Privacy Impact Assessment (PIA): FDA - TriCS - QTR1 - 2022 - FDA2033810

Date Signed: 2/10/2022

Acronyms
ATO - Authorization to Operate
CAC - Common Access Card
FISMA - Federal Information Security Management Act
ISA - Information Sharing Agreement
HHS - Department of Health and Human Services
MOU - Memorandum of Understanding
NARA - National Archives and Record Administration
OMB - Office of Management and Budget
PIA - Privacy Impact Assessment
PII - Personally Identifiable Information
POC - Point of Contact
PTA - Privacy Threshold Assessment
SORN - System of Records Notice
SSN - Social Security Number
URL - Uniform Resource Locator

General Information

Status:	Approved	**PIA ID:**	1423610
PIA Name:	FDA - TriCS - QTR1 - 2022 - FDA2033810	**Title:**	FDA - CTP Call Center System
OpDIV:	FDA		

PTA

PTA - 1A:	Identify the Enterprise Performance Lifecycle Phase of the system	Operations and Maintenance
PTA - 1B:	Is this a FISMA-Reportable system?	No
PTA - 2:	Does the system include a website or online application?	No

URL Details

Type of URL	List Of URL
Other	https://datadashboard.fda.gov

PTA - 3:	Is the system or electronic collection, agency or contractor operated?	Contractor
PTA - 3A:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA - 5:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	Yes
PTA - 5A:	If yes, Date of Authorization	5/31/2018
PTA - 5B:	If no, Planned Date of ATO	2/25/2022
PTA - 7:	Describe in further detail any changes to the system that have occurred since the last PIA	No changes since last PIA.
PTA - 8:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions?	The 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 - 9:	List and/or describe all the types of information that are collected (into), maintained, and/or shared in 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, password). TriCS does not maintain system-specific logon credentials (e.g., username and password for FDA personnel or any other individuals).
PTA -9A:	Are user credentials used to access the system?	Yes
PTA - 9B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS/OpDiv PIV Card
PTA - 10:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should 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. While CTP does not use any personal identifier from its customers to retrieve records from TriCS, it routinely uses full name of case workers (permanent agency employees and direct contract employees) to retrieve records about a specific inquiry in order to better assist customers.
PTA - 10A:	Are records in the system retrieved by one or more PII data elements?	Yes
PTA - 10B:	Please specify which PII data elements are used.	Name While CTP does not use any personal identifier from its customers to retrieve records from TriCS, it routinely uses full name of case workers (permanent agency employees and direct contract employees) to retrieve records about a specific inquiry in order to better assist customers.
PTA - 11:	Does the system collect, maintain, use or share PII?	Yes

PIA

PIA - 1:	Indicate the type of PII that the system will collect or maintain	Name E-Mail Address Phone numbers Mailing Address
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared	Business Partners/Contacts (Federal, state, local agencies) Employees/ HHS Direct Contractors Public Citizens
PIA - 4:	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. CTP uses the PII about case workers to track the workflow of assigned inquiries and to inform case worker performance assessments.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research)	None.
PIA - 7:	Identify legal authorities, governing information use and disclosure specific to the system and program	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 - 8:	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.	OPM/GOVT-1 General Personnel Records OPM/GOVT-2 Employee Performance File System Records
PIA - 9:	Identify the sources of PII in the system	Directly from an individual about whom the information pertains In-person Hard Copy Mail/Fax Email Other Government Sources State/Local/Tribal Non-Government Sources Members of the Public Private Sector
PIA - 9A:	Identify the OMB information collection approval number or explain why it is not applicable.	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 - 9B:	Identify the OMB information collection expiration date.	2/8/2022
PIA - 10:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 11:	Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason	Customers submit their information voluntarily and are aware of FDA's use of their information. They may also view FDA's Website and privacy policies permanently available via link on all FDA intranet and internet pages. FDA personnel (e.g., employees, direct contractors, and fellows) are notified at the time of hire and consent to the submission and use of their personal information as a condition of employment. FDA center representatives, and the various individuals involved with the specific data collection and use provide notification to newly hired employees. This PIA provides further notice.
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 13:	Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information	While submission of PII is "voluntary" as that term is used in the Privacy Act, there is no option to

	collection, provide a reason	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 - 14:	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). Alternatively, describe why they cannot be notified or have their consent obtained	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 - 15:	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 Systems Management Center. 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 - 16:	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. 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 - 17:	Identify who will have access to the PII in the system and the reason why they require access	Users Administrators Contractors
PIA - 17A:	Provide the reason of access for each of the groups identified in PIA -17 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 - 17B:	Select the type of contractor	HHS/OpDiv Direct Contractor
PIA - 18:	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 - 19:	Describe the technical methods in place to allow those with access to PII to only access 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 - 20:	Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system 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 - 21:	Describe 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 - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific 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 - 24:	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.