

US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

02/27/2017

OPDIV:

FDA

Name:

FDA CTP Electronic Submissions

PIA Unique Identifier:

P-7465194-382822

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

Significant System Management Change

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

eSubmissions contains two modules added subsequent to the prior Privacy Impact Assessment (PIA) approval:

The Industry Document Analyst Tool (iDAT) is a database with a User Interface (UI) to receive, store, and analyze tobacco industry documents submitted to FDA.

The Risk Modeling and Simulation Tool (RMST) module of the eSubmissions system improves the efficiency of FDA's tobacco product reviews.

The Portal/Tobacco Regulatory Information System (ToRIS) provides visibility for regulated industry (i.e. tobacco manufacturers) to view information about their submissions.

Additionally, eSubmissions is now connected to the Safety Reporting Portal (SRP) operated by the National Institutes of Health (NIH). SRP is a database that captures adverse events data submitted by the public via the portal and makes it available to FDA.

Describe the purpose of the system.

The Center for Tobacco Products (CTP) eSubmissions system (also referred to as eSub) is a suite of database-supported applications that facilitates the collection, logging, tracking, and retrieval of documents provided to FDA by the tobacco industry and others (e.g., adverse events reports from the general public). CTP uses this data to evaluate tobacco products, develop policy, and assess industry compliance with the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The eSubmissions suite is comprised of the following applications:

CTP uses PreLoader to pass submitted materials to the Loader application that extracts files from submissions and loads attachments into the CTP Electronic Document Room (EDR) and metadata files into the eSub database.

The CTP Portal/Tobacco Regulatory Information System (ToRIS) provides visibility for regulated industry (i.e. tobacco manufacturers) to view information about their submissions.

Inventory Tracking Recording and Control (iTRAC) is the application used by the CTP Document Control Center (DCC) to track incoming documents from the tobacco industry. CTP Database stores metadata extracted from submissions.

CTP Image and Documentum Services are tools used to view documents and electronic media files stored in the EDR.

Address Book is used to supplement and report on industry contact information.

Adverse Events is the application used to store adverse events data received by the National Institute of Health's (NIH) Safety Reporting Portal (SRP) and shared with FDA.

The Industry Document Analyst Tool (iDAT) is a database with a User Interface (UI) for CTP Office of Science (OS) staff to receive, store, and analyze tobacco industry documents.

The Risk Modeling and Simulation Tool (RMST) module of eSub enhances tobacco product reviews, specifically the regulatory review process, regulatory review scientific standards, Reports of Substantial Equivalence (SE) and Ingredients listings.

eSub applications are not available to or used by the general public. They do receive and store information from other agency applications that interface with the public. For example, the FDA's eSubmitter Tool is public-facing and used by the tobacco industry entities to submit materials to FDA, and the NIH SRP is an NIH managed submission tool available to the public. The eSubmitter Tool and SRP user interfaces are not part of the CTP eSubmissions system and are not addressed in this Privacy Impact Assessment (PIA).

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

The system collects information from members of the tobacco industry regarding tobacco registration, tobacco products, their ingredients and where they are made. In accordance with the provisions of the FSPTCA, tobacco manufacturers submit registration and product listing, ingredient listing, documents describing health effects of tobacco product ingredients, and other tobacco-related data. This information is used to make scientific and regulatory decisions regarding these products and the tobacco industry. Submissions may contain the name and contact information of the person submitting the information, although in most cases inclusion of this information is optional. This information is maintained in the CTP Database and iDAT.

The CTP Portal/Tobacco Regulatory Information System (ToRIS) provides visibility for regulated industry (i.e., tobacco manufacturers) to view information about their submissions such as: submission date, Submission Tracking Numbers (STN) and date received.

Address Book contains names, addresses, phone numbers, work addresses, employer names, and e-mail addresses of industry points of contact.

Stored adverse events submissions (reports of problems experienced by a product user) are maintained in the system and may contain personally identifiable information (PII). This PII can include name, e-mail, phone and mailing address, race/ethnicity, gender, age group, date/cause of death, and pregnancy information.

FDA users of eSub do not use PII to retrieve records from any of the applications in eSub.

eSubmissions does not use or store system-specific usernames, passwords or other access and authentication information. System access is controlled via a single-sign-on process providing multi-factor authentication.

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

In accordance with the provisions of the FSPTCA, industry entities (e.g., tobacco manufacturers) submit registration and product listing, ingredient listing, ingredient health effect documents, and other data. This information may be submitted via the eSubmitter application, through the FDA Electronic Submissions Gateway (ESG), on physical media such as CD or on paper. In addition, members of the public are able to submit adverse event reports that are subsequently received by eSubmissions. However, the public makes these submissions via SRP, a system owned and managed by NIH. Adverse event reports are reports of adverse effects to individuals' health that those individuals believe are attributable to the use of FDA-regulated products; they may be submitted by any member of the public.

The eSubmitter system streamlines the submissions process and equips CTP to manage actions to regulate the tobacco industry. It provides a means to: load/record submissions received via the ESG and mail; track and review all submissions received; store the submissions and all documents associated with the submission; and make data available to CTP staff. CTP staff retrieve documents that are part of adverse event reports using product names only and no personal identifier.

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

Yes

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

Date of Birth

Name

E-Mail Address

Mailing Address

Phone Numbers

Medical Notes

Other: For adverse events submissions, potential PII (when combined with other data): race/ethnicity, gender, age group, date/cause of death, pregnancy. Additionally, Work/Professional contact information is gathered from industry, but only on a voluntary basis.

Collection of medical information (no medical record numbers) is possible, although not expected.

The SRP system accepts open text, and a user may choose without prompting to provide a medical record number, or any other unsolicited information.

For tobacco industry submissions, the name of a POC may be included. Information is not retrieved using this professional contact information.

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

Public Citizens

Public citizens refers to individual citizens as well as industry points of contact. It can also include people who experience adverse events as patients, but FDA does not itself treat patients, and neither do any of the other submitters of information into this system.

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

The point of contact information received from industry will be used in eSubmissions as an address book in order to maintain and update correct contacts with industry. FDA/CTP personnel use adverse events information to make scientific and regulatory decisions regarding the products involved in the adverse events reports. In rare circumstances, submitter contact data PII is used to contact the submitter when follow-up is required.

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.

21 U.S.C. 301, sections 375(b), 387d, and 387e of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31, 123 Stat. 1776), incorporated at 18.U.S.C. 1001, Sections 904(a) and 904(b).

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

Other

Government Sources

Within OpDiv

Other HHS OpDiv

Other Federal Entities

Non-Governmental Sources

Public

Private Sector

Identify the OMB information collection approval number and expiration date

OMB No. 0910-0650, expiring January 31, 2019; and 0910-0654, expiring June 30, 2019.

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.

For PII submitted by members of the tobacco industry, CTP provides notice on FDA submission form 3741 and 3743. FDA privacy policies are also permanently available across all fda.gov web pages and describe FDA policies and practices for information collection and sharing. Submission of PII by members of the tobacco industry is voluntary. Where other systems (NIH SRP, FDA ESG) not addressed in this Privacy Impact Assessment (PIA) are the source of PII stored in eSub, the operators of those systems are responsible for providing notice to individuals.

Is the submission of PII by individuals voluntary or mandatory?

Voluntary

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.

Individuals do not have to provide their PII at all; the submission of PII is completely voluntary.

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

Individuals whose PII is in the system will be notified of a major change by the most efficient and effective means available and appropriate to the specific change(s). This may include a formal process involving written and/or electronic notice, or 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.

Individuals have the ability to notify and seek assistance from FDA and CTP by dedicated phone numbers and/or a dedicated email address. This information is available on our general website 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.

All PII is solicited using approved forms and is relevant to facilitate communication between CTP and regulated organizations. CTP reviews industry submissions on a quarterly basis, and evaluates them to determine whether they are consistent with previous submissions as well as public information. Data integrity and accuracy are important to the extent that PII permits communication with regulated organizations; industry organizations can supply the name of any individual who is able to communicate with FDA on behalf of the organization. Integrity, as well as availability, are both protected by security controls selected according to the risk level of the system and consistently with federal guidance from the Office of Management and Budget (OMB) and the National Institutes of Standards and Technology (NIST).

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

Users:

CTP staff to make determinations for adverse events.

Developers:

For system development and upkeep.

Contractors:

FDA direct contractors access eSub for system development and upkeep.

Others:

Submitters have access to their own information only, not to that submitted by others.

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

CTP employees and direct contractors with valid network accounts who require access to eSubmissions must have supervisory approval and signature before access is granted. An internal form 3530, "User Access Request" form, must be completed and approved by the Program Manager, Business Owner, and FDA System Owner before access to eSubmissions is granted. The agency reviews the system access list on a quarterly basis to adjust users' access roles and permissions and delete unneeded accounts from the system.

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.

A Standard Operating Procedure (SOP) and System Access Request (SAR) form are used to grant different levels of system access based on work need and role. The relevant supervisor will indicate on the eSubmissions user account creation form the minimum access that is required in order for the user to complete his/her job. The scope of access is restricted based on role-based criteria. All users are authenticated.

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.

FDA provides mandatory IT security and privacy awareness training for all FDA personnel. A portion of this training is dedicated to the protection of PII overall for the agency.

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

None currently. Privacy guidance and training is available via the 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.

The electronic data captured by eSubmissions will be retained indefinitely, pending receipt of an FDA file code consistent with the National Archives and Records Administration (NARA) guidelines. CTP anticipates that the file code will be FDA's file code 6132, consistent with NARA-approved schedule N1-88-07-2, for Adverse Events Reporting System Database Records, which are cutoff annually at the end of the calendar year after a case is closed and deleted 30 years after cutoff or when no longer needed for trend analysis or reference purposes, whichever is the latest. The selection of this retention schedule is under review and will be updated as necessary.

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

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.

