US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/30/2013

OPDIV:

FDA

Name:

Center Tracking System

PIA Unique Identifier:

P-2730822-075716

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)?

No

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.

None.

Describe the purpose of the system.

FDA uses the Center Tracking System (CTS) to track the progress of industry submitted pre-market documents through the review process. CTS is a workflow/work management system that provides support for the Center for Devices and Radiogical Health (CDRH) business processes and business rules, for all stages of the product lifecycle for medical devices.

CTS includes CDRH Entry (CEntry) and Premarket Applications (APPS) which are the data entry components of the system where device information submitted by manufacturers is stored.

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

The system collects information regarding the processing and management of device application submissions. This information is related to specific activities or processes currently supported by CTS which include Premarket Division Tracking, Clinical Laboratory Improvement Act submissions, Requests for Designations, Condition of approvals, Device Nomenclature data, Postmarket Surveillance Studies, Compliance Operation Program Support, and eConsults.

CTS contains business submitter (individual) contact information included with legally required submissions, and, internal FDA personnel data such as name and location for CDRH personnel assigned to review those documents. Firms submitting materials must supply contact information. This information is necessary to enable FDA to process and respond to submissions. The submitted materials may also include legal documents and device identifiers that could potentially constitute PII (be used to identify an individual).

Information about devices that have successfully completed any required pre-market review by the FDA is made public through the CDRH and FDA Freedom of Information Act (FOIA) Offices. Information about devices that are under review, or which were not approved, is not shared. The business contact information in CTS is also not published, but can be made available under a Freedom of Information (FOI) request.

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

Prior to marketing a medical device, manufacturers must apply for FDA approval of the product(s). This requires the submission of materials for FDA review. CTS is a workflow and work management system that enables FDA to track the progress of industry submitted pre-market documents through the review process.

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

Legal Documents

Device Identifiers

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

Employees

Public Citizens

Public citizens above refers to individuals submitting legally required documents on behalf of a company.

How many individuals' PII is in the system?

100-499

For what primary purpose is the PII used?

The FDA uses the PII in CTS to process and respond to 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.

All submissions maintained in CTS are in support of FDA activities authorized by the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 301.

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

Email

Online

Government Sources

Within OpDiv

Non-Governmental Sources

Private Sector

Identify the OMB information collection approval number and expiration date

OMB No. 0910-0120, expiring 12-31-13.

Is the PII shared with other organizations?

Yes

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

Within HHS

Name and contact information is not shared with the public, but is shared within FDA by various applications for purposes of registration, listing, and further contacts with the document submitter. Information about devices that have successfully compl

Describe any agreements in place that authorizes the information sharing or disclosure.

None.

Describe the procedures for accounting for disclosures.

Not applicable.

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

There are no formal notice and consent procedures specific to this system. External submitters provide their contact information as a practical requirement in order to communicate with FDA about submissions. At the time of hire, system users (FDA employees/contractors) consent to the agency's use of their work contact information as a condition of employment. They are also advised at the CEntry and CTS login screen that they are accessing a U.S. Government information system, their system usage may be monitored, recorded, and subject to audit, unauthorized use of the system is prohibited and subject to criminal and civil penalties; and use of the system indicates consent to monitoring and recording.

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 are no opt-out procedures specific to any of the system componenets (CEntry, CTS, or APPS). The PII is necessary in order for FDA to process submissions and contact submitters.

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

If FDA's privacy practices change or FDA changes its collection, use, or sharing of PII data in either CEntry, CTS or APPS, the individuals whose PII is in the system will be notified 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 (e.g., paper, email, online advisory). Alternatively, notification will be made by informal processes such as email notice to the individuals.

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.

FDA personnel may raise concerns through the FDA's Employee Resource and Information Center (ERIC) via phone or email. External individuals (submitter points of contact) who have concerns may contact FDA or CDRH by phone, mail or email using the contact information provided 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 responsible for maintaining up to date and accurate work contact information and may self-correct their information or request assistance through ERIC. External submitters may also update and correct their work contact information within their submissions and by contacting FDA/CDRH.

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

Users:

Review, manage and track submissions and assignments

Administrators:

Monitor the system and manage system access

Developers:

Developers and DBAs require access to database tables to manage the system

Contractors:

Developers are contract personnel

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 obtain 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.

When an employee/user requests access, his/her supervisor will indicate on the account creation form the access limitations necessary to restrict it to the minimum amount of information that is required in order for the user to perform his/her duties. The access list for the information system is also reviewed on a quarterly basis during which time users' access permissions are reviewed/adjusted, and unneeded accounts are removed 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.

At least once a year, personnel must complete information security and privacy awareness training.

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

Personnel are trained on the use of the system and review the Rules of Behavior. Additional role-based training on privacy is available via FDA'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.

Records are maintained indefinitely subject to CDRH's Records Officer guidance. A number of control schedules apply to the various records in CTS. For example, NARA citation N1-088-08-1, Items 2.1-2.5; General Records Schedule 20, item 2a4; and FDA file codes in the 2000-2700 family. These typically call for deletion of records when no longer needed for business and regulatory purposes, or after 20 or in some cases 30 years, whichever is later.

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

Information contained within this system is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, the National Institute of Standards and Technology (NIST), and the Office of Management and Budget (OMB). These controls include guarded and secure access-controlled facilities, firewall, passwords, VPN, encryption, intrusion detection and smart cards.

Security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.