


General Information			
PTA / PIA Name:	FDA - TUFA - QTR3 - 2025 - FDA4949593	PTA / PIA ID:	3540029
Component Name:	FDA - CTP Tobacco User Fee Application	ATO Boundary Name:	CTP Tobacco User Fee Application
Overall Status:	Complete 	# of Days - Open:	12
Submitter:		Submit Date:	7/24/2025
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.		12/23/2022
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		Raymond Hawkins
PTA 01A:	POC Title and Organization		IT Project Manager CTP/OS/DRSI
PTA 01B:	POC Email Address		Raymond.Hawkins@fda.hhs.gov
PTA 01C:	POC Phone Number		301-796-6831
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.	FDA has made no changes to this system/component since the last Privacy Threshold Analysis/Privacy Impact Assessment was approved.
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>The United States Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is responsible for carrying out the Family Smoking Prevention and Tobacco Control Act, which Congress passed in 2009. This law, commonly called the Tobacco Control Act, gives the CTP broad authority to regulate the manufacturing, distribution, and marketing of tobacco products. To accomplish its mission, CTP relies on a number of systems and one of them is the Tobacco User Fee Application (TUFA). TUFA is a web-based interface application that enables the CTP users (FDA employees and Direct Contractors) to calculate the user fee market share percentage of regulated manufacturers and tobacco importers. The production application is hosted in FDA's Ashburn Data Center. This application is not accessible to the public, contractors, or other internal FDA resources. The system is only accessible by the FDA CTP TUFA business team.</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.

TUFA collects and maintains information related to tobacco manufacturers and tobacco importers (regulated industry members, referred to collectively as “firms”). The information collected includes personally identifiable information (PII) in the following form for a firm’s point of contact: name (first and last); email address; and phone number. This PII is collected to address tobacco assessments and communicate directly with the industry’s point of contact (POC). In addition, the system collects non-PII in the following form: firm’s name; firm’s address; firm’s phone number; firm’s email address; and TTB firm permit number (issued by the Tobacco Tax and Trade Bureau within the National Revenue Center). It also collects user fee assessment data that may include period of activity (month and year), number of tobacco products and amount of taxes paid; also considered non-PII.

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The system does not collect PII about FDA employees and Direct Contractors; all collected PII relates to public citizens who are designated as the firm’s point of contact. FDA employees and Direct Contractors access TUFA via a network-level single-sign-on process using multi-factor authentication; TUFA does not maintain system specific logon credentials (no username, password). Firm points of contact do not access TUFA application.

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.	TUFA is a standalone application housed on the FDA intranet that supports CTP business processes related to the collection of data submitted by tobacco manufacturers and tobacco importers in compliance with the Family Smoking Prevention and Tobacco Control Act. TUFA is web-based and allows FDA users (FDA employees and Direct Contractors) to manually enter tobacco manufacturer and importer data (number of tobacco products and amount of taxes paid) contained in forms submitted by firms via mail or email. The system uses specific calculations and algorithms to generate the user fee market share percentage for the registered company.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	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) 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.	100 – 499
PIA 25:	For what primary purpose is the PII used?	The PII, consisting of business contact information of firm points of contact is collected for communicating with firms in relation to forms they submitted.
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 enactment of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in fiscal year (FY) 2009 authorized the FDA to collect user fees from domestic manufacturers and importers of tobacco products to pay for FDA tobacco regulation activities. FDA created the Center for Tobacco Products (CTP) to oversee the implementation of the FDA tobacco program, pursuant to the FSPTCA. 21 U.S.C. 387s (section 919 User Fees) requires FDA to assess user fees on, and collect such user fees from, each domestic manufacturer and importer of tobacco products.
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> <p>Hard Copy Mail/Fax</p> <p>Non-Government Sources</p> <p>Members of the Public</p>
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).	FDA Form 3852, OMB No. 0910-0749 Expiration date: 08/31/2025
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.	Submitters provide their contact information as a practical requirement in order to communicate with FDA and to gain access to the system. There are no opt-out procedures specific to TUFA. While FDA requires that regulated entities supply the PII of a point of contact, that person can be anyone who is authorized to send and receive communications on behalf of the regulated entity.
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 FDA changes its practices regarding 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), the 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). All FDA personnel are required to rapidly report any suspected and/or known breach to the CIOCC.

<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>Individuals voluntarily provide their PII. 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.</p> <p>PII relevancy is supported through the design of the system to require and collect only the PII elements necessary to administer the system and enable its intended use. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).</p> <p>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 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. CTP performs 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</p> <p>Administrators</p> <p>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>Users: Enter data and generate market share percentage report as part of their job duties.</p> <p>Administrators: Troubleshoot issues with the system, performance, and access.</p> <p>Contractors: Direct contractors enter data and generate market share percentage report as part of their job duties.</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 and Direct Contractors with valid network accounts who require access to the system must obtain supervisory approval and signature before access 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.</p>
<p>PIA 41:</p>	<p>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.</p>	<p>The relevant supervisor will indicate on the 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.</p>

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 individuals successfully complete the training.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	Personnel are trained on the use of the system and review the 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).	Dispositions authorities for TUSA records fall under file code 9995a National Archives and Records Administration (NARA) General Records Schedule 5.2 with the disposition DAA-2017-0003-0002 for Intermediary Records which indicates records will be destroyed by the agency upon verification of successful creation of the final document or file, or when no longer needed for business use, whichever is later.
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 use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools.</p> <p>Physical controls include that all system servers are located at 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:	7/24/2025
Privacy Analyst Review Comments:		# of Days - PA Review:	0

SOP Review

SOP Review Decision:	Approved	SOP Review Date:	7/24/2025
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:	7/30/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 7/30/2025 Have not rec'd a response from FDA regarding the PIA Submission. This PIA is ready for SAOP review and approval.	# of Days - APA Review:	6

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:	6

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/5/2025 7:10 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	VILLAFUERTE, NESTOR	7/25/2025	Q3 states that the PIA does not have an ATO, however, the stated date has passed.	
PTA 01	BLAND, CRYSTAL	7/30/2025	See attached email.	7-25-2025 EMAIL_FDA PIA Submissions.pdf
PTA 01	BLAND, CRYSTAL	7/30/2025	<p>Per FDA's Email Response:</p> <p>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)?"</p> <ul style="list-style-type: none"> o The FDA instance of Archer is automatically entering the answer "No," which is incorrect. The ATO date is 12/23/2022. o At this time, we are unable to update Archer to reflect the correct answer "Yes." <p>The FDA Archer Team is aware of this occurrence and is working on a solution.</p>	<p>7-30-2025 EMAIL_RE_FDA PIA Submissions.pdf</p> <p>CTP Tobacco User Fee Application PIA_SOP Approved.pdf</p>