PTA / PIA: FDA - FWA - QTR3 - 2025 - FDA4949679

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General Information

PTA / PIA Name:	FDA - FWA - QTR3 - 2025 - FDA4949679	**PTA / PIA ID:**	3562616
Component Name:	FDA - OC FOIA Workflow Application	**ATO Boundary Name:**	OC FOIA Workflow Application
Overall Status:	Complete	**# of Days - Open:**	8
Submitter:		**Submit Date:**	7/28/2025
Next Assessment Date:	08/04/2028	**Expiration Date:**	8/4/2028
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?	Yes
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.	3/5/2025
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	Meredith Schlaifer
PTA 01A:	POC Title and Organization	Supervisory Government Information Specialist Office of Disclosure, Information Governance, and Accessibility / Division of Headquarters Freedom of Information
PTA 01B:	POC Email Address	meredith.schlaifer@fda.hhs.gov
PTA 01C:	POC Phone Number	301-796-0583
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	New

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.	The Office of the Commissioner (OC), Freedom of Information Act (FOIA) Workflow Application (FWA) is a commercial off the shelf (COTS) software tool developed by FEITH systems. OC FWA provides an enterprise end-to-end workflow solution for the Food and Drug Administration (FDA) FOIA processors. FOIA requests are imported from existing external public portals (FDA.gov and FOIA Online, assessed separately) which allows members of the public to submit FOIA requests using a form located on the FDA.gov webpage. Although these public portals collect personally identifiable information (PII), requests do not reside on the public portals. Rather, requests are transferred to OC FWA for processing. OC FWA interfaces with the following FDA systems/components: Documentum and the User Fee Management System (UFMS) (each assessed separately). Users of OC FWA consist of FDA permanent employees, Direct Contractors, and Fellows from across FDA's component organizations who specialize in processing and responding to FOIA requests. Internal users access this internal only system via FDA's single sign-on (SSO)/PIV authentication method. The key functional elements of OC FWA include: (1) Process automation to manage repetitive tasks throughout the FOIA lifecycle; (2) Centralized structure to manage FOIA requests in private, single-tenant environments; (3) Search capabilities to find exact words or phrases in text, search by metadata and save common searches; (4) interfacing capabilities with public facing portal to collect request through secure and public facing request form; (5) Redaction capabilities to remove (withhold) sensitive information without utilizing external applications; (6) Security controls to enforce security from request to delivery through tools including access controls, authentication, encryption modules and audit logs; (7) Records management to maintain FOIA requests for the appropriate records lifecycle; and (8) Reporting and dashboards to monitor response activities and case status.

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.	OC FWA may collect, maintain and/or share any of the following personal or professional contact information about requesters or their third-party representatives: (1) name; (2) email address; (3) telephone number; (4) mailing address; (5) financial account information (e.g., credit/debit card numbers, bank account numbers or similar information associated with requester payment of fees charged by FDA to process a request); (6) case numbers; (7) copies of documents related to requests made (PDF or other format which may include PII); and (8) itemized accounts of charges invoiced for services and records of payments received (which may include the PII). OC FWA also collects and maintains the following information about FDA permanent employees, Direct Contractors, and Fellows ((e.g., FOIA specialists processing and responding to FOIA requests): (1) names; (2) business email address; (3) business telephone numbers; (4) organization and/or job title (PII when combined with other PII about the requestor); (5) communication logs documenting actions taken by FDA office personnel when assembling request responses (which may include names and email addresses of other FDA collaborators); and (6) Itemized accounts of charges invoiced for services and records of payments received (which may include PII). Note that while not requested, many FOIA submissions contain additional information such as the reason(s) for the request and/or additional information about the requester and/or third-party representative acting on behalf of a requester (e.g., date of birth (DOB)) that is recognized PII. Requested records may contain PII. In the event that PII is included in a releasable record, PII will be redacted so as to avoid an unauthorized disclosure. The total number of requests recorded in the application may exceed a half-million. However, not all of these records will contain PII. Retrieval of records is most often accomplished by utilizing an individual's case number. However, records may be retrieved by a combination of requestor name, email address, phone number, case number, and financial account information in order to follow up on individual requests. PII is stored in the system on a temporary basis in accordance with the following National Archives and Records Administration (NARA) records retention schedules: General Records Schedule (GRS) 4.2, Item 20.
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.	Active Directory
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.	Requester PII (name, personal/business mailing address, personal/business telephone number, and personal/business email address), as well as associated billing and payment information, non-solicited data contained within other materials submitted by a requester or gathered internally in response to a request, is collected, maintained and/or shared to process and respond to FOIA requests. PII is also used to communicate with requesters and/or their representatives about submitted FOIA requests. OC FWA also collects and maintains professional contact information of FDA personnel who process, research, and respond to FOIA requests. Information includes name, business email address, business phone number, organization, and job titles. The system also maintains copies of communication logs documenting actions taken by FDA office personnel when assembling and processing request responses. Itemized accounts of charges invoiced for services and records of payments received are also collected and maintained by the system. Information is collected to coordinate and manage requests. PII from the OC FWA about FOIA requesters is shared internally within the Department of Health and Human Services (HHS) to coordinate responses to FOIA inquiries, including locating and collecting relevant documents. FDA applies “need-to-know” principles and shares only the information necessary to identify and obtain the relevant documents. FDA may forward FOIA requests and the PII therein to other agencies' FOIA offices if they hold the information requested who may elect to respond directly to the requester. FDA may also share information about a FOIA request with the Department of Justice (DOJ), a court or other adjudicative authority where required by law (e.g., FOIA Appeal and/or Judicial review).
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).	Internal: https://fda-foia.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.	OC FWA is a web-based application that is only available internally to FDA personnel. It is accessed using an internal only uniform resource locator (URL) and SSO authentication process. OC FWA interfaces with other FDA systems/components (FOIA online and FDA.gov) to collect publicly submitted FOIA requests through an integration with FDA's public portal/URL at https://www.accessdata.fda.gov/scripts/foi/foirequest/requestinfo.cfm. Members of the public access the public portal/web page from the public URL listed above and have the option to login with a username and password.
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?	No
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 Financial Account Information (e.g., account numbers, credit card numbers) Biographical Information Name Date of Birth Contact Information Email Address (Personal) Mailing Address (Personal) Phone Numbers (Personal) Email Address (Business) Mailing Address (Business) Phone Numbers (Business) Other Other

PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Financial information (itemized accounts of charges invoiced for FDA FOIA services and records of payments received; credit card/debit numbers; bank account numbers); requester case numbers; unsolicited PII included in additional documentation provided by requesters; internal communications which may include name and email address; organization, and job titles (when combined with other unique identifiers belonging to requester).
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Business Partners/Contacts (Federal state, local agencies) Employees/HHS Direct Contractors Grantees Patients Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	100,000 – 999,999
PIA 25:	For what primary purpose is the PII used?	The FDA uses the PII for the primary purpose of responding to records requests, invoicing/payments from requesters, and communication with requesters.
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.	Use and disclosure of information in FOI is governed by the Freedom of Information Act (FOIA), 5 U.S.C. 552. Responding to FOIA requests is a significant activity at many federal agencies, and the interpretation and application of its requirements often involve reliance on case law (i.e., court decisions) and other guidance. For the invoicing, 5 U.S.C. 552 (a)(4)(A) establishes the conditions under which fees may be charged for responses to FOIA requests, and requires each agency to "promulgate regulations, pursuant to notice and receipt of public comment, specifying the schedule of fees applicable to the processing of requests under this section and establishing procedures and guidelines for determining when such fees should be waived or reduced." 5 U.S.C. 301
PIA 29:	Are records in the system retrieved by one or more PII data elements?	Yes
PIA 29A:	Please specify which PII data elements are used to retrieve records.	While records in the system are usually retrieved using case number, records may also be retrieved using a combination of name, email address, phone number, case number, and financial account information.

PIA 29B:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	SORN 09-90-0058, Tracking Records and Case Files for FOIA and Privacy Act Requests and Appeals (applies to FOI) https://www.federalregister.gov/documents/2016/03/29/2016-07060/privacy-act-of-1974-system-of-records-notice SORN 09-90-0024, Financial Transactions of HHS Accounting and Finance Offices (applies to invoicing) https://www.federalregister.gov/documents/2015/11/03/2015-27980/privacy-act-of-1974-system-of-records-notice SORN 09-40-0012, Debt Management and Collection System (applies to invoicing) https://www.federalregister.gov/documents/2018/02/14/2018-03014/privacy-act-of-1974-system-of-records
PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Phone Email Online Government Sources Within the OPDIV Other HHS OPDIV State/Local/Tribal Other Federal Entities Non-Government Sources Members of the Public Private Sector
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA 31A:	Provide the information collection approval number(s) and expiration date(s).	The OMB information collection approval number is: OMB 0910-0832. Expiration Date: 6/30/2026
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	Yes
PIA 32A:	Identify with whom the PII is shared or disclosed.	Other Federal Agency/Agencies Within HHS

PIA 32B:	For each disclosure, name the organizations/systems the system shares PII with and the purpose(s) of the disclosure.	PII from OC FWA about FOIA requesters is shared internally within HHS to coordinate responses to FOIA inquiries, including locating and collecting relevant documents. While unlikely, FDA may disclose PII to other federal agencies (e.g., DOJ) when FDA has determined that an agency maintains responsive records subject to a request. Given the variety and volume of FOIA requests received by FDA, each determination is approached on a case-by-case basis. If Privacy Act records are disclosed, the disclosing agency will maintain an accounting of disclosure. When disclosing information FDA applies "need-to-know" principles and shares only the information necessary to identify and obtain the relevant documents for purposes of processing and managing FOIA requests.
PIA 32C:	List any agreements in place that authorize the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	FDA FOIA Analysts may contact other HHS Operating Divisions (OpDivs) or other federal agencies in the course of determining how to respond to FOI requests and where responsive records are held. Specific Memorandum of Understanding (MOU) are not usually executed to conduct these exchanges which will differ case-by-case given the variety of requests.
PIA 32D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	FDA FOIA Analysts may contact other HHS Operating Divisions (OpDivs) or other federal agencies in the course of determining how to respond to FOI requests and where responsive records are held. Specific Memorandum of Understanding (MOU) are not usually executed to conduct these exchanges which will differ case-by-case given the variety of requests.
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.	Submission of FOIA requests is voluntary. However, the submission of PII is necessary in order to communicate and send responses to requests. Submitters may not opt out of submitting PII if they wish to receive a response, because FDA would not know where to send the response nor who to contact to clarify requests. There is no method for employees to opt out 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.

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.	No such changes are anticipated. If the agency changes the collection, use, or sharing of PII data in this application, the affected individuals will be notified by the most efficient and effective means available and appropriate to the specific change(s). This may include a notice on relevant web sites, email notice to the individuals, an amended Privacy Act Statement, and/or publication of an updated PIA and/or System of Records Notice (SORN).
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 often use the FOIA process-or the related Privacy Act request process-to make that determination. They then have a number of avenues available to request to rectify the situation. Individuals may contact the office or division where they have determined that their records are held and request their information be corrected or amended. FDA considers these requests and, if appropriate, makes the requested changes. Individuals may also communicate directly with the FOIA office or assigned analyst to request corrections or additions. Additionally, individuals may contact FDA offices via email, telephone, and standard mail avenues (all listed on fda.gov). Employees concerned about the use of their PII, can work with their supervisors, the Employee Resource and Information Center (ERIC), or FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). FDA personnel are required to immediately report any suspected incidents or breaches to the FDA CIOCC. Contractors are required to safeguard all information and to report potential data breaches to the FDA.
PIA 37:	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.	PII is used transactionally to address a specific business function (responding to FOIA requests). It would not represent a benefit to the public or to FDA to maintain PII and update or correct it after it has been used for the intended purpose. Administrative and technical controls applied to the system support system and data availability, integrity and accuracy. FDA employee users' access credentials are updated consistent with security practices. Security and technical controls are applied to support information integrity, availability, accuracy and relevance.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors

PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	Users are FDA employees requiring access to PII to perform their jobs. Users require full access to systems in order to conduct activities related to delegating and responding to FOIA analysis assignments. Administrators grant access to FDA employee users based on each user's role and activities. 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 as developers review and adjust users' access permissions, and to remove unnecessary accounts from the system.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Users who require access to OC FWA 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 these applications on a quarterly basis to review and adjust users' access permissions, and to remove unnecessary accounts from the application.
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.	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. Members of the public do not have access to the system.
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 complete 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 individuals have completed the training.

PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	The product vendor provides system training to FDA employees on OC FWA functionality and features and system documentation and user guides for FDA employee use. All users are instructed on adhering to the HHS Rules of Behavior in the context of their work involving the application. For additional privacy guidance, personnel may contact the agency's Privacy Office. Privacy program materials are available to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.
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).	Information in OC FWA is retained under General Records Schedule (GRS) 4.2, Item 20 (access and disclosure request files). Temporary. Destroy when 3 years old, but longer retention authorized if needed for business use.
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.	Administrative Safeguards include training and awareness provided for all users; system manuals that advise on the proper use; implementation of Need to Know and minimum necessary principles when awarding access, and others. FDA and the vendor will secure PII in the system using technical controls such as firewalls, multi-factor identity authentication, encryption, and others. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls. More broadly, 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.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	7/28/2025
Privacy Analyst Review Comments:	Due to an Archer error, General Q 03: “Does the system have or is it covered by a Security Authorization to Operate (ATO)??" erroneously reports that no ATO is in place. The correct response should be "Yes" and ATO date is 3/5/2025., At this time, we are unable to update Archer to reflect the correct answer “Yes.”	**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	7/28/2025
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:**	8/5/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 8/5/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	8

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	8/5/2025
SAOP Review Comments:	Approved on behalf of the SAOP.	**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/5/2025 10:49 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	BLAND, CRYSTAL	7/29/2025	Per FDA's Email: The PIA is experiencing an Archer error with question General 03: "Does the system have or is it covered by a Security Authorization to Operate (ATO)?" The FDA instance of Archer is automatically entering the answer "No," which is incorrect. The ATO date is 3/5/2025. At this time, we are unable to update Archer to reflect the correct answer "Yes." The FDA Archer Team is aware of this occurrence and is working on a solution.	7-29-2025 EMAIL_PIA in Queue OC Freedom of Information Act Workflow Application (OC FWA)_FDA-FWA-QTR 3-2025-FDA4949679.pdf OC FWA SOP approved 7.28.2025.pdf