


General Information		
PTA / PIA Name:	FDA - Quality Documents - QTR2 - 2025 - FDA4941520	PTA / PIA ID: 3340741
Component Name:	FDA - CDER Quality Documents	ATO Boundary Name: CDER OGDWeb
Overall Status:	Complete 	# of Days - Open: 9
Submitter:		Submit Date: 6/16/2025
Next Assessment Date:	06/24/2028	Expiration Date: 6/24/2028
Office:		OpDiv: FDA
Security Categorization:	Moderate	
Make PIA available to Public?:	Yes	PIA Required: Yes
General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	No
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
General 04:	ATO Date or Planned ATO Date.	11/21/2022
General 05:	Is the system or electronic information collection, agency or contractor operated?	Agency
History Log:	View History Log	

Privacy Threshold Analysis		
Privacy Threshold Analysis		
PTA 01:	Point of Contact (POC) Name	John Ibrahim
PTA 01A:	POC Title and Organization	Pharmacist FDA/CDER/Office of Generic Drugs
PTA 01B:	POC Email Address	John.Ibrahim@fda.hhs.gov
PTA 01C:	POC Phone Number	240-402-5919
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)

PTA 02A:	Describe in further detail any changes to the system that have occurred since the last PIA.	Not Applicable (N/A) - This is the initial dedicated Privacy Threshold Analysis/Privacy Impact Assessment (PTA/PIA) for Center for Drug Evaluation and Research (CDER) Quality Documents (QDoc). There have been no changes to QDoc since the Food and Drug Administration (FDA) previously assessed it in a PIA that covered multiple components within the same system boundary.
PTA 03:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA 04:	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>In support of the Food and Drug Administration's (FDA's) mission to protect and promote public health, the Center for Drug Evaluation and Research (CDER) ensures that individuals have access to safe and effective over the counter and prescription drugs. CDER utilizes the Office of Generic Drugs web application server (OGDweb, the subject of a separate assessment) to support various Office of Generic Drugs internal tracking systems using a web interface. The subject of this assessment is CDER Quality Documents (CDER QDoc).</p> <p>CDER QDoc provides OGD with a framework for extending new capabilities on an as needed basis. This primary application provides tools for tracking communications, user defined projects, controlled document management and facilitates collaboration. CDER QDoc is integrated with the FDA cloud exchange server, which provides support for automated messages and calendar events.</p> <p>CDER QDoc is an internal only system used by FDA permanent employees, Direct Contractors, and Fellows. Users access the application via single sign-on (SSO) authentication process. Access does not require the use of username and password. Point of contacts for the sponsor are provided via the Agency electronic submissions gateway (ESG, the subject of a separate assessment) for any application. When CDER reviewers use the QDOC internal system, they do data entry of the POCs into the system based on what is submitted via Gateway.</p>

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.	<p>CDER QDoc collects personally identifiable information (PII). PII is collected and shared as part of the Abbreviated New Drug Application (ANDA) review process. PII collected about industry professionals and/or FDA personnel consists of the following professional contact information: (1) Name (first and last); (2) Business phone number; (3) Business mailing address; and (4) Business email address.</p> <p>The system also collects and shares the following additional information about FDA OGD personnel only: (1) Photographic identifiers (whatever a user uploads on SharePoint); (2) Personnel calendars; (3) Staffing Assignments and (4) Employee numbers via FDA Lightweight Directory Access Portal (LDAP).</p> <p>PII (name of an entity POC) collected by system applications is used to retrieve records about business related data only. PII is not used to retrieve records about individuals, and the system is therefore not subject to the Privacy Act and does not require a SORN.</p> <p>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.</p> <p>Information collected and shared by the system is retained in accordance with National Archives and Records Administration approved records control schedules. Records are destroyed/deleted 30 years after cutoff or when no longer needed for reference or research, whichever is later.</p>
PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	<p>HHS User Credentials</p> <p>HHS/OpDiv PIV Card</p>
PTA 06:	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>CDER uses names, email addresses, and employee numbers to track ANDA employee assignments and the point of contact (POC) for entities that have applied for ANDAs. Email address and employee number are used to query application 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. POC information provided by industry professionals is provided voluntarily when completing and submitting ANDA applications.</p>
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	https://ogd.fda.gov/
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No

PTA 09:	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.	The purpose of the website is to provide organized web pages for easy access and retrieval of business data along with reports. FDA permanent employees, Direct Contractors, and Fellows have access to the website. Users access the website using an internal uniform resource locator (URL) and SSO authentication.
PTA 10:	Does the website have a posted privacy notice?	Yes
PTA 11:	Does the website contain links to non-federal government websites external to HHS?	No
PTA 12:	Does the website use web measurement and customization technology?	Yes
PTA 12A:	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
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA 14:	Does the system have a mobile application?	No
PTA 20:	Are any third-party websites or applications (TPWA) associated with the system?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment

PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Identifying Numbers Employee ID Number Biographical Information Name Contact Information Email Address (Business) Mailing Address (Business) Phone Numbers (Business) Biometrics/Distinguishing Features Photographic Identifiers
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	CDER uses PII to track employee ANDA submission assignments and the POCs for entities that have applied for ANDAs.
PIA 26:	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.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The legal authorities that govern information use and disclosures specific to the system and program are the Food, Drug, and Cosmetic Act, at 21 U.S.C. sec. 355(j), and 5 U.S.C. 301.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No

PIA 30:	Identify the sources of PII in the system.	<p>Directly from an individual about whom the information pertains</p> <ul style="list-style-type: none"> In-person Email Online <p>Government Sources</p> <ul style="list-style-type: none"> Within the OPDIV <p>Non-Government Sources</p> <ul style="list-style-type: none"> Members of the Public
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA 31B:	Explain why an OMB information collection approval number is not required.	N/A. An OMB information collection approval number is not required for CDER QDoc because CDER QDoc does not collect information using an information collection request as defined by the Paperwork Reduction Act.
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
PIA 34:	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. Individuals can opt-out of collection or use of their PII, however doing so will impact the individual's ability to submit the ANDA for review and approval.
PIA 35:	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 with regard to the collection or handling of PII related to the 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.
PIA 36:	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-FDA personnel only), the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail avenues (all listed on fda.gov and the FDA intranet).

<p>PIA 37:</p>	<p>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>	<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 collect 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. OGDweb administrators perform annual reviews to evaluate user access.</p>
<p>PIA 38:</p>	<p>Identify who will have access to the PII in the system.</p>	<p>Users Administrators Developers Contractors</p>
<p>PIA 38A:</p>	<p>Select the type of contractor.</p>	<p>HHS/OpDiv Direct Contractors</p>
<p>PIA 38B:</p>	<p>Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?</p>	<p>Yes</p>
<p>PIA 39:</p>	<p>Provide the reason why each of the groups identified in 38 needs access to PII.</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- may have access to PII in the course of updating and maintaining the system.</p> <p>Users-PII is used to communicate with regulated entities and to track internal business processes. All users are FDA employees and/or Direct Contractors.</p> <p>Contractors-Some administrators/developers are contractors. PII is used to communicate with regulated entities and to track internal business processes.</p>
<p>PIA 40:</p>	<p>Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.</p>	<p>FDA users with valid network accounts who require access to CDER QDoc 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.</p>

PIA 41:	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 CDER QDoc 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.
PIA 42:	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.
PIA 43:	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.
PIA 44:	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>
PIA 45:	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

Privacy Analyst Review Decision:	Approved	Privacy Analyst Review Date:	6/16/2025
Privacy Analyst Review Comments:	Please be advised that the FDA instance of Archer is automatically generating a "No" response to general question 3. At this time, we are unable to update Archer to reflect the correct response "YES." The ATO date is 11/21/2022.	# of Days - PA Review:	0

SOP Review

SOP Review Decision:	Approved	SOP Review Date:	6/16/2025
SOP Review Comments:	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.	# of Days - SOP Review:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	Agency Privacy Analyst Review Date:	6/17/2025
Agency Privacy Analyst Review Comments:	Reviewer: Crystal Bland 6/17/2025 This PIA is ready for SAOP review and approval.	# of Days - APA Review:	1

SAOP Review

SAOP Review Decision:	Approved	SAOP Review Date:	6/25/2025
SAOP Review Comments:		# of Days - SAOP Review:	8

SAOP Signature

Date	User	Type	Name	Original Value	New Value
6/25/2025 8:13 AM	BLAND, CRYSTAL	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 01	Data Feed Service, pta_pia_FDA_Release	6/16/2025	Alternate POC: Muthusubha Shanmugam /Muthusubha.Shanmugam@fda.hhs.gov/240-402-5134	
PTA 01	BLAND, CRYSTAL	6/17/2025	6/16/2025 Per FDA's Email: Please be advised that the FDA instance of Archer is automatically generating a "No" response to general question 3. At this time, we are unable to update Archer to reflect the correct response "YES." The ATO date is 11/21/2022.	6-16-2025 EMAIL_PIA in Queue (CDER Quality Documents FDA326104).pdf CDER QDoc SOP approved 6.16.20-2025.pdf