PTA / PIA: FDA - eHCTERS - QTR3 - 2025 - FDA4950125

Created Date: 8/12/2025 4:43 PM Last Updated: 8/29/2025 4:42 PM

General Information

PTA / PIA Name:	FDA - eHCTERS - QTR3 - 2025 - FDA4950125	**PTA / PIA ID:**	3640117
Component Name:	FDA - CBER Electronic Human Cell and Tissue Establishment Registration System	**ATO Boundary Name:**	CDRH Scientific and Research General Support Systems
Overall Status:	Complete	**# of Days - Open:**	17
Submitter:		**Submit Date:**	8/21/2025
Next Assessment Date:	08/28/2028	**Expiration Date:**	8/28/2028
Office:		**OpDiv:**	FDA
Security Categorization:	High		
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?	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.	12/21/2022
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	Christopher Kiem
PTA 01A:	POC Title and Organization	POC Title: Business Owner POC Organization: FDA/CBER
PTA 01B:	POC Email Address	Christopher.kiem@fda.hhs.gov
PTA 01C:	POC Phone Number	240-402-8093
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.	No changes to the system have occurred since the last approved Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA).
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 Food and Drug Administration (FDA) uses a set of information technology applications to collect basic information about the Human Cell and Tissue Product (HCT/P) industry and its products. Establishments must register and submit a list of every HCT/P that they manufacture. The baseline information collected enables FDA to efficiently and effectively respond to emerging public health concerns related to human cells or tissues, and in conducting inspections. The list of industry members and their HCT/Ps also assists the agency with the dissemination of educational materials and other important information regarding FDA policies and requirements. The subject of this assessment is the electronic Human Cell and Tissue Establishment Registration System (eHCTERS). CBER eHCTERS is an external web application that allows HCT/P industry personnel (also known as Reporting Officials and US Agents) to electronically submit HCT/P registration information over the internet through a secure web server. Industry access eHCTERS via the CBER On-Line system (a login and account maintenance portal assessed separately) and use it to create, update, administer, track and report on HCT/P establishment registration and product listing information. Information from eHCTERS is shared with the CBER Human Cell and Tissue Establishment Registration System (HCTERS) (the subject of a separate assessment) an internal FDA system. eHCTERS also includes two query modules, eHCTERS Intranet Query and eHCTERS Internet Query. eHCTERS Intranet Query is used by certain authorized internal users (FDA permanent employees and Direct Contractors) at FDA Centers (Center for Biologic Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and the Office of Regulatory Affairs (ORA)) to view establishment registration information for active, inactive, and pre-registered firms collected by eHCTERS and maintained in HCTERS. This module does not collect or maintain information. eHCTERS Internet Query is the external query tool used by industry to view establishment registration information for active, inactive, and pre-registered firms as collected and maintained in eHCTERS. This module is a view only tool that does not collect or maintain information.

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.	CBER eHCTERS collects cell and tissue establishment registration information. It shares that information with HCTERS and is viewable by FDA users (permanent employees and Direct Contractors) via eHCTERS Intranet Query, and by external industry users via eHCTERS Internet Query. Neither eHCTERS Intranet Query nor eHCTERS Internet Query collect or maintain information. They are view only tools used in conjunction with eHCTERS (the subject of this assessment) or HCTERS. eHCTERS collects and contains personal identifiable information (PII) for external individuals. The PII is mainly about external individuals (industry professionals) except for one screen that allows for the maintenance of a list of FDA District Contacts for Tissue Establishment Registration. PII collected is contact information and may include point of contact (POC) name, business email address, business phone number, and business mailing address. Non-PII includes cell and tissue establishment registration information which includes Establishment Name, Establishment Function, Product listings, Establishment Status, State, Zip Code, and Country. Data elements are collected for tissue establishment registration are detailed on Form FDA-3356. For all of these applications, Industry users (aka Reporting Officials and US Agents) must provide a business telephone number and a business e-mail address. eHCTERS industry users access the system through the CBER Online login portal. A username and password are required. All authorized FDA network users gain access to this system via the CBER Menu application (the subject of a separate assessment) using single sign-on (SSO) authentication. Users of the system are full time employees of the federal government and Direct Contractors with FDA badges and smart cards.
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.	CBER Online

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.	This system collects cell and tissue establishment registration information such as establishment name, point of contact information, and a list of HCT/Ps that the establishments recover, process, package, store, label, distribute, and screen or test. Screening or testing may involve testing the HCT/P donor individual. This information provides the FDA with a list of establishments and products to inspect and to efficiently and effectively respond to emerging public health concerns. The establishment registration information is shared with FDA field inspectors.
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://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm
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 external uniform resource locator (URL) allows industry users (reporting Officials and US Agents) to electronically submit and update establishment registration information over the Internet through a secure web server. This system allows authorized FDA users to create, update, administer, track and report on establishment registration and product listing information. The eHCTERS system also includes a query module (eHCTERS Internet Query) that allows industry users to search on establishment registration information for active, inactive, and pre-registered firms. eHCTERS industry users access the systems through the CBER Online login portal. A username and password are required. All authorized FDA network users gain access to this system via the CBER Menu application (the subject of a separate assessment) using SSO authentication. Users of the system are full time employees of the federal government and Direct Contractors with FDA badges and smart cards.
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.	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.	10,000 – 49,999
PIA 25:	For what primary purpose is the PII used?	The PII collected by this component is part of the required information to satisfy the regulatory requirement to register cell/tissue/blood establishments or update existing registration on an annual basis. The PII is contact information associated with the registration.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	A potential secondary use is integration testing.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	FDA regulates HCT/Ps under the authority of section 361 of the Public Health Service (PHS) Act. Under section 361 of the PHS Act, FDA makes and enforces regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. HCT/Ps that meet the criteria in 21 CFR part 1271 are regulated solely under section 361 of the PHS Act. HCT/Ps that do not meet all the criteria in part 1271 for regulation solely under section 361, are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or Food, Drug and Cosmetic Act. The implementation of these applications is also authorized by 5 U.S.C. 301 which permits agency heads to create the usual and expected infrastructure necessary for the organization to accomplish its purposes and mission. In addition, the security and privacy measures of the applications are required by the Federal Information Security Management Act (FISMA) and the statutes underlying Office of Management and Budget (OMB) Circular A-130 for the secure and efficient use of government systems and resources.
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 Online Non-Government Sources Members of the Public Private Sector
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 3356. OMB No. 0910-0543. Expires 02/28/2026
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.	The reporting official is the person appointed by the owner or operator to register the form and answer all the correspondence and inquiries relative thereto. The United States Agent is a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. Reporting is required, but any person can serve as the industry member's Reporting Official or United States Agent, and reporting is not "mandatory" as that term is used by the Privacy Act. Individuals are not allowed to opt-out of the collection of name and address. This information is specified in the regulation. This information is used to contact people to clarify data associated with their registration.
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 a major change in the collection and use or sharing of PII data for this application occurs, users will be notified via individual e-mail notification or in updated notice statements on submission forms and Federal Register publications. 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.	FDA personnel who suspect their PII maintained by or on behalf of the FDA has been inappropriately obtained, used or disclosed have several avenues available to resolve the situation. Employees can work with their supervisors, the FDA Privacy Office, the Employee Resource and Information Center (ERIC), FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC), and other channels. Contact information for these offices and resources are available across FDA's internet and intranet pages. External individuals who suspect their PII maintained by or on behalf of the FDA has been inappropriately obtained, used or disclosed have several avenues available to resolve the situation. These individuals may contact the office or division where they have determined that their information is held. They may contact the FDA Privacy Office via email address provided on FDA.gov. FDA personnel are required to rapidly report any suspected or confirmed incidents or breaches to the FDA CIOCC. Contractors are required to safeguard all information and to report potential data breaches to the FDA.
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.	Submitter's PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Integrity and availability are protected by security controls selected and implemented during providing the system with an authorization to operate (ATO). Controls are selected based on National Institute of Standards and Technology (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. CBER 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. Data discrepancies identified during system use are addressed when discovered.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators 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 - Industry submitters have access to the PII for submissions they make. FDA users will have access to PII to review and manage the registrations received from product manufacturers. Note that "FDA users" may include subject individuals, supervisors, or business function administrators. Administrators - Business administrators may have access to PII to conduct business functions. System administrators may have access to PII to support system administration activities. Developers - Developers may have access to PII to maintain the system and provide technical assistance to users. Contractors - Some developers and system administrators may be Direct Contractors and will have access under the same circumstances as developers.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FDA users who maintain the applications need to have supervisor approval before access is granted. The user's supervisor will use an account creation form to specify the minimum application access that is required in order for the user to complete his/her job. The agency reviews the access list for the application on a quarterly basis to review and adjust users' access permissions, and to remove unnecessary accounts from the application.
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.	Before granting access, supervisors determine the minimum application access that is required in order for the user to complete his/her job.
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 Digital Transformation (ODT) 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.	Help links are available within applications, and instructional materials are available on the FDA intranet for all applications. All users are instructed on adhering to the Department of Health and Human Services (HHS) Rules of Behavior in the context of their work involving this system. For additional privacy guidance, personnel may contact the Agency's privacy office. Privacy program materials are provided to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.
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).	DAA-GRS-2013-0001-0004-Temporary-Destroy 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.	There are several controls in place for the securing of PII within the system. 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. 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:**	8/21/2025
Privacy Analyst Review Comments:	This PIA was externally approved on 2/26/2025. The approved copy is attached.	**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	8/21/2025
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:**	8/22/2025
Agency Privacy Analyst Review Comments:	Reviewer: Crystal Bland 8/22/2025 Comment has been address this PIA is ready for SAOP review and approval. 8/21/2025 Please see comment and update accordingly. PIA-22: Per PTA-5, "Phone Numbers (Business)" should be marked instead of Phone Numbers (Personal).	**# of Days - APA Review:**	1

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	8/29/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	7

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/29/2025 1:37 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	BLAND, CRYSTAL	8/13/2025	8/13/2025 Per FDA's Emails: This PIA was SAOP approved on 2/26/2025 but needed to be entered in Archer 4.0 because of a sync issue.	8-13-2025 EMAIL_PIA in Queue (CBER Electronic Human Cell and Tissue Establishment Registration System).pdf CBER Electronic Human Cell and Tissue Establishment Registration System_8.12.2025.pdf CBER Electronic Human Cell and Tissue Establishment Registration System_SAOP Approved 2.26.2025.rtf
PIA 22	BLAND, CRYSTAL	8/21/2025	Per PTA-5, "Phone Numbers (Business)" should be marked instead of Phone Numbers (Personal).	