PTA / PIA: FDA - BLT - QTR1 - 2026 - FDA5125605

Created Date: 1/9/2026 3:25 PM Last Updated: 1/23/2026 3:37 PM

General Information

PTA / PIA Name:	FDA - BLT - QTR1 - 2026 - FDA5125605	**PTA / PIA ID:**	4181957
Component Name:	FDA - CBER Blood Logging and Tracking	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	14
Submitter:		**Submit Date:**	1/9/2026
Next Assessment Date:	01/22/2029	**Expiration Date:**	1/22/2029
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.	8/3/2025
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.	The Food and Drug Administration (FDA) has made no changes to this system/component since the last Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) 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.	The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) regulate biological products, including blood and blood products, blood derivatives, cellular therapies, and human cells and tissue products. CBER has multiple applications in place designed and used for administrative reporting purposes in promoting and enhancing public health. The subject of this assessment is the CBER Blood Logging and Tracking (BLT) application which is a component of the CBER Office of Regulatory Operations (ORO) system boundary. The CBER BLT system is used to maintain information related to the status and review progress of submissions for the approval of devices and products related to blood handling, known as 510(k) applications (a“510(k)” submission is a premarket submission to FDA to demonstrate that the device to be marketed is, substantially equivalent to (at least as safe and effective) a legally marketed device that is not subject to a pre-market approval, which requires submitters to compare their device to one or more similar legally marketed devices to support their substantial equivalency claims. CBER BLT does not collect personally identifiable information (PII) about FDA employees or any contractors, sponsors, or holders (submitters) but may maintain PII of patients or subjects that have taken part in a clinical trial (e.g., an adverse event report may be submitted with PII such as individuals date of birth and contact information). PII may also include professional credentials (e.g., PhD, MD) and business contact information for points of contact at regulated entities.
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 BLT does not collect PII about users of the system (FDA employees, Direct Contractors, sponsors, or holders (submitters)). However, the system may maintain the PII of patients or clinical trial subjects that have voluntarily disclosed this information although not solicited by FDA (e.g., adverse event reporting). This information can include date of birth, name and other contact information such as telephone number, email address and mailing address. PII may also include professional credentials (e.g., PhD, MD) and business contact information for points of contact at regulated entities such as business telephone number, business email address and business address. Filings handled in this system consists of submissions seeking various FDA approvals. An Investigational New Drug Application (IND) is a

request for FDA to permit the applicant to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application (NDA) or Biologics/Product License Application (BLA). An investigational device exemption (IDE) allows the investigational device to be used in a clinical study to collect safety and effectiveness data. A “510(k)” submission is a premarket submission to FDA to demonstrate that the device to be marketed is substantially equivalent to (at least as safe and effective) a legally marketed device that is not subject to a pre-market approval, which requires submitters to compare their device to one or more similar legally marketed devices to support their substantial equivalency claims. A drug/device master file (DMF) is a confidential, detailed document submitted to the FDA by Active Pharmaceutical Ingredient (API) manufacturers. A DMF contains the chemistry, manufacturing, and controls of a drug component or the product (e.g., ingredient, subassembly, or accessory) or facility in the manufacture of the device. The information in a DMF may be used to support other submissions such as an IND or NDA.

Another type of submission is a request for an Emergency Use Authorization (EUA). Per the FD&C Act, FDA strives to protect against chemical, biological, or radiological/nuclear agent (CBRN) threats by facilitating the availability and use of Medical Countermeasures (MCMs) during public health emergencies. By law, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

A “Blood Variance Request” is a petition for exemption from requirements (methods, facilities, controls) proposed for the manufacture, packing, storage, and use of a blood product, to ensure the product will be safe and effective for public consumption; a Blood Donor Requalification is a request to allow a previously deferred donor to donate blood if the donor meets the eligibility criteria. The request is submitted to the FDA for approval along with supporting documents and test results.

All data collected in the ORO System is provided to users "as-is" in that it shares information that it has received from other source systems but does not create or modify any data it contains. Information about the users themselves (the medical reviewers, systems administrators) are managed through network access protocols and all have FDA system access credentials. All users are

		authorized FDA network users and access to the system is granted through the CBER Menu application (the subject of a separate assessment) employing FDA's Single Sign-On authentication process. Users of the system are either FDA employees or 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.	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.	CBER BLT does not collect PII about FDA employees, Direct Contractors, sponsors, or holders (submitters). CBER BLT may maintain PII of patients or clinical trial subjects that have voluntarily provided PII not solicited by FDA (e.g., when submitting an adverse event report). This information can include date of birth, name and contact information. PII may also include professional credentials (e.g., PhD, MD) and business contact information for points of contact at regulated entities. All data collected in the ORO System is provided to users "as-is" in that it shares information that it has received from other source systems but does not create or modify any data it contains. Information about the users themselves (the medical reviewers, systems administrators) are managed through network access protocols and all have FDA system access credentials. All users are authorized FDA network users and access to the system is granted through the CBER Menu application (the subject of a separate assessment) employing FDA's Single Sign-On authentication process. Users of the system are either FDA employees or Direct Contractors with FDA badges and smart cards. Filings handled in this system consists of submissions seeking various FDA approvals, including INDs, NDAs, BLAs, IDEs, 510(k), DMFs, EUAs, Blood Variance Requests, and Blood Donor Requalification.
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).	http://cberforms.fda.gov/forms/cber_images/cbermenu.html
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No
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.	CBER BLT provides electronic bridges to existing databases and documents. Users of CBER BLT (FDA employees and Direct Contractors) access the web site via an internal uniform resource locator (URL) and FDA's Single Sign-On authentication process.

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 Date of Birth Contact Information Email Address (Personal) Mailing Address (Personal) Phone Numbers (Personal) Email Address (Business) Mailing Address (Business) Phone Numbers (Business) Other Other
PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Fax number Professional credentials (e.g., PhD, MD)
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors Patients 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?	Data collected by this system is used for scheduling meetings, tracking contacts and subjects, reporting safety progress, tracking submission receipt, tracking quality control and workflow.
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 governing information use and disclosure include Title 21 Code of Federal Regulations (CFR) part 312; Title 21CFR part 812; Title 21CFR parts 814.3 & 314.420; Title 21 sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended and added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA); Title 21 CFR parts 600-680; Title 21 CFR parts 640.120; and 5 U.S.C. 301.
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.	Government Sources Within the OPDIV 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).	OMB Information Collection Approval Number: 0910-0338 Expiration Date: 10/31/2026 OMB Information Collection Approval Number: 0910-0543 Expiration Date: 08/31/2026 OMB Information Collection Approval Number: 0910-0458 Expiration Date: 02/28/2026 OMB Information Collection Approval Number: 0910-0308 Expiration Date: 09/30/2027
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.	There is no method for employees to opt-out of submitting their PII. Permanent FDA employees, Direct Contractors, and other personnel must provide their PII in order for the Agency to process administrative materials and securely administer access to Agency information and property. External individuals submitting comments to the Federal Register are not mandated to submit any PII. External individual (non-employees) submitters were notified on forms they submitted (no longer in use), in Federal Register publications (e.g., comment submission guidance and SORNs), privacy statements on the FDA.gov and in other resources provided on FDA.gov. FDA's Federal Register notices inform individuals of the procedures for commenting on a notice and advise that submitted comments may be made public.
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, use or sharing of PII data for this application occurs, users will be notified via individual e-mail notification, FDA wide e-mail and/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 is available across FDA's internet and intranet pages. Any changes to an individual's name or address would need to be updated using a Standard Form 50 or 52, 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. 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 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.	Patient 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. FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. 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 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-require access to the system in order to track and monitor submissions for regulatory approval. Note that "users" may include subject individuals, supervisors, or business function administrators. Administrators- May be application administrators who require access to conduct business functions, or application administrators who require access to create and manage user accounts for specific applications. Developers-will not normally have access to PII but may in the course of maintaining the systems or providing technical assistance. Contractors - Some developers 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 and Direct Contractors who require access to the application need to have supervisor approval and sign off 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.	All users including administrators, developers, and Direct Contractors are granted only the minimal privileges that they require to do their job. The users' supervisor indicates on the account creation form the minimum system access that is required. All users are FDA network users and must have a current Personal Identity Verification (PIV) compliant badge.

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 must complete 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 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).	All Adverse Event files are temporary, and destroyed according to the instructions cited in the following records schedules: FDA 5, Adverse Event/Experience and Product Defect Reports; 5.1, Adverse Event Reports Management Files; 5.2, Adverse Event Reports or Forms; 5.3, Adverse Event Reporting Systems; 5.3.2, AERS Database Records; 5.3.3, Extracts of the Adverse Event Data for Public Access: Output Records, General Records Schedule (GRS) 5.1, Item, 020, Non-recordkeeping copies of electronic records. Disposition: TEMPORARY. Destroy immediately after copying to a recordkeeping system, though longer retention is allowed if needed for business use. GRS 5.2, Transitory and Intermediary Records, Items 010 & 020. Disposition: TEMPORARY. Destroy when are no longer needed for business use. CBER Records Control Schedule DAA-0088-2017-0004, Item 15, Post-marketing safety summaries are PERMANENT. These records are to be transferred to the National Archives. DAA-0088-2017-0004, Item 16, Post-marketing surveillance and lot analysis reports are Temporary. Destroy 15 years after the date of the report. Adverse Drug Experience Records (Industry): Must be maintained for 10 years per 21 CFR 310.305. Post-Market Reports (Tobacco): Must be retained for at least 4 years from submission or until FDA inspection. CBER Specific (B-34/B-35): Retired to the Washington National Records Center 3 years after cutoff; destroyed 20 years after cutoff.
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 NIST Special Publication 800-53, as determined using FIPS199.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	1/9/2026
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	1/9/2026
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:**	1/13/2026
Agency Privacy Analyst Review Comments:	Reviewer: Godisgreat Peters 1/13/2026 One minor comment to spell out an acronym that can be updated during the 508 process. This PIA is ready for SAOP review and approval. update during 508 process PTA-5: FD&C Act (Federal Food, Drug, and Cosmetic Act)	**# of Days - APA Review:**	4

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	1/23/2026
SAOP Review Comments:		**# of Days - SAOP Review:**	10

SAOP Signature

Date	User	Type	Name	Original Value	New Value
1/23/2026 12:39 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	1/12/2026	1-12-2026 Per FDA Email: Note the Archer error associated with question General 03: “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” o The FDA instance of Archer is automatically entering the answer “No” which is incorrect. o At this time, we are unable to update Archer to reflect the correct answer “Yes.” The ATO date is *8/3/2025*. The FDA Archer Team is aware of this occurrence and is working on a solution.	FDA5125605 CBER Blood Logging and Tracking_SOP Approved_1-9-2026.pdf 1-9-2026 EMAIL_PIA in Queue (CBER Blood Logging and Tracking) _FDA5125605.pdf
PTA 04	PETERS, GODISGREAT	1/12/2026		
PTA 05	PETERS, GODISGREAT	1/12/2026	Please spell out FD&C at for use instance	
PTA 06	PETERS, GODISGREAT	1/12/2026	Please remove all syntax in response.	
PTA 08A	PETERS, GODISGREAT	1/12/2026	URL not working. Please provide the right URL.	
PIA 22A	PETERS, GODISGREAT	1/12/2026	Please remove all syntax from response.	
PIA 31A	PETERS, GODISGREAT	1/12/2026	Please remove all syntax from response.	
PIA 34	PETERS, GODISGREAT	1/12/2026	Please remove all syntax from response.	
PTA 06	BLAND, CRYSTAL	1/13/2026	Disregard the previous comment.	
PTA 08A	BLAND, CRYSTAL	1/13/2026	Please disregard previous comment.	
PIA 22A	BLAND, CRYSTAL	1/13/2026	Please disregard the previous comment.	
PIA 31A	BLAND, CRYSTAL	1/13/2026	Please disregard previous comment.	
PIA 34	BLAND, CRYSTAL	1/13/2026	Please disregard the previous comment.	
PTA 05	BLAND, CRYSTAL	1/13/2026	FD&C Act (Federal Food, Drug, and Cosmetic Act)	