


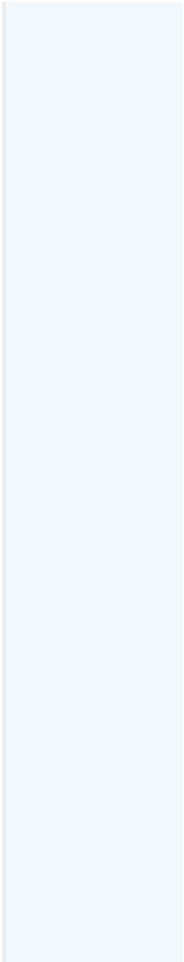
**General Information**

<b>PTA / PIA Name:</b>	FDA - OGDweb - QTR2 - 2025 - FDA4916510	<b>PTA / PIA ID:</b>	3034061
<b>Component Name:</b>	FDA - CDER OGDWeb	<b>ATO Boundary Name:</b>	CDER OGDWeb
<b>Overall Status:</b>	Complete 	<b># of Days - Open:</b>	14
<b>Submitter:</b>		<b>Submit Date:</b>	4/23/2025
<b>Next Assessment Date:</b>	04/24/2028	<b>Expiration Date:</b>	4/24/2028
<b>Office:</b>		<b>OpDiv:</b>	FDA
<b>Security Categorization:</b>	Moderate		
<b>Make PIA available to Public?:</b>	Yes	<b>PIA Required:</b>	Yes
<b>General 01:</b>	Identify the Enterprise Performance Lifecycle Phase of the system.		Operations and Maintenance
<b>General 02:</b>	Is this a FISMA-Reportable system?		Yes
<b>General 03:</b>	Does the system have or is it covered by a Security Authorization to Operate (ATO)?		No
<b>General 04:</b>	ATO Date or Planned ATO Date.		11/21/2022
<b>General 05:</b>	Is the system or electronic information collection, agency or contractor operated?		Agency
<b>History Log:</b>	<a href="#">View History Log</a>		

**Privacy Threshold Analysis****Privacy Threshold Analysis**

<b>PTA 01:</b>	Point of Contact (POC) Name	David Holovac, R.Ph.
<b>PTA 01A:</b>	POC Title and Organization	POC Title: Pharmacist POC Organization: FDA/CDER/Office of Generic Drugs
<b>PTA 01B:</b>	POC Email Address	David.Holovac@fda.hhs.gov
<b>PTA 01C:</b>	POC Phone Number	240-402-8956
<b>PTA 02:</b>	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)

<b>PTA 02A:</b>	Describe in further detail any changes to the system that have occurred since the last PIA.	FDA has made no changes to this component since the last Privacy Threshold Analysis/Privacy Impact Assessment was approved.
<b>PTA 03:</b>	Is the data contained in the system owned by the agency or contractor?	Agency
<b>PTA 04:</b>	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	<p>OGDweb is an application server supporting various Office of Generic Drugs (OGD) internal web tracking systems. Only Food and Drug Administration (FDA) users (permanent agency employees, contractors, and fellows) 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).</p> <p>OGDWeb is an evolving set of programs, all which are evaluated in this privacy assessment, created to respond to the needs of OGD personnel. It includes:</p> <p>BioProd – Created by and for OGD’s Office of Bioequivalence. Each bioequivalence (BE) product application Reviewer (FDA Employees and Direct Contractors) enters their productivity information, and a report is produced for management showing the number of assignments each reviewer completed every month.</p> <p>Data is retained from retired applications and remains available through search interface. Retired systems include Review Flow System (RFS), Master Queue (MQ), Consults, Controlled Correspondence, Standard Letters, and Citizen Petitions. Staff that were associated with data rows within those retired systems remain known.</p> <p>Quality Dashboard Operations Center (QDOC) is a program used for administering the Generic Drug User Fee Act (GDUFA) mandated research and science program, which includes third party grants and contracts. QDOC provides OGD with a framework for extending new capabilities on as needed basis. The application provides services for collaboration, search, reporting, project management, knowledge management, file management, record management, and controlled document management.</p> <p>Calltrack (eLog a QDOC application) is used for tracking phone inquiries and email to OGD from new drug Applicants regarding ANDAs and Drug Master Files (DMFs). Typically, incoming information request are related to application status and its remaining discipline reviews.</p> <p>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</p>



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.

OGDWeb utilizes a combination of FDA owned systems/applications consisting of MS SharePoint, MS Exchange, Documentum, File Shares and Lightweight Directory Access Protocol (LDAP).

The relationship of OGDWeb to other FDA systems/components/information collections is to function as a supportive program to assist OGD staff track data that is not tracked in current FDA systems.

OGDweb contains several different ANDA-related tracking systems which are necessary for CDER's OGD to effectively review, manage and track ANDA submissions. Only FDA users (permanent agency employees, contractors, and fellows) have access to the OGDweb set of applications and access is gained through a Single Sign-On process of two-factor authentication; no username and password is needed or stored within any of the applications.

System users consist of only FDA users (permanent agency employees, direct contractors, and fellows), and only they can access the applications on OGDWeb.

**PTA 05:**

List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.

The system collects and shares information about the ANDA review process. Collected professional contact PII of individuals submitting ANDA materials consists of the contact's name (first and last), work phone number, work mailing address, and work email address. This also includes whether the individual is the primary contact. There is also information concerning what assignments for internal reviews have been made to which OGD staff, who are identified by name (first and last, considered internal PII). Calendars of OGD staff, specifying when they will be out of the office and who will be working in their places is also stored.

Information collected about the ANDA review process also includes the business names of regulated entities that are seeking approvals, names and descriptions of the drugs submitted for approval, and other information relevant to making an approval determination; all of which is considered non PII.

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 such as name and mailing address).

All users of the system are FDA employees/direct contractors. 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.

Records are retained and destroyed in accordance with The National Archives and Records Administration's (NARA) approved Records Control Schedule (RCS) N1-088-08-02: File Code 2310 Item 3.1, Disposition: TEMPORARY. Cut off at the end of the calendar year following final action. Records are destroyed/deleted 30 years after cutoff or when no longer needed for reference or research, whichever is later.

**PTA 05A:**

Are user credentials used to access the system?

Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system.

**PTA 05C:**

Please identify the system that maintains the user credentials or controls access to this system.

The system providing credentials is Microsoft managed FDA Domain and Microsoft Azure.

<b>PTA 06:</b>	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	<p>OGDweb contains several different ANDA-related tracking systems which are necessary for CDER's OGD to effectively review, manage, and track ANDA submissions. The set of tracking systems include BioProd, Call Track and Consult Tracking, Review Flow System (RFS), and QDoc. Only FDA users (permanent agency employees) have access to the OGDweb set of applications and access is gained through a Single Sign-On process of two-factor authentication. No username and password is needed or stored within any of the applications.</p> <p>CDER uses first and last names, email addresses, and employee numbers to track which employee is working on an ANDA submission and the points of contact for entities that have applied for ANDAs. With the email address and employee number, the applications query Lightweight Directory Access Protocol (LDAP) and/or SharePoint/Exchange for any PII information as needed. Data is cached to speed subsequent duplicate requests. The Office of Information Management and Technology (OIMT) supplies data and security for those services.</p> <p>Other PII that is utilized by the system includes photographic identifiers (whatever a user uploads on SharePoint) and employee numbers via LDAP.</p> <p>OGDweb also lists testing sites associated with an application (which may be employment locations for points of contact (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.</p> <p>PII from OGD web is shared with OGD employees and OGD supervisors to track which employee is working on an ANDA submission and the points of contact for entities that have applied for ANDAs.</p>
<b>PTA 07:</b>	Does the system collect, maintain, use, or share PII?	Yes
<b>PTA 08:</b>	Does the system include a website or online application?	Yes
<b>PTA 08A:</b>	Provide the URL(s).	<a href="https://ogd.fda.gov/">https://ogd.fda.gov/</a>
<b>PTA 08B:</b>	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No

<b>PTA 09:</b>	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	<p>The purpose of the website is to provide organized web pages for easy access and retrieval of data along with reports.</p> <p>The following categories of individuals have access to the website: Users, Administrators, and Developers.</p> <p>FDA users with valid network accounts who require access to OGDweb must have supervisory approval and signature before they can receive the required PIV card for authentication. The agency reviews the system access list on a bi-annual basis to adjust users' access roles and permissions.</p>
<b>PTA 10:</b>	Does the website have a posted privacy notice?	Yes
<b>PTA 11:</b>	Does the website contain links to non-federal government websites external to HHS?	No
<b>PTA 12:</b>	Does the website use web measurement and customization technology?	Yes
<b>PTA 12A:</b>	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	Session Cookies- Does Not Collect PII
<b>PTA 13:</b>	Does the website have any information or pages directed at children under the age of thirteen?	No
<b>PTA 14:</b>	Does the system have a mobile application?	No
<b>PTA 20:</b>	Are any third-party websites or applications (TPWA) associated with the system?	No
<b>PTA 21:</b>	Does this system use artificial intelligence (AI) tools or technologies?	No

### Privacy Impact Assessment

#### Privacy Impact Assessment

<b>PIA 22:</b>	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	<p>Biographical Information</p> <p style="padding-left: 20px;">Name</p> <p>Contact Information</p> <p style="padding-left: 20px;">Email Address (Business)</p> <p style="padding-left: 20px;">Mailing Address (Business)</p> <p style="padding-left: 20px;">Phone Numbers (Business)</p> <p>Biometrics/Distinguishing Features</p> <p style="padding-left: 20px;">Photographic Identifiers</p>
<b>PIA 23:</b>	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	<p>Employees/HHS Direct Contractors</p> <p>Members of the public</p>
<b>PIA 24:</b>	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999

<b>PIA 25:</b>	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.
<b>PIA 26:</b>	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA makes no secondary use of the PII.
<b>PIA 28:</b>	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 Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. sec. 355(j).
<b>PIA 29:</b>	Are records in the system retrieved by one or more PII data elements?	No
<b>PIA 30:</b>	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains In-person Hard Copy Mail/Fax Email Online Government Sources Within the OPDIV Non-Government Sources Private Sector
<b>PIA 31:</b>	Is there an Office of Management and Budget (OMB) information collection approval number?	No
<b>PIA 31B:</b>	Explain why an OMB information collection approval number is not required.	This does not meet the definition of "information collection request" as defined by the Paperwork Reduction Act (PRA).
<b>PIA 32:</b>	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
<b>PIA 33:</b>	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
<b>PIA 34:</b>	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	The submission of PII is voluntary. The PII listed on ANDA submissions is contact information which voluntarily added by the submitter. If an employee/direct contractor does not want to provide their PII, they will not have access to the system and therefore will not be able to complete the FDA-required work for reviewing ANDA submissions.

<b>PIA 35:</b>	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). If they cannot be notified or have their consent obtained, explain why.	If FDA changes its practices regarding the collection or handling of PII related to the ODGweb system, the Agency will adopt 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.
<b>PIA 36:</b>	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. If no process exists, explain why not.	Individuals who suspect their PII has been inappropriately obtained, used, or disclosed in any FDA system have many avenues available for assistance. These individuals may contact FDA offices, including the Privacy Office, the Employee Resource, and Information Center (ERIC), the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC), the FDA Privacy Office, and other agency offices, via email, phone, and standard mail avenues (all listed on fda.gov and the FDA intranet).
<b>PIA 37:</b>	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	<p>PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting. FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. PII relevancy is also ensured through the design of the system to solicit and collected only the limited PII that is necessary for the purposes and functionality of the system.</p> <p>Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Integrity and availability are protected by privacy and security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on National Institute of Standards and Technology (NIST) guidance concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199. ODGweb administrators perform annual reviews to evaluate user access.</p>
<b>PIA 38:</b>	Identify who will have access to the PII in the system.	<p>Users</p> <p>Administrators</p> <p>Developers</p> <p>Contractors</p>
<b>PIA 38A:</b>	Select the type of contractor.	HHS/OpDiv Direct Contractors
<b>PIA 38B:</b>	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes

<b>PIA 39:</b>	Provide the reason why each of the groups identified in 38 needs access to PII.	<p>Users: PII is used to communicate with regulated entities and to track internal business processes. All users are FDA employees or direct contractors.</p> <p>Direct Contactors: Are users of OGDweb and PII is used to communicate with regulated entities and to track internal business processes.</p> <p>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.</p> <p>Developers: Developers may have access to PII in the course of updating and maintaining the system.</p>
<b>PIA 40:</b>	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FDA users with valid network accounts who require access to OGDweb must have supervisory approval and signature before they can receive the required PIV card for authentication. 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.
<b>PIA 41:</b>	Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.	The relevant supervisor will indicate on the OGDweb 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.
<b>PIA 42:</b>	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) to make them aware of their responsibilities for protecting the information being collected and maintained.	All system users at FDA take annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure). The FDA Office of Information Management and Technology (OIMT) verifies that training has been successfully completed.
<b>PIA 43:</b>	Describe the 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 sensitive, but drug manufacturing information in the system is proprietary, and users are made aware of the need to exercise caution when handling the information.
<b>PIA 44:</b>	Describe the process and guidelines in place for the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	<p>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 calendar year following final action.</p> <p>Records are destroyed/deleted 30 years after cutoff or when no longer needed for reference or research, whichever is later.</p>

<b>PIA 45:</b>	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	<p>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.</p> <p>Technical safeguards include role-based access settings, firewalls, passwords and others. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls.</p> <p>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.</p>
----------------	--	---

**Review and Comments**

**OpDiv Privacy Analyst Review**

<b>Privacy Analyst Review Decision:</b>	Approved	<b>Privacy Analyst Review Date:</b>	4/23/2025
<b>Privacy Analyst Review Comments:</b>		<b># of Days - PA Review:</b>	0

**SOP Review**

<b>SOP Review Decision:</b>	Approved	<b>SOP Review Date:</b>	4/24/2025
<b>SOP Review Comments:</b>	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	<b># of Days - SOP Review:</b>	1

## Agency Privacy Analyst Review

**Agency Privacy Analyst Review Decision:** Approved **Agency Privacy Analyst Review Date:** 4/24/2025

**Agency Privacy Analyst Review Comments:** Reviewer: Nestor Villafuerte **# of Days - APA Review:** 0

4/24/2025 All comment addressed this PIA is ready for SAOP review and approval.

4/23/2025 Please see comments and update accordingly:

Q3- Does this system have an ATO? If so what is the ATO date?

PTA-5: Please write out NARA on its first instance.

PIA-22: Per PTA-6, Please include photographic identifiers as one of the PII elements as mentioned in the PTA.

PIA-38: Per PIA-34, contractors should be checked.

PIA-39: Per PIA-34, please provide contractor's reason for access to PII.

## SAOP Review

**SAOP Review Decision:** Approved **SAOP Review Date:** 4/25/2025

**SAOP Review Comments:** **# of Days - SAOP Review:** 1

### SAOP Signature

Date	User	Type	Name	Original Value	New Value
4/25/2025 1:52 PM	GUENTHER, BRIDGET	Signature	SAOP (Email PIN)		Content Signed

## Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments				
Question Name	Submitter	Date	Comment	Attachment
PTA 05	VILLAFUERTE, NESTOR	4/22/2025	Please write out NARA on its first instance.	
PTA 01	VILLAFUERTE, NESTOR	4/22/2025	Q3 states that the system does not have an ATO date; the stated ATO date has passed.	
PIA 22	VILLAFUERTE, NESTOR	4/22/2025	Please include photographic identifiers as one of the PII elements as mentioned in the PTA.	
PIA 38	VILLAFUERTE, NESTOR	4/22/2025	Per PIA-34, contractors should be checked.	
PIA 39	BLAND, CRYSTAL	4/23/2025	Per PIA-34, please provide reason for contractors' access to PII.	