PTA / PIA: FDA - ELIST - QTR3 - 2025 - FDA4950317

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General Information

PTA / PIA Name:	FDA - ELIST - QTR3 - 2025 - FDA4950317	**PTA / PIA ID:**	3690627
Component Name:	FDA - CDER Electronic Listing System	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	11
Submitter:		**Submit Date:**	8/21/2025
Next Assessment Date:	08/28/2028	**Expiration Date:**	8/28/2028
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?	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.	1/31/2023
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	Andriy Chut
PTA 01A:	POC Title and Organization	IT Specialist, Office of Digital Transformation
PTA 01B:	POC Email Address	andriy.chut@fda.hhs.gov
PTA 01C:	POC Phone Number	240-338-7846
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 since the last Privacy Threshold Analysis/Privacy Impact Assessment 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's (FDA's) Center for Drug Evaluation and Research (CDER) Electronic Listing System (CDER eList) supports the Food and Drug Administration (FDA's) over-arching mission to safeguard and promote the health of the public. eList interfaces with internal FDA systems (e.g., CBER Regulatory Management; Document Archiving, Reporting, and Regulatory Tracking; Drug Quality and Compliance; and FAERS/FAERS II- all separately assessed), as well as external systems (e.g., Dun and Bradstreet; National Library of Medicine; and Electronic Submissions Gateway) for submission validation and distribution. The system provides a validation engine for private industry electronic submission of product listing and registration data using a Structured Product Labeling (SPL) format. It also enables the FDA to review labeling submissions and generate up-to-date SPL format labeling for all drug products marketed in the United States. With these tools FDA maintains timely and accurate product information that can be provided to the public and prevent medication errors. eList distributes the valid SPL submissions to FDA internal Center application systems to support further business functions, as well as to external Federal Agencies for data exchange and/or drug information publishing. Additionally, CDER eList also validates, accepts, and stores in SPL format annual submissions regarding Warehouse Drug Distributor (WDD) licenses and Third-Party Logistics (3PL) licenses to support the tracking and tracing of the drug supply chain. CDER eList also processes and distributes indexing/dictionary type of data associated with the drug in SPL format for inter-agency information exchange. Users of CDER eList include FDA permanent employees and Direct Contractors. Users have the option to access the system using the FDA single sign-on (SSO) authentication process. Administrators and/or Developers can access the system using username and password. High-level administrators including database administrators (DBA) and System Owner(s) have access to usernames, but not passwords.

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.	The CDER eList system serves as a central holding place for product registration and listing data. It provides a means to validate, process, and distribute industry electronic submissions made pursuant to the FDA post market drug registration regulation. Submissions are in eXtensible Markup Language (XML) format following Structured Product Listing XML schema (based on Health Level 7 ("HL-7") data standards which are becoming a healthcare standard). eList collects and maintains the following personally identifiable information (PII) about FDA permanent employees and Direct Contractors: (a) name; (b) business email address; (c) business telephone number; and (d) user credentials. Database usernames and passwords for privileged application user authentication and authorization are for FDA employees and Direct Contractors serving in Administrator and Developer roles. The user account information is only accessible by Database Administrators and application system owners. The eList system also maintains the following PII for company and/or manufacturer point of contacts (POCS): (a) name; (b) business mailing address; (c) business telephone number; and (d) business email address. Non-PII related data maintained by the system includes: (a) company name and address; (b) drug listing information (including drug ingredients); (c) drug packaging information; and (d) drug use labeling information. SPL file information contains the following medication and registration information: (a) medication direction for use (dosing recommendations, monitoring use, indications, clinical effects (e.g. drug interactions and adverse events); (b) description of the medication (names of medication, ingredients, strength, appearance, dosage form); (c) medication manufacturing (name of manufacturer, manufacturing operations, package type, quantity); (d) registrant and/or manufacturers' DUNS number (possible PII when combined with other unique personal identifiers); (e) Facilities Establishment Identifier (FEI) number ((possible PII when combined with other unique personal identifiers); and, (f) Drug/Device/Cosmetics listing information, i.e., product ingredients, packaging, and usage.
PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS/OpDiv PIV Card HHS Username Password

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.	FDA uses the information gathered in eList to validate drug, manufacturer, and labeling information and to publish publicly accessible drug label information. Likewise, in support of their joint public health mission, FDA collaborates with the National Institutes of Health (NIH) National Library of Medicine (NLM) in a collaborative drug product imaging project using drug product data in eList (drug product imaging information generated by this project is housed in NIH systems and not in eList or any other FDA system). The FDA also has a separate Electronic Drug Registration and Listing System (eDRLS) that interfaces with eList to receive, process, store, retrieve, and internally share product labeling and submissions data for all drug-related entities. FDA addresses eDRLS in a separate privacy impact assessment (PIA). Access to the system is via the FDA intranet only and it is not accessible by the general public. eList receives, validates, and processes Drug Pharmacological Classification SPL submissions, Drug Billing Unit SPL submissions, Substance SPL submissions, drug manufacturers' annual registration SPL submissions, drug labeler registration SPL submissions, and product Listing SPL submissions (for drugs, medical devices, and cosmetics). These submissions come from other FDA systems that are used for submission purposes (e.g., FDA's ESG and Direct systems). Source system are individually assessed and have their own dedicated PIAs. In the future, FDA plans to use the eList to receive, validate, and process additional types of submissions following Health Level Seven (HL 7) standard in Structured Product Label (SPL) message format. Submission of the product, labeling and related industry point of contact information (organization/manufacturer mailing address and telephone number) in eList is mandatory. FDA does not disclose the point of contact information to the public. System users and administrators do not use name or other PII to retrieve records stored in eList. Records would only ever be retrieved using other primary indexes, such as the SPL Product ID of the drug manufacturing entity to review submissions.
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).	Internal use only: https://elist.fda.gov
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.	The purpose of the CDER eList website is to provide internal users of the system with the capability to run web-based data search/reports to provide the most up-to-date information to the FDA user community to prevent medication errors. FDA personnel access the website via an internal only uniform resource locator (URL).
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.	Identifying Numbers DUNS Biographical Information Name User Credentials Contact Information 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.	Other: Both DUNS and FEI are identifiers for manufacturers. Username and password. All contact information is professional contact information only.
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?	The primary purpose of FDA’s use of the PII in eList is to facilitate pharmaceutical industry submission, FDA processing of information, and related communications between pharmaceutical industry and FDA.

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.	Federal Food, Drug and Cosmetic Act; 21 U.S.C. Sections 360(b)-(f) (i), (p); 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.	Directly from an individual about whom the information pertains Online Government Sources Within the OPDIV Non-Government Sources 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 No. 0910-0045 Expiration Date: 07/31/2028
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	Yes
PIA 32A:	Identify with whom the PII is shared or disclosed.	Within HHS
PIA 32B:	For each disclosure, name the organizations/systems the system shares PII with and the purpose(s) of the disclosure.	ystem information is not shared outside HHS. Information is shared within FDA and with the National Institutes of Health (NIH) National Library of Medicine (NLM). Information is shared with FDA staff who play a role in registration, listing and inspection. Industry POC information is not shared outside of the FDA.
PIA 32C:	List any agreements in place that authorize the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	FDA has a Memorandum of Understanding (MOU) with NIH NLM governing the disclosure of information for the purposes of the agencies' collaborative project.
PIA 32D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	There is currently no process in place as sharing is authorized by terms of a MOU which includes permissible uses.
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.	FDA personnel and Direct Contractors are notified at the time of hire of the Agency's necessary collection and use of PII about them for authorized FDA purposes. Individuals may opt-out of the use of their PII but they will not be able to access and use the eList system.

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.	Should FDA's use of PII in the system change, the Agency will employ measures to provide any required notice and obtain consent from individuals regarding the collection and use of PII. This may include email or paper notice to individuals and adding or updating online notices and guidance materials.
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 employees may contact a system administrator or the Employee Resource and Information Center (ERIC). Additionally, employees may work with their supervisors, the Privacy Office, and FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). External individuals may contact the FDA Privacy Office, or their FDA point of contact or general points of informational contact at the FDA. Contact information for these offices and resources is available across FDA's internet and intranet pages. All personnel are required to report suspected instances of PII compromise or misuse to FDA's CIOCC.

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.	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. Relevancy is supported by design of system and related processes to solicit or collect only the PII necessary for the system's purpose and supporting functionality. Access is granted and restricted at the individual level as appropriate to the individual's duties (rolebased access). Integrity and availability are protected by privacy and 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 concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199. FDA's Office of Information Management and Technology (OIMT) 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 in the course of 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: Receive and review submissions. Administrators: Monitor the system, control system access and manage users. Developers: Maintaining & troubleshooting the system. Contractors: System maintenance. Developers are Direct Contractors.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Users who require access to the information system need to have supervisor approval and sign off before access is granted. A User Access Request form is sent to a System Administrator, who reviews the application and provides access if appropriate and maintains a record of those who have been granted 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.	The user's supervisor will 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 is also reviewed twice a year at which time users' access permissions are reviewed and adjusted or removed for lack of system use. Unneeded accounts are purged from the system. Users who require access to confidential data in the eList system must obtain specific permission from the system owner. The system owner determines the necessary level of access that will be granted to each user. Different levels of access include access to information submitted by manufacturers including confidential data, specific reports for a specific user group. The business owner has the permission to submit the submission for validation rule override.
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 FDA system users complete mandatory annual security and privacy awareness training. This training includes federal laws, policies and regulations relating to privacy and data confidentiality, integrity and availability, as well as the handling of data. FDA's Office of Information Management Technology (OIMT) verifies that training has been successfully completed.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	No additional specific security/privacy-oriented training is provided. 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. Users may also obtain additional privacy guidance from FDA's Privacy Office.
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).	System information is retained/destroyed under: FDA File Code 7210 (Registration and Listing Systems) and the National Archives and Records Administration (NARA) approved citation N1-88-07-2; Code 7221 (Input Records) and Code 7222 (Database Records) and the related NARA approved citation N1-88-07-2. Temporary. Records are retained for ten years after the relevant firm goes out of business or the relevant product is no longer marketed or for as long as necessary for legal, research, historical or reference purposes.

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.	Administrative safeguards include user training, system documentation that advises on proper use, implementation of Need to Know and Minimum Necessary principles when awarding access and others. Technical safeguards include use of multi-factor access authentication, firewalls, encryption, network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, key cards, cipher locks, and climate controls. Other appropriate controls have been selected from NIST's Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199. The Rules of Behavior for using FDA systems are clarified and mandated to the user by the HHS guidelines and security documentation. Users agree to abided by these rules when receiving access to FDA system and upon passing a background clearance check.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	8/21/2025
Privacy Analyst Review Comments:	The PIA is experiencing an Archer error with question General 03: “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. The ATO date is 1/31/2023. At this time, we are unable to update Archer to reflect the correct answer “Yes.”	**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	8/22/2025
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:**	1

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	8/29/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 8/29/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	7

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	8/29/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/29/2025 1:43 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	8/22/2025	8/22/2025 Per FDA's 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 1/31/2023. The FDA Archer Team is aware of this occurrence and is working on a solution.	8-22-2025 EMAIL_PIA in Queue-CDER Electronic Listing System (eList)_FDA 4950317.pdf CDER eList PIA SOP Approved 8.23.25 DN.pdf