US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

07/28/2017

OPDIV:

FDA

Name:

FDA CVM Corporate Database Portal

PIA Unique Identifier:

P-6266584-472548

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?

New

Does the system have Security Authorization (SA)?

Yes

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

Describe the purpose of the system.

The Corporate Database Portal system (CDP) is a web based application consisting of several integrated modules sharing a common database used by FDA Center for Veterinary Medicine (CVM) employees to track and report on their work. CDP uses web services to share data and integrate with other FDA/CVM systems. The system supports activities related to pre-market approval of animal drugs and animal food additives, post-market animal drug safety surveillance activities, compliance activities, export certificate activities, animal drug listings and establishment registrations, bioresearch monitoring of animal drug studies, time reporting tracking, and minor use/minor species drug index files.

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

CDP contains information on: pre-market animal drugs and feeds such as research sponsor name (corporate owner), active drug ingredients, indications for use, and relevant species; post-market safety of animal drugs and feeds (such as adverse drug events and drug experience reports); animal drug products and related establishments (i.e., manufacturers and distributors); employees'daily activities and times worked; animal drug research monitoring (clinical investigators, contract research labs, manufacturing sites); correspondence contacts; export certificates; regulatory actions; and similar FDA programs administered by CVM.

The system collects this information to track the drug approval process and other administrative functions performed by CVM in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The personally identifiable information (PII) in this system consists of name and professional contact information, such as office address and phone number of clinical investigators and research sponsor personnel serving as the sponsoring entity's point of contact for interaction with FDA and animal owners. Additionally, the system collects and maintains name and office phone number of CVM personnel who use CDP. PII about CVM personnel using CDP is collected for activity time reporting and other administrative purposes. Submission of this information is required in order to comply with the FD&C Act.

The only individuals who can access the CDP system are CVM employees including direct contractors who have been approved as CDP users. Once approved, CDP users access the system via a single-sign-on (SSO) process using multi-factor authentication. CDP does not require, use, collect or maintain system-specific user logon credentials (e.g., username and password).

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

CDP is the CVM's main transactional database that supports various data applications for CVM divisions such as CVM's Office of New Animal Drug Evaluation (ONADE), Office of Surveillance and Compliance (OSC), Office of Research (OR), Office of Minor Use, Minor Species (OMUMS), and Office of Management (OM). It is comprised of three application systems: CDP, CDP-Web, and the Compliance Log system (LOG). It is a relational database system consisting of several subsystems. CDP supports common data tables with, and provides a link to, CVM's Corporate Document Management System (CDMS).

CDP is the entry portal for six modules for data entry, data storage, data tracking and reporting throughout CVM: Submission Tracking and Reporting System (STARS), Drug Experience Reporting System (DERS), Drug Product Listing (DPL), Bioresearch Information Monitoring (BIMO), Minor Use/Minor Species (MUMS) Index File System (MIFS), and Activity Time reporting (ATR).

These CDP modules support pre-market and post-market business processes related to safety, product quality, administrative, food safety, drug indexing, bioresearch monitoring, and compliance. They enable FDA to administer and manage the review and processing of data necessary to ensure the quality and safety of animal drugs. This includes processing animal drug application submissions, maintaining post-market animal drug and feed safety reporting information, and performing internal accounting tasks.

CDP-Web is the Java-based version of the user interface, currently providing access exclusively to STARS.

The Compliance Log System (LOG) used by the Division of Compliance consists of three modules: (1) The Correspondence Tracking module that tracks correspondence received by the division with regard to animal drugs and provides various internal reports; (2) The Regulatory Action module that tracks regulatory actions taken against a company or person subject to animal drug regulations (various types of reports are available for management use); and (3) The Export Certificate Logging module that tracks information related to requests for animal drug and animal food/feed export certificates. Information from this module is sent to the Office of Financial Management (OFM) to invoice those external customers requesting certificates for billing purposes.

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

All contact information is assumed to be professional contact information, it may also be personal

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

Employees

Public Citizens

“Public Citizen” above refers to animal owners, laboratory personnel (contact persons), clinical investigators, drug manufacturer (contact persons), or veterinarians.

How many individuals' PII is in the system?

5,000-9,999

For what primary purpose is the PII used?

PII about FDA is used for time reporting. PII about members of the public is used as professional contact information, namely regulatory contacts for external stakeholders doing business with FDA.

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

Not applicable.

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

Information in this system is collected, used and disclosed pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301. Provisions of the FFDCA require regulated entities to maintain records and submit reports to FDA and CVM, e.g., sections 360b(1), 360cc and 379.

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

Within OpDiv

Non-Governmental Sources

Public

Private Sector

Identify the OMB information collection approval number and expiration date

0910-0284, 02/28/2018 (FDA 2301); 0910-0032, 08/31/2019 (FDA 356v); 0910-0645, 05/31/2019 (FDA 1932 & 1932a); 0910-0454, November 30, 2019 (FDA 3538); 0910-0498, March 31, 2018 (FDA 3613, 3613a & 3613b).

Is the PII shared with other organizations?

Yes

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

Within HHS

FDA's Office of Financial Management (OFM). Sharing is restricted to need-to-know for the performance of authorized agency activities.

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

None. Disclosures are within FDA and restricted to need-to-know for the performance authorized agency activities.

Describe the procedures for accounting for disclosures.

FDA does not expect or plan to disclose records in this system to any individuals or entities outside of FDA. This is not a Privacy Act system of records and the Act does not require that FDA/CVM maintain an accounting of disclosures.

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

CVM personnel receive notice at the time of hire. External submitters receive notice in the following ways: on a submission form, in the online form instructions and guidance, and through the online website and privacy policy available via link on every fda.gov web page.

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.

In many cases, submission of information to this system is required in order to conduct business related to animal feed and drugs in the United States. Clinical investigators, veterinarians, animal owners and other external submitters receive notice as displayed on the submission forms; on fda.gov where the various submission processes are described and where a link to the FDA privacy policy is permanently displayed; and within the relevant statute, regulations and related Federal Register notices. In addition, certain submission forms provide for submitter confidentiality or allow the submitter to choose whether his/her identity is disclosed to the manufacturer of a drug about which an adverse event or problem report is submitted.

For employees, there is not a notice/consent or opt-out process specific to the CDP system. At the time of hire, CVM personnel are given notice of and consent to FDA's use of their professional information in relation to their work as a federal/FDA employee. They can update and correct the information at any time through existing procedures.

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

If FDA changes its practices with regard to the collection or handling of PII related to the CDP system, the Agency will employ measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include e-mail to individuals, adding or updating online notices or forms, or other available means to inform the individual.

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 may contact FDA or CVM by phone, mail or email using the contact information provided on fda.gov and the specific fda.gov web pages associated with the various submissions, e.g., pet food complaint, animal drug problem report.

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 (contact data) is self-submitted. Incorrect data is corrected in the course of FDA/CVM’s use of the system/information, e.g., updating name and phone number for entity point of contact.

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

Users:

Receive, review, manage and track submissions.

Administrators:

Monitor the system, manage the work flow and system access.

Contractors:

"Contractors" refers to FDA direct contractors who receive, review, manage and tract submissions.

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 written supervisor approval and sign off before access is granted. The user's supervisor 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.

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.

All users of the system may require access to any and all PII in the system. While access requires authorization, all users need and have access to all PII. The access list for the information system is reviewed on a semi-annual basis during which time 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 complete security and privacy awareness training at least once annually.

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

Users are trained by CVM personnel, and have standard operating procedures (SOP) or policy and procedure guides (P&P) to follow. FDA’s Staff Manual Guides for Privacy (policies and procedures) are available on FDA’s intranet and internet.

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.

CVM has drafted a records schedule specific to CDP which is in the process of being finalized. Pending an effective approved records schedule, CVM follows General Records Schedule (GRS) 3.1 and its retention guidelines.

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.