US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/12/2016

OPDIV:

FDA

Name:

Administrative Applications: Support Applications for the Offices of Orphan Products and Women’s Health

PIA Unique Identifier:

P-2697807-859852

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?

Yes

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.

Note that the applications addressed in this document are among numerous applications that reside within FDA's overarching "AdminApps" (Administrative Applications) system.

This PIA covers six related applications. The purposes of these systems are to support the missions of two FDA Offices: the Office of Women's Health (OWH), and the Office of Orphan Products Development (OOPD). These systems were grouped together to be addressed in a single document on the grounds that they are used to conduct similar activities and are governed by many of the same authorities (systems of records notices; legal authorities to collect; retention schedules; etc.). The six applications addressed are OWH Grants Management, OOPD Grants and Applications, OOPD Natural History Grants, OWH Outreach Activities, OOPD Designations, and OOPD Pediatric Device Consortiums.

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

This PIA covers six related applications. The purposes of these applications are to support the missions of two FDA Offices: the Office of Women's Health (OWH), and, the Office of Orphan Products Development (OOPD).

The mission of the OWH is to protect and advance the health of women through policy, science, and outreach and to advocate for the participation of women in clinical trials and for sex, gender, and subpopulation analyses. OWH achieves its mission by supporting scientific research and collaborating with other government agencies and national organizations to sponsor scientific and consumer outreach efforts.

The mission of the OOPD is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions (aka "orphan products"). In fulfilling that task, OOPD evaluates scientific and clinical data submissions from product sponsors to identify and designate products as promising for the treatment of rare diseases and to further advance scientific development of such promising medical products. The office also works on rare disease issues with the medical and research communities, professional organizations, academia, governmental agencies, industry, and rare disease patient groups.

More specifically, the applications support these missions as follows: Three of the six related applications support grants management efforts. OWH Grants Management, OOPD Grants and Applications, and OOPD Natural History Grants are used to manage grants awarded to product sponsors; OOPD additionally uses their system to collect and maintain grant application materials collected prior to awarding a grant.

The purpose of the OWH Outreach Activities application is to document OWH's success in conducting outreach and meeting its mission. When stakeholders elect to make use of OWH outreach materials, notations may be added in the system regarding when and where these will be used.

The OOPD Designations application contains information about orphan products including the sponsor (the party seeking approval of orphan status, such as an owner or manufacturer), a product's generic name or trade product name, and indications of approved uses. It is a reference tool to look up this information as needed.

The goal of the FDA’s Pediatric Device Consortia (PDC) Grant Program is to support the development of nonprofit consortia designed to stimulate projects which will promote pediatric device development. Specific areas of expertise provided by the consortia include intellectual property advising, prototyping, engineering, laboratory and animal testing, grant-writing, and clinical trial design. The PDC application tracks the complete lifecycle of consortia, from application to grant, as well as the lifecycle of devices funded by each consortia. This includes budget tracking, quarterly tracking of device metrics, document upload functionality for reports and tracking documentation, and canned reports used to track metrics for pediatric devices. Primary users are the Office of Orphan Products Development staff, as well as several CDRH and OAGS team members; there are approximately 25 regular users.

Authentication and logon credential information that is potential PII: The OOPD Grants and Applications and OOPD Designations systems/applications contain a record of users' (agency personnel) usernames and passwords.

The two OWH applications; OOPD Natural History Grants; and OOPD Pediatric Device Consortia operate using a single-sign on (no username or password) process to control access.

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

For OWH Grants Management, OOPD Grants and Applications, and OOPD Natural History Grants, collected documents and information may include the contact information for a point of contact (names, addresses, e-mails, phone numbers, fax numbers, social media contact information), and information concerning proposed projects and research including methods, budgets, needed resources and materials, and records of progress and outcomes. Neither application currently contains personal background information about scientific researchers such as resumes or curricula vitae (CVs) of researchers (e.g., containing contact information, education, work and other relevant history), but may do so in the future. Contents of CVs will include the usual elements of contact information; work history; educational history; skills; certifications; honors and awards; publications; professional interests; and any other relevant information. This information would be used as part of an effort to evaluate grant applications and to communicate with individuals representing institutions applying for grants. Some of the information collected in these applications may be proprietary.

OOPD's Grants Management system is populated by a data file sent from a National Institutes of Health (NIH) system. The OWH Outreach Activities application is used to record assignments or tasks related to outreach, which may include promotional materials, schedules or agendas of events, contact information for stakeholders or collaborators (names, addresses, e-mails, phone numbers, fax numbers, social media contact information), and communications among FDA staff or others related to planning events. The purpose of the application is to document OWH's success in conducting outreach and meeting its mission. When stakeholders elect to make use of OWH outreach materials, notations may be added in the application regarding when and where these will be used. Personally identifiable information (PII) may be incidentally included in communications, for example, if FDA staff communicate with external stakeholders and the communications are retained in the system.

The Designation system contains information about orphan products including the sponsor (the party seeking approval of orphan status, such as an owner or manufacturer), a product's generic name or trade product name, and indications of approved uses. For example: the organizations that have approved use of the orphan product; the conditions or symptoms for which a product can be used as an approved treatment; the demographic that may use the product (e.g., men over 65), and what concentrations are approved for use. While Designation does have a publicly-available web site (http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm), there is no PII collected, used, stored or disclosed by this system.

The OOPD Grants Management and Designation applications contain users' (agency personnel) access and authentication data. The two OWH applications operate using a single-sign on process to control access and do not store usernames or passwords.

The OOPD Pediatric Device Consortiums application tracks the lifecycle of designating and funding Consortiums in the Office of Orphan Products and Development. Primary users are the Office of Orphan Products and Development staff. There will be approximately 15 users. The application tracks the complete lifecycle of the Consortiums funded by OOPD. It manages the budget, reporting requirements, tracking of non-FDA funded work of the Consortiums, and general oversight. It also maintains the contact list by Organization with individual person contact information associated to an Organization. The application operates using a single-sign on process to control access and does not store usernames or passwords.

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

Certificates

Both Grants Management systems may include contact information for points of contact and OWH Outreach may contain point of contact information for stakeholders and collaborators as well as incidental PII contained in copies of communications.

"Certificates" may include copies of diplomas, licenses, transcripts, or other documentation of accomplishments.

The OOPD applications require user credentials that may be PII, such as username and password. The OWH applications do not store such information.

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

Employees

Public Citizens

Business Partner/Contacts (Federal/state/local agencies)

Grant recipient points of contact, OWH stakeholders and customers. "Employees" includes direct contractors.

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

The primary purposes of use for the PII: Coordinate efforts of staff; coordinate evaluation of grants (OOPD); assist in project management oversight of grants; document activities and accomplishments; and assess progress and outcomes of grant activities.

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.

The Federal Food, Drug, and Cosmetic Act (FFD&CA), 21 U.S.C. 399(b), 399ee, and 399bb(c).

OWH Outreach: The FFD&CA provides that the Director of the Office of Women's Health will "(3) provide information to women and health care providers on those areas in which differences between men and women exist; [and] (4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women." 21 U.S.C. 399(b). This system is used to document OWH's efforts to meet this mandate. It may capture PII incidentally.

OWH Grants Management: Section 399(b) further provides that the Director OWH will "establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women's health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies." Grants are provided in furtherance of this requirement.

OOPD Grants and Applications: The FFD&CA, at 21 U.S.C. 360ee (a), states that “The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the costs of qualified clinical testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions." The Grants Management system is used to met these objectives. The use of PII in the system is necessary for the evaluation of applications and communications with grant applicants and recipients.

OOPD Designations: The FFD&CA, at 21 U.S.C. 360bb (c), states that “Notice respecting the designation of a drug under subsection (a) [as an “orphan drug”] shall be made available to the public."

OOPD Pediatric Consortiums: the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, incorporated into the FFD&CA at 21 U.S.C. 505B et seq., 514A et seq., the Public Health Service Act at 42 U.S.C. 282(b)(23) et seq. and else where, among many other effects requires the FDA to maintain "an internal committee within the Food and Drug Administration to carry out the activities as described in sections 505A(f) and 505B(f). Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry, and other individuals designated by the Secretary.’’

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

No

Identify the sources of PII in the system.

Email

Online

Government Sources

Within OpDiv

Other HHS OpDiv

Identify the OMB information collection approval number and expiration date

Not Applicable.

Is the PII shared with other organizations?

Yes

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

Within HHS

System access is restricted. To the extent users across FDA components require read/view access to perform their duties, the specified PII is shared outside the FDA's Office of the Commissioner. PII in the system is not shared outside HHS/FDA.

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

Not Applicable. Information is not shared outside of HHS.

Describe the procedures for accounting for disclosures.

System records are not subject to the Privacy Act, and are not disclosed outside HHS. No accounting of disclosures is required under section 552a(c) of the Privacy Act.

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

No specific prior notice is provided. Applicants voluntarily submit applications and related information and are thereby aware of the PII or other information they choose to submit.

Information is either submitted by the subject individuals themselves (as noted above, e.g., in the case of the Grants Management applications); concerns employees who are aware that information about their activities will be known to their employers; or, is a record of communications with members of the public. Regarding OOPD Grants and Applications, the NIH would address providing notice to individuals whose data is collected in the data file NIH provides to FDA as noted elsewhere in this assessment.

FDA personnel (permanent employees, direct contractors, fellows, etc.) are notified at the time of hire and consent to the submission and use of their personal information as a condition of employment. HHS and FDA Center Representatives, and the various individuals involved with the specific data collection and use provide notification to personnel at the time the data is requested.

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.

For grants applicants, applicant organizations choose to submit information in order to apply for grants. Individual PII is limited to points of contact and individuals that may participate in grants activities. Submission is voluntary; individuals and organizations may opt not to apply or submit information.

Some PII about members of the public may be maintained in the OWH Outreach application. This information will concern collaborations with stakeholder groups or individuals. Members of the public can exercise control over PII they include in communications with FDA. PII retained will concern activities conducted cooperatively and the inclusion of PII will be incidental to this documentation.

Some of these systems use employee PII for authentication and access controls. There is no method for employees to opt not to submit PII. Permanent employees, direct contractors, fellows and other personnel must provide their PII in order for the Agency to process administrative materials and securely administer access to Agency information and property.

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

No such major changes are expected. If a major change or use of data were to occur, users would be notified via individual e-mail, FDA-wide e-mail and/or in updated public documents such as FDA.gov, this PIA, or other publications.

If changes were to affect employee information, many other channels may be used to inform them, including phone, e-mail, notices on the FDA intranet, or through supervisors.

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 have existing procedures and services available such as FDA’s Employee Resources and Information Center (ERIC). External individuals may use any of a number of avenues to raise concerns, including contacting FDA offices through FDA.gov (phone, mail, e-mail) and by using information provided on forms submitted by individuals.

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

External submitters are responsible for the accuracy and relevancy of the information they submit. Information related to external submitters is corrected in the course of use and/or at the request of the individual.

Personnel are responsible for providing accurate information and may independently update and correct their information at any time. Information is relevant because it is strictly limited to information needed for access and authentication purposes.

For all PII in all of these applications, integrity and availability are protected by security safeguards. Each system has appropriate controls selected based on its level of risk (as categorized under the National Institute of Standards and Technology's (NIST's) Federal Information Processing Standard (FIPS) 199) and NIST's Special Publication 800-53 on Security Controls.

Security authorization is conducted for the overarching AdminApps system as a whole and encompasses the four systems addressed in this PIA.

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

Users:

For the purposes of this document users are FDA employees. Users require full access to grants applications in order to conduct activities related to the mission of the Office

Administrators:

All administrators with access to PII are also application users for those applications and will have access as users.

Developers:

Developers will not normally have access to PII, but may in the course of maintaining the systems or providing technical assistance.

Contractors:

Some developers may be direct contractors and will have access under the same circumstances.

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 need to have supervisor approval and sign off before access is granted. The user's supervisor will use an account creation form to specify the minimum information system access that is required in order for the user to complete his/her job. The Agency reviews the access list for the system on a quarterly basis to review and adjust users' access permissions, and, to remove unnecessary 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.

Management establishes roles for individual personnel, with role-based restrictions permitting access only to information that is required for each individual to perform his/her job.

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/users are required to complete FDA's IT Security and Privacy Awareness training at least annually.

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

Each application within the AdminApps system has user training and user documentation for the system users. Access is restricted through system access control. All users are instructed on adhering to the HHS Rules of Behavior in the context of their work involving this system. For additional privacy guidance, personnel may contact the Agency's Privacy Office. Privacy program materials are provided to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.

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.

For OWH Grants Management, OOPD Grants and Applications, and OOPD Natural History Grants, records are retained under FDA File Code 1721, (NARA N1-88-04-03), Grants Awarded by FDA.

Records are destroyed or deleted seven years after the grant is terminated or after the last payment is made.

For applications for grants received but not awarded maintained in OOPD Grants and Applications and OOPD Natural History Grants, records are retained under FDA File Code 1722, (NARA N1-88-04-03), Grants Approved (but not funded) or Disapproved Applications. Records are destroyed or deleted three years after the date of cancellation or the date of competitive review.

OOWH Outreach, records are retained under FDA File Code 8420, (NARA NC 188-07-02), Program Management Files. The "cutoff date" is after the final action/report for which the record is needed, or at the end of the calendar year in which they are needed. Records are maintained a minimum of three years then destroyed seven years after cutoff date, or when no longer needed for reference, whichever is sooner.

For OOPD Designations, records are retained under FDA File Code 7222 (NARA NC 1-88-07-2), Database Files. Cutoff is after the establishment owning the product goes out of business or the product is no longer commercially marketed. Records are deleted or destroyed ten years after cutoff or when no longer needed for legal, research, historical or reference purposes, whichever is the latest. If data are migrated into a new system or replaced by a successor system, delete/destroy after the verification of successful data migration.

As discussed previously, OOPD Designations contains no PII and does not require a retention schedule for PII.

OOPD Pediatric Device Consortiums data is retained under General Records Schedule 26, Temporary Commissions, Boards, Councils and Committees ," Item 4, "Committee Management Records." These records are to be destroyed or deleted when they are six years old.

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

The information in the system is protected by user identification requirements, passwords, VPN, firewall, encryption, intrusion detection, smart cards, and secure guarded and monitored facilities. Each system has appropriate controls selected based on its level of risk (as categorized under the National Institute of Standards and Technology's (NIST's) Federal Information Processing Standard (FIPS) 199) and NIST's Special Publication 800-53 on Security Controls.

Security authorization is conducted for the overarching AdminApps system as a whole and encompasses the four systems addressed in this PIA.

Identify the publicly-available URL:

http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm

Note: web address is a hyperlink.

Does the website have a posted privacy notice?

Yes

Is the privacy policy available in a machine-readable format?

No

Does the website use web measurement and customization technology?

Yes

Select the type of website measurement and customization technologies is in use and if it is used to collect PII.

Session Cookies that do not collect PII.

Does the website have any information or pages directed at children under the age of thirteen?

No

Does the website contain links to non- federal government websites external to HHS?

No

Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?

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