) is self-submitted. Incorrect data is corrected in the course of FDA/CFSAN's use of the system/information, e.g., updating name and phone number for point of contact. Individuals and entities may submit corrections or updates at any time by phone, mail or email using the contact information provided on fda.gov and the specific fda.gov web pages associated with the program.

Identify who will have access to the PII in the system and the reason why they require access.

Users:

Receive, review and manage submission; to contact firms.

Administrators:

Monitor the system, manage the workflow and system access.

Contractors:

Same as User

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

Users who require access to the information system need to have supervisor approval and sign off before access is granted.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

Supervisors will indicate on the account creation form the minimum information system access that is required in order for the user to complete his/her job. The 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.

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 maintained.

All personnel must complete IT security and privacy awareness training at least once a year.

Describe training system users receive (above and beyond general security and privacy awareness training).

Because proprietary data is maintained in the system, all users receive specialized training regarding the use of the system. Personnel may obtain additional privacy guidance from the agency's privacy office.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.

CFSAN maintains the records in accordance with FDA file code 5020, Food Applications Regulatory Management System (FARM). Records in this system are kept 30 years.

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

The information in the FARM system is protected by administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. These include user-specific access restrictions, firewall use, user identification and password requirements, virtual network, encryption, intrusion detection and secure, guarded facilities.