

US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/23/2013

OPDIV:

FDA

Name:

Recall Enterprise System

PIA Unique Identifier:

P-9180297-810413

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 PIA reason(s) for updating this PIA.

PIA Validation

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

The system has been enhanced to provide Recall Coordinators with the ability to create and/or update assignment requests for Recall Audit Check (RAC) field work; to create, upload, and manage distribution lists; to generate RAC summary reports; and to view RAC status and completed FDA forms 3177 (RAC Report).

Describe the purpose of the system.

The Food and Drug Administrations's Mission Accomplishment and Compliance Tracking - Recall Enterprise system (MARCS RES or Recalls) is an internal system that automates the process by which FDA-regulated products are removed from the marketplace. MARCS Recalls automates FDA's identification, processing and tracking of health and safety alerts and product recalls. RES provides centralized safety and health alerts, and, regulated product recall information internally at the FDA. FDA alerts and recalls are an effective method of providing alert notices to the public, and for removing or correcting consumer products that are in violation of the laws administered by the FDA.

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

Almost all of the data captured through the RES application is non-personal and can be grouped into the following categories of information: Firm information; Product information; Center-specific information; Recall Event, Recommendation and Classification information; and Recall Summary and Termination information.

The system handles a limited amount of personal information consisting of the business contact information for FDA personnel and industry points of contact. For FDA personnel the system holds names and e-mail addresses of the individual FDA employees who create or work with system records. This information is supplied by the FDA's Field Accomplishments and Compliance Tracking system (FACTS) database, and provides access to information regarding each user's role, and the FDA Center with responsibility for oversight of a recall activity.

Coordinator names are also included for data collection needs related to the recall event, work flow processing, and for the application to submit proper notifications. In addition, comment fields are available within the system in which the users will add necessary information, when applicable, in order to ensure information is provided for "recall" requirements.

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

This system automates FDA's identification, processing and tracking of health and safety alerts and product recalls. In order to effectively do so, the system collects certain contact information for individuals.

RES contains the name, work mailing address, work phone and work e-mail for the recalling Firm's "Most Responsible Individual." This individual's information is captured in RES because this is the person with whom FDA will communicate when notifying the firm that its action meets the definition of a recall and that FDA has assessed the hazard level of the relevant product(s). This individual's name, title, and work address are often publically available, particularly if the firm is traded on the stock market. In rare circumstances, particularly with small firms, the business address may be the same as the individual's home address.

The system also contains the name, title and contact information for a firm's "Recall Contact." This is the individual at the firm that is providing recall information to the FDA. And, in support of FDA Form 3177 (Recall Audit Check Report (internal)), RES captures the recall consignee name as well as the potential explanation from the consignee regarding their awareness of any injuries, illness or complaints associated with a recall.

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

Yes

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

Name

E-Mail Address

Mailing Address

Phone Numbers

PII collected is work contact information.

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

Employees

Public Citizens

No

How many individuals' PII is in the system?

10,000-49,999

For what primary purpose is the PII used?

Communicating with firms in relation to recall activities, and, tracking and managing FDA's processing and administration of the activity.

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.

FDA uses this system to protect and promote the health and safety of the American public under: the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301); the Federal Records Act; Electronic Communication Privacy Act of 1986; Homeland Security Act of 2002; the Computer Security Act of 1987; Information Technology Management Reform Act (also known as the Clinger-Cohen Act of 1996); Electronic Freedom of Information Act Amendments of 1996; the E-Government Act of 2002, Title III, Federal Information Security Management Act of 2002; and Executive Order (EO) 13231.

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**

In-Person

Hardcopy

Email

Online

Government Sources

State/Local/Tribal

Non-Governmental Sources**Identify the OMB information collection approval number and expiration date**

None.

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.

At the time of hire, FDA/HHS notify agency personnel and as a condition of their employment obtain consent to FDA's use of their information in relation to their work with FDA. Industry contacts submit their work contact information in the context of recall activities and are aware of FDA's use of their information. Individuals may also view FDA's website and privacy policies permanently available via link on all FDA intranet and internet pages.

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 no option to opt-out. The PII is required in order to communicate with the firm points of contact in regard to product recall activities.

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

If there are major system changes impacting use of PII, FDA will assess the need to notify individuals and implement appropriate notice mechanisms such as e-mail or letters to firm contacts and/or posting notices online.

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.

Personnel may contact IT security to report a personal privacy incident, may contact the agency privacy office, and may seek assistance through FDA's Employee Resource and Information Center (ERIC). Firm points of contact may submit concerns to their FDA liaison or other agency offices using the mailing addresses, email addresses and phone numbers available on FDA.gov.

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

FDA personnel are directed to keep their office information current and can update or correct their information at anytime. Firms and their points of contact are responsible for submitting accurate current contact information, and updating this information as needed by contacting FDA. Incorrect or out of date information is also addressed when identified in the course of system use.

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

Process and Manage Data Submission of recalls.

Administrators:

Review, processing and administering the system, files and data as well as access control.

Developers:

Troubleshooting issues with the system, performance and access.

Contractors:

Supporting the IT team for administration, troubleshooting and development of the system.

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 must first obtain supervisory approval.

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 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 users are trained on the system, and all users must annually complete FDA's information security and privacy awareness training.

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

Users receive system-specific training, and may obtain additional privacy guidance from the agency's privacy officials.

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.

Recall action records fall under FDA File Code families 7100 (7110) and 8100 (8120), and NARA approved citation N-1-088-05-01. Record destruction schedules vary by subtype and range from four to 75 years after close of a recall action.

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

FDA employs numerous technical, physical and administrative safeguards to protect PII and other data in the system. Safeguards include supervisor access controls, user identification, passwords, firewall, encryption, virtual private network, intrusion detection, guarded facilities and closed circuit TV.