### 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 Name**: FDA - TriCS - QTR1 - 2022 - FDA2033810
- **Title**: FDA - CTP Call Center System
- **OpDIV**: FDA

### PTA

<table>
<thead>
<tr>
<th>PTA - 1A</th>
<th>Identify the Enterprise Performance Lifecycle Phase of the system</th>
<th>Operations and Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA - 1B</td>
<td>Is this a FISMA-Reportable system?</td>
<td>No</td>
</tr>
<tr>
<td>PTA - 2</td>
<td>Does the system include a website or online application?</td>
<td>No</td>
</tr>
</tbody>
</table>

### URL Details

<table>
<thead>
<tr>
<th>Type of URL</th>
<th>List Of URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td><a href="https://datadashboard.fda.gov">https://datadashboard.fda.gov</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PTA - 3</th>
<th>Is the system or electronic collection, agency or contractor operated?</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA - 3A</td>
<td>Is the data contained in the system owned by the agency or contractor?</td>
<td>Agency</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PTA - 5</th>
<th>Does the system have or is it covered by a Security Authorization to Operate (ATO)?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA - 5A</td>
<td>If yes, Date of Authorization</td>
<td>5/31/2018</td>
</tr>
<tr>
<td>PTA - 5B</td>
<td>If no, Planned Date of ATO</td>
<td>2/25/2022</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PTA - 7</th>
<th>Describe in further detail any changes to the system that have occurred since the last PIA</th>
<th>No changes since last PIA</th>
</tr>
</thead>
</table>

| 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 |

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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 |
| PTA - 11 | Does the system collect, maintain, use or share PII? | Yes |

| 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
<table>
<thead>
<tr>
<th>PIA - 5:</th>
<th>Describe any secondary uses for which the PII will be used (e.g., testing, training, or research)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PIA - 7:</strong></td>
<td>Identify legal authorities, governing information use and disclosure specific to the system and program</td>
</tr>
<tr>
<td><strong>PIA - 8:</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>PIA - 9:</strong></td>
<td>Identify the sources of PII in the system</td>
</tr>
<tr>
<td><strong>PIA - 9A:</strong></td>
<td>Identify the OMB information collection approval number or explain why it is not applicable.</td>
</tr>
<tr>
<td><strong>PIA - 9B:</strong></td>
<td>Identify the OMB information collection expiration date.</td>
</tr>
<tr>
<td><strong>PIA - 10:</strong></td>
<td>Is the PII shared with other organizations outside the system's Operating Division?</td>
</tr>
<tr>
<td><strong>PIA - 11:</strong></td>
<td>Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason</td>
</tr>
<tr>
<td><strong>PIA - 12:</strong></td>
<td>Is the submission of PII by individuals voluntary or mandatory?</td>
</tr>
<tr>
<td><strong>PIA - 13:</strong></td>
<td>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</td>
</tr>
</tbody>
</table>

CTP uses the PII about case workers to track the workflow of assigned inquiries and to inform case worker performance assessments.

None.


OPM/GOVT-1 General Personnel Records

OPM/GOVT-2 Employee Performance File

System Records

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

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.

2/8/2022

No

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.

Voluntary

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
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).

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.

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.

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.