PTA / PIA: FDA - CTP eSub Modernization - QTR4 - 2025 - FDA4972632

Created Date: 10/2/2025 12:21 PM Last Updated: 11/28/2025 3:34 PM

General Information

PTA / PIA Name:	FDA - CTP eSub Modernization - QTR4 - 2025 - FDA4972632	**PTA / PIA ID:**	3886664
Component Name:	FDA - CTP eSub Modernization	**ATO Boundary Name:**	CTP Electronic Submissions
Overall Status:	Complete	**# of Days - Open:**	57
Submitter:		**Submit Date:**	11/20/2025
Next Assessment Date:	11/27/2028	**Expiration Date:**	11/27/2028
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.	Initiation
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.	9/4/2025
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	Deborah Sholtes
PTA 01A:	POC Title and Organization	POC Title: Branch Chief POC Organization: CTP/OS/DRSI
PTA 01B:	POC Email Address	deborah.sholtes@fda.hhs.gov
PTA 01C:	POC Phone Number	301-796-0560
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 Center for Tobacco Products (CTP) eSubmissions Modernization system (eSub Mod) is a suite of applications that facilitates the collection, logging, storing, tracking and retrieval of tobacco industry-provided submissions, that include product-related data and documents as well as contact data and will be both internal/external facing. The eSubmissions suite is comprised of the following User facing applications: CTP Portal Next Gen (NG) application: The CTP Portal NG application allows the regulated industry (i.e., tobacco manufacturers) to electronically submit tobacco-related data and documents to FDA for review. The CTP Portal NG application is also used by industry to use webforms to create required OMB forms for submission packages or to upload eSubmitter generated submission packages. The eSubmitter application is an FDA system that allows Users to prepare submission packages of documents to send to FDA. The industry users can view information about their submissions such as submission date, Submission Tracking Numbers (STN) and date received. The CTP Portal NG only allows approved industry users to log in using credentials, to view or perform any actions on the application. The CTP Portal NG application is also accessed by the CTP Document Control Center (DCC) to submit data and documents extracted from mailed-in submissions to FDA (Paper submissions, Hard drives, Thumb drives and other Media files). The CTP Portal NG supports Single Sign On (SSO) for DCC and other FDA user access. Submission data and documents ingested and stored in the eSubmissions Modernization data stores is made available to other CTP systems to support the evaluation of the Industry Submissions, develop policy, and assess industry compliance with FSPTCA (Family Smoking Prevention and Tobacco Control Act) while supporting the regulatory and public health goals and objectives of CTP. System Users are: CTP Document Control Center (DCC), who are the primary users of the system. CTP Office of Science (OS), who need to assess the submissions to develop the science that supports and drives tobacco regulations and policy. CTP Office of Compliance and Enforcement (OCE), who are responsible for monitoring and enforcing compliance with the tobacco regulations.

		Authorized Tobacco Industry users and their agents are the data providers.
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 information tobacco industry representatives regarding tobacco products, their ingredients, and constituents. In accordance with the provisions of the Family Smoking Prevention and Tobacco Control Act (FSPTCA), tobacco industry submit product listing, ingredient listing, documents describing health effects of tobacco product ingredients, and other tobacco-related data. This information is used to make scientific and regulatory decisions regarding these products. Submissions may contain the name and contact information (i.e., email address, mailing address, and telephone number) of the person submitting the information, although in most cases inclusion of this information is optional. This information is maintained in the CTP Databases which are housed within the FDA's secure AWS GovCloud environment or at the FDA's Ashburn Data Center. User Credentials used for accessing the system are stored and managed by FDA Identity, Credential and Access Management (ICAM) system. No other information collected by the system (tobacco product-related data and documents, or contact data), is shared outside the Center for Tobacco Products. Currently there is no lifecycle expiration defined for all collected data, including PII data and hence all the collected data is stored in the system indefinitely.
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.	FDA Identity, Credential and Access Management (ICAM) system.
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.	CTP eSub Modernization collects information tobacco industry representatives regarding tobacco products, their ingredients, and constituents. In accordance with the provisions of the Family Smoking Prevention and Tobacco Control Act (FSPTCA), tobacco industry submit product listing, ingredient listing, documents describing health effects of tobacco product ingredients, and other tobacco-related data. This information is used to make scientific and regulatory decisions regarding these products. Submissions may contain the name and contact information (i.e., email address, mailing address, and telephone number) of the person submitting the information, although in most cases inclusion of this information is optional.
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://ctpportal-ng.fda.gov/
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	Yes
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 CTP Portal NG application allows tobacco industry users to submit information to the FDA regarding their tobacco products, ingredients, and constituents in accordance with the provisions of the FSPTCA so that the FDA can make scientific and regulatory decisions regarding these products and the tobacco industry. The CTP Portal NG URL is accessible to public on the Internet, but the application is only available for use to approved (industry) users after they are successfully authenticated with multifactor authentication (MFA) (User credentials and Email Confirmation). Categories of individuals having access to the website - Industry Users - CTP Portal NG only allows approved industry users to log in using multi-factor authentication, User credentials and email OTP, to access the website. FDA Users - CTP Portal NG supports FDA single sign on solution for CTP Document Control Center (DCC) Users and Users from other CTP offices such as Office of Science (OS), Office of Compliance and Enforcement (OCE), and Office of Management (OM).
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.	Biographical Information Name Contact Information Email Address (Business) Mailing Address (Business) Phone Numbers (Business)
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	50,000 – 99,999
PIA 25:	For what primary purpose is the PII used?	The FDA uses the PII for the primary purpose of the point of contact (POC) information received from industry users will be used in CTP Portal NG to allow industry users to auto-populate contact data within the submission forms to ease the data entry burden, and is used by the FDA to contact the submitter for correspondence and when follow-up is required.
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: 21 U.S.C. 301, sections 375(b), 387d, and 387e of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31, 123 Stat. 1776), incorporated at 18.U.S.C. 1001, Sections 904(a) and 904(b).
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.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Email Online Non-Government Sources Members of the Public
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).	0910-0732, expiring 11/30/2028 0910-0654, expiring 11/30/2028 0910-0650, expiring 11/30/2028 0910-0673, expiring 4/30/2028 0910-0684, expiring 11/30/2028 0910-0312, expiring 01/31/2026 0910-0775, expiring 11/30/2028 0910-0671, expiring 12/31/2025 0910-0731, expiring 11/30/2028 0910-0879, expiring 03/31/2028
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.	There is no option to object to or opt-out of the information collection because individuals do not have to provide their PII to the FDA. The submission of PII to CTP is completely voluntary.
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.	Individuals whose PII is in the system will be notified of a major change by the most efficient and effective means available and appropriate to the specific change(s). This may include a formal process involving written and/or electronic notice, or informal processes such as email notice to the individuals.
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 and CTP system have a number of avenues available to resolve the situation using contact and reporting information available across FDA.gov including contacting or submitting concerns to the FDA Privacy Office. Employees aware of potential unauthorized use of PII in the system may submit concerns to their supervisor, the FDA Privacy Office, a 24-hour technical assistance line, and/or FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC).

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.	In support of data accuracy and relevance, CTP reviews industry submissions on a quarterly basis and evaluates them to determine whether they are consistent with previous submissions as well as public information. All PII is solicited using approved forms and is relevant to facilitate communication between CTP and regulated organizations. Forms and processes designed to collect only necessary PII ensure PII relevance. Data integrity and accuracy are important to the extent that PII permits communication with regulated organizations; industry organizations can supply the name of any individual who is able to communicate with FDA on behalf of the organization. Integrity, as well as availability, are both protected by privacy and security controls selected according to the risk level of the system and consistently with federal guidance from the Office of Management and Budget (OMB) and the National Institute of Standards and Technology (NIST).
PIA 38:	Identify who will have access to the PII in the system.	Users 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 - FDA employees at CTP may use submitter contact PII to contact the submitter when follow-up is required. Submitters have access to their own information only, not to PII that is submitted by others. Developers - For system development and upkeep and for trouble shooting issues related to the system, performance, and access. Contractors - CTP uses Direct Contractors for system development and upkeep. They trouble shoot issues with system, performance, and access. Direct Contractors do not analyze the data that is collected.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	CTP employees and Direct Contractors with valid network accounts who require access to eSubmissions must have supervisory approval and signature before access is granted. An internal form 3530, "User Access Request", must be completed and approved by the Program Manager, Business Owner, and FDA System Owner before access to eSubmissions is granted. 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.

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.	A Standard Operating Procedure (SOP) and System Access Request (SAR) form are used to grant different levels of system access based on work need and role. The relevant supervisor will indicate on the eSubmissions user account creation form the minimum access that is required for the user to complete his/her job. The scope of access is restricted based on role-based criteria. All users are authenticated.
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 and maintains a record of certificates of training on all FDA employees and Direct Contractors.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	Personnel are trained in the use of the system and review the HHS/FDA Rules of Behavior. Additional role-based training on privacy is available via FDA's Privacy Office.
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).	The electronic data captured is currently retained indefinitely, pending receipt of the requested FDA file code consistent with the National Archives and Records Administration (NARA) guidelines. The selection of this retention schedule is under review and will be updated as necessary. CTP anticipates that the file code will be FDA's file code 6132, consistent with NARA-approved schedule N1-88-07-2, for Adverse Experience Reporting System Database Records, for which record retention are cutoff annually at the end of the calendar year after a case is closed and deleted 30 years after cutoff or when no longer needed for trend analysis or reference purposes, whichever is the latest.

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 user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	11/20/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	11/20/2025
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:**	11/25/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 11/25/2025 Comment was addressed. This PIA is ready for SAOP review and approval. 11/19/2025 Please see comment and update accordingly: PIA-31A: Please update the following expiration dates: 0910-0732, expiring 11/30/2025 0910-0654, expiring 11/30/2025 0910-0650, expiring 11/30/2025 0910-0684, expiring 11/30/2025 0910-0312, expiring 01/31/2026 0910-0775, expiring 11/30/2025 0910-0671, expiring 12/31/2025 0910-0731, expiring 11/30/2025 0910-0879, expiring 03/31/2028	**# of Days - APA Review:**	5

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	11/28/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	3

SAOP Signature

Date	User	Type	Name	Original Value	New Value
11/28/2025 12:06 PM	BAUR, VANESSA	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	VILLAFUERTE, NESTOR	10/10/2025	Per FDA's e-mail, Q3 is showing as "No", however, the ATO date listed is correct. They are aware of the issue and have reported to the Archer	

			team.	
PTA 01	BLAND, CRYSTAL	11/19/2025	11/19/2025 Per FDA email on 10/2/2025 "Note the Archer error associated with question General 03: “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” o The FDA instance of Archer is automatically entering the answer “No” which is incorrect. o At this time, we are unable to update Archer to reflect the correct answer “Yes.” The ATO date is *9/4/2025*. The FDA Archer Team is aware of this occurrence and is working on a solution.	10-2-2025 EMAIL_RE_ PIA in Queue (CTP eSub Modernization) PTA _ PIA 4972632.pdf
PIA 31A	BLAND, CRYSTAL	11/19/2025	Please update the following expiration dates: 0910-0732, expiring 11/30/2025 0910-0654, expiring 11/30/2025 0910-0650, expiring 11/30/2025 0910-0684, expiring 11/30/2025 0910-0312, expiring 01/31/2026 0910-0775, expiring 11/30/2025 0910-0671, expiring 12/31/2025 0910-0731, expiring 11/30/2025 0910-0879, expiring 03/31/2028	
PTA 01	BLAND, CRYSTAL	11/25/2025	11/25/2025 Per FDA's Email, "The HHS comments have been addressed, and the attached PIA has been resubmitted for continued review. Note the Archer error associated with question General 03: “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” o The FDA instance of Archer is automatically entering the answer “No” which is incorrect. o At this time, we are unable to update Archer to reflect the correct answer “Yes.” The ATO date is	PIA in Queue (CTP eSub Modernization) PTA _ PIA 4972632.pdf CTP eSub Modernization_SOP Approved.pdf

9/4/2025.

The FDA Archer Team is aware of this occurrence and is working on a solution."