US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

03/08/2017

OPDIV:

FDA

Name:

CDER OGDweb

PIA Unique Identifier:

P-5392607-016785

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.

OGDweb is an application server supporting various Office of Generic Drugs (OGD) internal web tracking systems. Only FDA users (permanent agency employees) can access the applications on OGDWeb. Any personally identifiable information (PII) maintained in this system is used for administrative purposes in support of the efficient review of Abbreviated New Drug Applications (ANDAs) within the Center for Drug Evaluation and Research (CDER).

OGDWeb is an evolving set of programs created to respond to the needs of OGD personnel. It includes:

BioProd – Created by and for OGD's Office of Bioequivalence. Each bioequivalence (BE) product application Reviewer (FDA staff) enters their productivity information and a report is produced for management showing the number of assignments each reviewer completed every month.

CallTrack and Consult Tracking are used for tracking phone inquiries to OGD from new drug

Applicants and consult requests regarding ANDAs and Drug Master Files (DMFs).

Protocols Tracking tracks protocols submitted by applicants for BE studies comparing their test products to the reference listed drug product.

Review Flow System (RFS) – Serves as both a current review tracking system for DMFs and as a legacy system for general discipline reviews in OGD.

QDoc is a developing program in OGD used to track various requests within OGD. OGD Contacts/Contacts Search is a legacy system maintaining data collected during its period of use.

OGDweb is a conglomeration of applications accessed by staff in a single office (OGD) through one internal access portal to perform various functions all of which support the review and management of submitted ANDA materials. Although each application serves a unique function and the information handled can differ, they are collectively under the OGDweb application umbrella. Each component application handles PII about the same categories of individuals. None of the PII in any application is disclosed outside OGD.

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

The system collects and shares information about the ANDA review process such as the business names of regulated entities that are seeking approvals, names and descriptions of the drugs submitted for approval, contact information of individuals submitting ANDA forms (name, business e-mail, business phone number, business mailing address), and other information relevant to making an approval determination. There is also information concerning what assignments for internal reviews have been made to which OGD staff, who are identified by name. There are also calendars of OGD staff specifying when they will be out of the office and who will be working in their places.

Other information contained within the system includes descriptions of processes used to evaluate drugs, statuses of various types of applications, information about drug shortages, analyses of the productivity of the office, and documents and tools used to generate standard letters (which may use PII to identify points of contact receiving letters).

All users of the system are FDA employees. Users enter data sent to them through other means, such as e-mail, including data sent from business and manufacturers seeking ANDA approval. Users access the system by single sign-on authentication and no user credentials are collected, maintained or shared. No individuals that are associated with applicant organizations, or other members of the public, have access to the system.

Information collected in a specific application remains within the application. Collected work contact information of individuals submitting ANDA materials consists of the contact name, work phone number, work address, work email address, and whether the individual is the primary contact.

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

OGDweb contains several different ANDA-related tracking systems which are necessary for CDER's OGD to effectively review, manage and track ANDA submissions. For some of the programs within OGD, users occasionally retrieve records using the names of points of contact at regulated entities, although most often retrieval is by non-PII such as names of drugs, names of manufacturers, potency of compounds, and dosages.

For example, OGD uses system information to track which employee is working on an ANDA submission, applicants associated with an application, contacts associated with an application, testing sites associated with an application, and employee/office productivity. Without entity point of contact information, OGD cannot ensure information is received and processed for timely action and ANDA approval determinations.

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 information is professional contact information, either for employees of regulated entities or of the FDA.

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

Employees

Public Citizens

This includes points of contact for applicants submitting an Abbreviated New Drug Application (ANDA).

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

CDER uses PII to track which employee is working on an ANDA submission and the points of contact for entities that have applied for ANDAs. OGDweb also lists testing sites associated with an application (which may be employment locations for POCs), and this data is also used on occasion to analyze overall OGD productivity in reviewing ANDAs. FDA does not use this system to assess employee performance or as a basis for employment decisions. Nor does FDA use the system to make determinations or take actions regarding individuals who are serving as POCs for entities submitting ANDAs.

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.

This system is used to enable the OGD to execute its mission, which is required by the the Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. sec. 355(j).

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

Yes

Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.

However, because records retrieved using POC name do not contain information about the

NOTE: On occasion OGD will use PII (name of an entity point of contact) to retrieve records.

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

Private Sector

Identify the OMB information collection approval number and expiration date

Not applicable.

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.

There is no official process in place to notify individuals that their information will be collected in OGDweb. However,individuals or business points of contacts who are submitting materials to the ODGweb program for approvals will need to provide their contact information in order for the FDA to respond to their inquiry, update them on the status of their submission or notify them of an approval. Information about employee users is populated from other FDA-wide systems and employees would be notified via processes associated with those systems, and, through notice provided at the time of hire.

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.

The submission of PII is voluntary. Individuals can opt-out of collection or use of their PII, but this information would be required as part of the ANDA review process and making approval determinations.

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

Any major change in the information collected will be reflected in changes to the ANDA submission forms and/or in the related guidance materials provided on FDA.gov.

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.

Submitting information is voluntary. Entities (organizations) that wish to update or correct information about their POCs would need to contact the FDA using some other medium, and then system users would be able to edit records. Information about employee users is populated from other FDA-wide systems. If that information is inaccurate or otherwise needs to be changed, users have many opportunities to request changes, such as using FDA's 24-hour technical assistance hotline or working with supervisors or appropriate offices such as Human Resources or Information Technology. Any inappropriate use of the information in these systems is unlikely because of its low sensitivity, but any incidents could be reported to FDA's Systems Management Center.

System users who have a need to communicate with regulated entities and to track internal business processes can edit records. All system users are FDA employees accessing the OGDweb system.

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

The system is monitored constantly by the developers and by the users themselves for data integrity. The PII in this system is work contact information only and is not used for any other determinations regarding the subjects of the PII.

The programs are monitored by the system owners and the users for data integrity and accuracy.

System owners check for relevancy in terms of usage and will retire programs not being used or outdated. Since initial operation, there have been very few cases where the system and data has not been available. If this is the case, then the users notify the system owners or the FDA IT Call Center.

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

Users:

PII is used to communicate with regulated entities and to track internal business processes. All users are FDA employees.

Administrators:

PII may be viewed in the course of creating accounts that permit users to access the system, and administrators also use the system for its functions as well.

Developers:

Developers may have access to PII in the course of updating and maintaining the system.

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

Only users with a registered account (requires supervisory confirmation of their role and access need) may access PII in the system along with administrators and developers.

The system Administrators and Developers are essentially the same in terms of administrative rights. These individuals may view PII as they create accounts that permit users to access the system or in the course of updating and maintaining the system. General users cannot create accounts but may also view PII to communicate with regulated entities and track ANDAs.

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.

The system developers create web pages that only show a limited amount of information. All users who need to access the system potentially need to access any of the contact information therein, and therefore all users may access all PII in 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 receive annual Security Training and Privacy Awareness Training.

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

Users may receive additional on-the-job training. Note that the PII in the system is not very sensitive, but much other information is proprietary and users are made aware of the need to exercise caution when handling the information.

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 retained and destroyed in accordance with NARA's approved Records Control Schedule (RCS) N1-088-08-02: File Code 2310 Item 3.1, Disposition: TEMPORARY. Cut off at the end of the calender year following final action.

Records are destroyed/deleted 30 years after cutoff or when no longer needed for reference or research, whichever is later.

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

Administrative safeguards for OGDweb 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 uses of firewalls; access controls such as user authentication; and regular testing of information technology systems. Physical controls include that all system servers are located at FDA 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.

Note: web address is a hyperlink.

Session Cookies that do not collect PII.