PTA / PIA: FDA - TriCS - QTR3 - 2025 - FDA4949591

Created Date: 7/24/2025 12:43 PM Last Updated: 8/5/2025 12:43 PM

General Information

PTA / PIA Name:	FDA - TriCS - QTR3 - 2025 - FDA4949591	**PTA / PIA ID:**	3540030
Component Name:	FDA - CTP Call Center System	**ATO Boundary Name:**	CTP Call Center System
Overall Status:	Complete	**# of Days - Open:**	12
Submitter:		**Submit Date:**	7/30/2025
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)?	Yes
General 04:	ATO Date or Planned ATO Date.	7/26/2022
General 05:	Is the system or electronic information collection, agency or contractor operated?	Contractor
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	Ted Hsieh
PTA 01A:	POC Title and Organization	POC Title: IT Project Manager POC Organization: CTP
PTA 01B:	POC Email Address	Ted.Hsieh@fda.hhs.gov
PTA 01C:	POC Phone Number	301-796-6821
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 determined that this is not a Privacy Act system. There is no retrieval of individual records by using an individual identifier, and it does not store any PII beyond business contact information.
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 United States (U.S.) Food and Drug (FDA) Center for Tobacco Products (CTP or the Center) 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 Center authority to regulate the manufacturing, distribution, and marketing of tobacco products. One of CTP's key areas of focus is to provide information to help educate consumers. To accomplish that mission, CTP has developed a Call Center System named "TriCS" to manage all customer service-related inquiries originating from members of the public, government and regulated industry. The main goal of TriCS as a correspondence system is to facilitate collaboration and communication between these parties and the FDA about tobacco related guidance, compliance and education.
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.	TriCS collects and maintains information related to inquiries submitted by customers (members of the public, employees of other federal agencies, or employees of regulated industry) via phone, mail, and e-mail. The information collected about the customers may include name, e-mail address, phone number, mailing address and a narrative about the reason for the inquiry. TriCS assigns a case reference number to logged inquiries. The system also maintains information about case workers (CTP employees and direct contractors) assigned to a specific inquiry. The information about case workers may include their name, office name, and a timeline of the logged inquiry. Details on logged inquiries enable CTP to track previous interactions between the Center and customers (those calling, mailing or emailing the Center) for reference during communications. CTP case workers access the system via a network-level single-sign-on process using multi-factor authentication (no username or password). TriCS does not maintain system-specific logon credentials (e.g., username and password for FDA personnel or any other individuals).
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 (AD)

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.	TriCS is a cloud-based integrated system which enables CTP employees and direct contractors (referred to here as case workers) to log, manage, and respond to customer-related inquiries. When customers call, mail, or e-mail the Center, they voluntarily share their PII. The PII is stored, along with the narrative of their inquiry in TriCS. The inquiry is then assigned to a specific case worker who is familiar with the topic. If the inquiry does not warrant going through the typical workflow, it is immediately closed. The case worker can optionally send a draft response to other CTP personnel for review (sent internally via agency email, not within TriCS) and can track that review within TriCS. Once the response is returned to the case worker, they mark the review as complete and update the response draft within the system. The case worker contacts the customer and can track the communication history. Once a response has been successfully provided, the inquiry is closed, and actions are no longer performed on it. Notes and attachments can be added to inquiries at any time to track general information about the inquiry and are only visible to TriCS users. TriCS can generate aggregated reports that break down how quickly responses are being provided in a given fiscal quarter. CTP does not use any personal identifier from its customers to retrieve records from TriCS.
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 (Personal) Mailing Address (Personal) Phone Numbers (Personal)
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 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?	PII about customers is collected to allow CTP to contact them and to respond to their inquiry.
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. sections 301, 331, 333, 371, 373, 375, 379, and 387 (Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act).
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 In-person Hard Copy Mail/Fax Email Government Sources State/Local/Tribal Non-Government Sources Members of the Public Private Sector
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.	Not applicable. Per 5 CFR 1320.3(c), TriCs is not a “collection of information” as the information maintained in the system is not obtained by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, ten or more persons.
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.	While submission of PII is "voluntary" as that term is used in the Privacy Act, there is no option to opt-out other than choosing not to submit correspondence to CTP. The PII is required in order to communicate with the customers and provide them service in regard to their inquiry. There is no method for FDA personnel to opt out of submitting their PII. FDA employees, contract employees and fellows 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.	If FDA changes its practices with regard to the collection or handling of PII related to TriCS, 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 to include this PIA. However, no such changes that would affect the rights or interests of the individuals are anticipated.
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.	Customers have the ability to notify and seek assistance from FDA and CTP by dedicated phone numbers and/or a dedicated email address. This information is available on our general website on fda.gov. They may also contact the FDA Privacy Office. FDA personnel may resolve such concerns by contacting the appropriate system administrator, FDA's Employee Resources and Information Center (ERIC) or the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). Personnel may correct or update their information using the appropriate Standard Form, which is the process used to make such changes used by all FDA employees, and the data would be updated in the separate human resources information system.
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.	Customer PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Data discrepancies identified in the course of system use are addressed when discovered. FDA relies on its personnel to ensure the accuracy and integrity of the information entered into these applications. FDA personnel are responsible for providing accurate information and may independently update and correct their information at any time. 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. Integrity and availability are protected by 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, 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. One of the controls includes information system backups reflecting the requirements in contingency plans as well as other agency requirements for backing up information.

PIA 38:	Identify who will have access to the PII in the system.	Users Administrators 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 - CTP users need PII access to respond to inquiries Administrators - Require PII access to address defects in the system. Contractors - Badged FDA direct contractors have access to the system to customize and deploy TriCS based on stakeholder
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Users who require access to TriCS must first obtain management approval before being granted access to the system. This approval is requested and documented via an access request and account creation form that is required by standard procedure. Users granted access to TriCS must have a need for access in order to perform their job function. Approving management confirms the individual's role and need for access.
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.	Supervisors indicate on the account creation form the minimum information system access that is required in order for the user to complete his/her job. The access list for the information system is reviewed on a quarterly basis and users' access permissions are reviewed/adjusted, and unneeded accounts are purged from 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 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).
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	In-person training and User Acceptance Testing sessions. Demonstrations of the system have also been recorded and are available to users.

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 records in CTP TriCS Call Center System are maintained under General Records Schedule (GRS) 5.8 Administrative Helpdesk Records Item 010. Item 010 covers technical and administrative help desk operational records, records of incoming requests (and responses) made by phone, email, web portal, trouble tickets and tracking logs, quick guides and "Frequently Asked Questions" (FAQs), evaluations and feedback about help desk services, analysis and reports generated from customer management data, customer/client feedback and satisfaction surveys, including survey instruments, data, background materials, and reports. These exclude public customer service records which are covered under General Records Schedule (GRS 6.5). The disposition authority falls under DAA-GRS-2017-0001-0001 with the records being destroyed 1 year after resolved, or when no longer needed for business use, whichever is appropriate.
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.	There are several controls in place for the securing of PII within TriCS. The administrative controls include system users completing an access request form and an access review/approval process. The technical controls include firewalls, virtual private networks (VPNs), encryption, and intrusion detection systems. The physical controls are comprised of guarded facilities, gated access to these facilities, security barriers, and locked doors.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	7/30/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	7/30/2025
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. 7/30/2025 This is the FDA PIA that didn't sync properly **FDA - TriCS - QTR3 - 2025 - FDA4949591:** The PTA/PIA is blank, and the Chevron bar doesn't show the Department level Approvers.	**# 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:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/5/2025 11:23 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	7/30/2025	Please see attached email.	7-25-2025 EMAIL_FDA PIA Submissions.pdf
PTA 01	BLAND, CRYSTAL	8/4/2025	8/4/2025 Per FDA's Email: The PTA/PIA has synced properly, attached is the email and exported PIA.	8-4-2025 EMAIL_Resubmitted PIA CTP Call Center System (FDA - TriCS - QTR3 - 2025 - FDA4949591).pdf CTP Call Center System_SOP Approved.pdf
PTA 01	BLAND, CRYSTAL	8/4/2025	8/4/2025 FDA's Email from 7/30/2025 see attached.	7-30-2025 FDA EMAIL_RE_ FDA PIA Submissions.pdf