

**General Information**

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| <b>PTA / PIA Name:</b>                | FDA - IFTRACK II - QTR3 - 2026 - FDA5271910                                         | <b>PTA / PIA ID:</b>      | 4620306                                               |
| <b>Component Name:</b>                | FDA - HFP Infant Formula Tracking System II                                         | <b>ATO Boundary Name:</b> | CFSAN Food Safety & Nutrition Submission Applications |
| <b>Overall Status:</b>                | SAOP Review                                                                         | <b># of Days - Open:</b>  | 19                                                    |
| <b>Submitter:</b>                     |                                                                                     | <b>Submit Date:</b>       | 7/1/2026                                              |
| <b>Next Assessment Date:</b>          | N/A                                                                                 | <b>Expiration Date:</b>   |                                                       |
| <b>Office:</b>                        |                                                                                     | <b>OpDiv:</b>             | FDA                                                   |
| <b>Security Categorization:</b>       | Moderate                                                                            |                           |                                                       |
| <b>Make PIA available to Public?:</b> | Yes                                                                                 | <b>PIA Required:</b>      | Yes                                                   |
| <b>General 01:</b>                    | Identify the Enterprise Performance Lifecycle Phase of the system.                  |                           | Operations and Maintenance                            |
| <b>General 02:</b>                    | Is this a FISMA-Reportable system?                                                  |                           | Yes                                                   |
| <b>General 03:</b>                    | Does the system have or is it covered by a Security Authorization to Operate (ATO)? |                           | No                                                    |
| <b>General 04:</b>                    | ATO Date or Planned ATO Date.                                                       |                           | 12/19/2025                                            |
| <b>General 05:</b>                    | Is the system or electronic information collection, agency or contractor operated?  |                           | Agency                                                |
| <b>History Log:</b>                   | <a href="#">View History Log</a>                                                    |                           |                                                       |

**Privacy Threshold Analysis****Privacy Threshold Analysis**

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| <b>PTA 01:</b>  | Point of Contact (POC) Name                                                       | Kristine Mantaring                                                                      |
| <b>PTA 01A:</b> | POC Title and Organization                                                        | Consumer Safety Officer/Infant Formula Premarket Review Staff<br><br>HFP/NCE/OCF/IFPMRS |
| <b>PTA 01B:</b> | POC Email Address                                                                 | Kristine.Mantaring@fda.hhs.gov                                                          |
| <b>PTA 01C:</b> | POC Phone Number                                                                  | 240-402-1450                                                                            |
| <b>PTA 02:</b>  | Indicate the following reason(s) for this PTA. Choose from the following options. | PIA Validation (PIA Refresh)                                                            |

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| PTA 02A: | Describe in further detail any changes to the system that have occurred since the last PIA.                                                                                    | Since the last Privacy Impact Assessment (PIA), the team has focused on enhancing the capabilities around the integration between the Human Foods Program (HFP) Infant Formula Tracking System II (IFTRACK II) and Food Applications Regulatory Management (FARM). Significant improvements to the user interface within Appian have also been made. No changes to the amount nor usage of sensitive data have been changed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 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. | <p>The Human Foods Program (HFP) Infant Formula Tracking System (IFTRACK II) is a secure, web-based application used by the Food and Drug Administration (FDA) to manage and support the regulatory review of infant formula submissions from manufacturers. IFTRACK II replaced the legacy IFTRACK system and serves as the central electronic platform for tracking and maintaining records associated with infant formula regulatory submissions.</p> <p>This system is used primarily by the FDA's HFP and Office of Nutrition and Food Labeling (ONFL). Within ONFL, the Infant Formula and Medical Foods Staff (IFMFS) are primary users of the system. IFMFS is responsible for regulating infant formula and reviewing submissions and notifications from manufacturers of new or modified infant formula products submitted under Section 412 of the Federal Food, Drug, and Cosmetic Act. The FDA is required to review and respond to these submissions within 90 calendar days.</p> <p>IFTRACK II supports the collection, storage, and management of manufacturer submission data, including product formulation, labeling, manufacturing information, and supporting documentation. The system enables FDA reviewers to conduct scientific and regulatory assessments, track submission status, collaborate internally, and communicate with submitters during the review process.</p> <p>Additionally, IFTRACK II provides a centralized repository for all infant formula submissions, responses, and related review records. The system maintains historical records of submissions, regulatory decisions, and communications, allowing FDA staff to access past reviews, policy interpretations, and product histories to support consistent and efficient regulatory oversight.</p> |

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| <p><b>PTA 05:</b></p>  | <p>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.</p> | <p>IFTRACK II collects and maintains infant formula submission information from manufacturers. Submissions include the product name, manufacturer's name and addresses of all manufacturing locations, complete quantitative formulations, descriptions of reformulations or processing changes with rationale, medical conditions associated with the formula, ingredient and labeling information, and exemption requests with supporting justification.</p> <p>The system also maintains submission review data produced during the FDA review process, including review reports from FDA reviewer groups, consultants, and Consumer Safety Officers (CSOs), Team Lead comments, internal and external communications, interim and final memoranda, and signed CSO letters. The HFP Infant Formula and Medical Foods Staff (IFMFS) serves as the primary reviewer group responsible for regulatory oversight of infant formula submissions.</p> <p>Internal FDA users' access IFTRACK II through secure single sign-on (SSO) with multi-factor authentication. The system collects and maintains personally identifiable information (PII), including (a) industry manufacturer and external user login credentials(i.e., username, password), (b) manufacturer points of contact, including work-related first and last names, email addresses (business), phone numbers (business), and mailing addresses (business), and (c) FDA internal users' email address. External users receive a username and temporary password upon registration and must meet FDA security requirements by updating the password at initial login and every 60 days. PII is not shared with any other system or organization.</p> <p>IFTRACK II also maintains non-PII data, including (a) new or modified infant formula information submitted for FDA review, such as manufacturer, product, formulation, ingredient, labeling, nutritional, packaging, and processing information, (b) FDA reviewer comments and questions to manufacturers, including the non-PII content of final letters, and (c) submission status and tracking information. All information is retained according to FDA records management policies and applicable federal retention schedules.</p> |
| <p><b>PTA 05A:</b></p> | <p>Are user credentials used to access the system?</p>                                                                                                                                                      | <p>Yes</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>PTA 05B:</b></p> | <p>Please identify the type of user credentials used to access the system.</p>                                                                                                                              | <p>HHS User Credentials</p> <p>HHS/OpDiv PIV Card</p> <p>Non-HHS User Credentials</p> <p>Username</p> <p>Password</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

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| <p><b>PTA 06:</b></p>  | <p>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.</p> | <p>IFTRACK II collects and maintains multiple types of information to support the FDA's regulatory oversight of infant formula and to fulfill the HHS mission of protecting public health. Each type of information serves specific purposes:</p> <p>Submission Data: Includes product name, manufacturer name and addresses of manufacturing locations, complete formulations, descriptions of reformulations or processing changes with rationale, medical conditions associated with the formula, ingredient and labeling information, and exemption requests. These data are collected and maintained to enable accurate scientific and regulatory reviews, assess safety and nutritional adequacy, ensure regulatory compliance, and maintain a complete record of all submissions. Submission data may be shared internally within FDA systems to support review coordination and reporting.</p> <p>Review Data: Includes submission review reports, reviewer comments, Team Lead notes, internal and external communications, memoranda, and signed letters. Maintaining these data ensures thorough, consistent, and auditable review processes, facilitates collaboration among FDA reviewer groups, and preserves a historical record of regulatory decisions. Sharing is limited to internal FDA systems as necessary for regulatory functions.</p> <p>PII is collected for two groups: (a) External users (manufacturer representatives): login credentials and professional contact information including work-related name, email, phone, and mailing address, used to authenticate users, manage secure access, and communicate about submissions; (b) Internal user (FDA employees and HHS/Direct Contractors): work email addresses, used for authentication, internal communication, and review tracking. PII is strictly professional/work-related and not shared externally.</p> <p>Non-PII Data: Includes submission content, reviewer comments (non-PII portions), and submission status. These data support tracking, compliance monitoring, and historical reference and may be shared only within FDA as needed.</p> <p>All data are retained per FDA record management policies and applicable federal retention schedules to ensure regulatory compliance.</p> |
| <p><b>PTA 07:</b></p>  | <p>Does the system collect, maintain, use, or share PII?</p>                                                                                                                 | <p>Yes</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <p><b>PTA 08:</b></p>  | <p>Does the system include a website or online application?</p>                                                                                                              | <p>Yes</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <p><b>PTA 08A:</b></p> | <p>Provide the URL(s).</p>                                                                                                                                                   | <p><a href="https://hfp-bpm.fda.gov/suite/tempo/">https://hfp-bpm.fda.gov/suite/tempo/</a></p> <p><a href="https://hfp-bpm.fda.gov/suite/sites/manufacturer-home">https://hfp-bpm.fda.gov/suite/sites/manufacturer-home</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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| <b>PTA 08B:</b> | Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?                                                       | Yes                                                                                                                                                                                                                                                                                                                                                                         |
| <b>PTA 09:</b>  | 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. | This website allows infant formula manufacturers (external users) to submit new or updated infant formula submissions to FDA/HFP for review and approval. The IFTRACK II System Administrator provides the authorized external user a username and password when they register to make submissions. The external users must log in using their valid username and password. |
| <b>PTA 10:</b>  | Does the website have a posted privacy notice?                                                                                                                             | Yes                                                                                                                                                                                                                                                                                                                                                                         |
| <b>PTA 11:</b>  | Does the website contain links to non-federal government websites external to HHS?                                                                                         | No                                                                                                                                                                                                                                                                                                                                                                          |
| <b>PTA 12:</b>  | Does the website use web measurement and customization technology?                                                                                                         | Yes                                                                                                                                                                                                                                                                                                                                                                         |
| <b>PTA 12A:</b> | Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.                                                          | Session Cookies- Does Not Collect PII<br>Persistent Cookies- Does Not Collect PII                                                                                                                                                                                                                                                                                           |
| <b>PTA 13:</b>  | Does the website have any information or pages directed at children under the age of thirteen?                                                                             | No                                                                                                                                                                                                                                                                                                                                                                          |
| <b>PTA 14:</b>  | Does the system have a mobile application?                                                                                                                                 | No                                                                                                                                                                                                                                                                                                                                                                          |
| <b>PTA 20:</b>  | Are any third-party websites or applications (TPWA) associated with the system?                                                                                            | No                                                                                                                                                                                                                                                                                                                                                                          |
| <b>PTA 21:</b>  | Does this system use artificial intelligence (AI) tools or technologies?                                                                                                   | No                                                                                                                                                                                                                                                                                                                                                                          |

## Privacy Impact Assessment

### Privacy Impact Assessment

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| <b>PIA 22:</b> | Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share. | Biographical Information<br>Name<br>User Credentials<br>Contact Information<br>Email Address (Business)<br>Mailing Address (Business)<br>Phone Numbers (Business)                                      |
| <b>PIA 23:</b> | Indicate the categories of individuals about whom PII is collected, maintained, or shared.                          | Employees/HHS Direct Contractors<br>Members of the public                                                                                                                                              |
| <b>PIA 24:</b> | Indicate the approximate number of individuals whose PII is maintained in the system.                               | 100 – 499                                                                                                                                                                                              |
| <b>PIA 25:</b> | For what primary purpose is the PII used?                                                                           | The FDA uses the PII in the system to administer access and communicate with manufacturers, ask questions regarding their submissions, and respond back with the final FDA response to the submission. |
| <b>PIA 26:</b> | 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.                                                                                                                                                             |

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| <b>PIA 28:</b>  | Identify legal authorities, governing information use and disclosure specific to the system and program.                                                                                                                                                                                                               | Section 412(c)(1) of the Federal Food, Drug, and Cosmetic Act requires persons responsible for the manufacture or distribution of a new infant formula, including infant formula for export only, to register with FDA before a new infant formula may be introduced or delivered for introduction into interstate commerce. The requirements for registration can be found in 21 CFR 106.110 and include: the name of the new infant formula, the name of the manufacturer, the street address of the place of business of the manufacturer, and the name and street address of each establishment at which the manufacturer intends to manufacture the new infant formula. Manufacturers may register at any time before introducing a new formula into interstate commerce. However, FDA requests that they do so while they submit notice of their intent to market a new infant formula in accordance with section 412(c)(1)(B) and (d)(1) of the Act. |
| <b>PIA 29:</b>  | Are records in the system retrieved by one or more PII data elements?                                                                                                                                                                                                                                                  | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>PIA 30:</b>  | Identify the sources of PII in the system.                                                                                                                                                                                                                                                                             | Directly from an individual about whom the information pertains<br><br>Email<br><br>Non-Government Sources<br><br>Private Sector                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>PIA 31:</b>  | Is there an Office of Management and Budget (OMB) information collection approval number?                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>PIA 31A:</b> | Provide the information collection approval number(s) and expiration date(s).                                                                                                                                                                                                                                          | OMB Control No. 0910-0256,10/31/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>PIA 32:</b>  | Is the PII in the system shared directly with other organizations outside the system's Operating Division?                                                                                                                                                                                                             | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>PIA 33:</b>  | Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?                                                                                                                                                                                                                          | Voluntary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>PIA 34:</b>  | 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.                                                                                                                                        | If FDA changes its practices regarding the collection or handling of PII related to the website, 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 email to individuals, adding or updating online notices or forms, or other available means to inform the individual.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>PIA 35:</b>  | 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 the agency changes the collection, use, or sharing of PII data in this system, the affected individuals will be notified by the most efficient and effective means available and appropriate to the specific change(s). This may include a notice on an FDA web site, email notice to the individuals, inclusion in newsletters, or information provided to supervisors with instructions to further inform staff. However, no such changes that would affect the rights or interests of the individuals are anticipated.                                                                                                                                                                                                                                                                                                                                                                                                                                |

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| <b>PIA 36:</b>  | 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.                             | <p>Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have a number of avenues available to resolve the situation. Employees may submit concerns to their supervisor, the FDA Privacy Office, Employee Resource and Information Center (ERIC), and FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC).</p> <p>All FDA personnel are required to immediately report any suspected data breaches and security incidents to CIOCC.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>PIA 37:</b>  | 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. | <p>Individuals voluntarily provide their PII. 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. PII relevancy is supported through the design of the system to require and collect only the PII elements necessary to administer the system and enable its intended use.</p> <p>Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).</p> <p>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 the 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 performs quarterly reviews to evaluate and adjust user access.</p> |
| <b>PIA 38:</b>  | Identify who will have access to the PII in the system.                                                                                                                                                                                                | <p>Users</p> <p>Administrators</p> <p>Developers</p> <p>Contractors</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>PIA 38A:</b> | Select the type of contractor.                                                                                                                                                                                                                         | HHS/OpDiv Direct Contractors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>PIA 38B:</b> | Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?                                                                                                        | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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| <p><b>PIA 39:</b></p> | <p>Provide the reason why each of the groups identified in 38 needs access to PII.</p>                                                                                                                                                                                             | <p>Users: FDA internal reviewers require access to PII to review, verify, and approve submissions. Manufacturers need access to their own PII to submit, update, or track their submissions within the system.</p> <p>Administrators: Administrators access PII for account management purposes.</p> <p>Developers: Developers may have access to PII in the course of updating and maintaining the system. Some of the developers are Direct Contractors.</p> <p>Contractors: Contractors may have access to PII to perform specific support tasks, such as system maintenance. Direct Contractors are the developers of the system.</p>                                                                                      |
| <p><b>PIA 40:</b></p> | <p>Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.</p>                                                                                                                             | <p>All access to the system for users and administrators requires approval prior to the user gaining access. System access requires business owner approval, is reviewed on a quarterly basis to identify and remove unnecessary accounts. Internal users must obtain supervisory confirmation and approval of their need to access the system via the single sign-on/PIV card. Only the System Administrators and FDA internal users have the accesses to the PII. For the manufacturer/external users, the IFTRACK II System Administrator provides the authorized external user a username and password when they register to make submissions. The external users must log in using their valid username and password.</p> |
| <p><b>PIA 41:</b></p> | <p>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.</p>                                                                                                                  | <p>For internal users, the user's supervisor will indicate on the account creation form the minimum information system access that is required for the user to complete his/her job. The access list for the information system is regularly reviewed to adjust users' access permissions and remove unnecessary accounts. For external users, the level of access is uniform; each account holder has access only to the materials they submit and related FDA materials.</p>                                                                                                                                                                                                                                                 |
| <p><b>PIA 42:</b></p> | <p>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.</p> | <p>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.</p>                                                                                                                                                                                                                                                        |

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| <b>PIA 43:</b> | Describe the training system users receive above and beyond general security and privacy awareness training.                                                                                                                | HFP provides internal users with a user security policy and FDA Staff Manual Guide (SMG). For the external users, IFTRACK II Business Owner conducts system-specific training when onboarding the new users. 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.                                                                                                                                                                                                                                        |
| <b>PIA 44:</b> | 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). | PII in IFTRACK is retained according to NARA-approved schedules, with transitory records covered under GRS 5.2, Item 010 (DAA-GRS-2022-0009-0001) and intermediary records under GRS 5.2, Item 020 (DAA-GRS-2022-0009-0002). Records are securely stored during retention and destroyed when no longer needed for business use or after verification that the final record has been created, in accordance with authorized NARA schedules.                                                                                                                                                                                                                                                                                               |
| <b>PIA 45:</b> | Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.                                                                    | <p>Administrative Safeguards include training and awareness provided for all users; system manuals that advise on the systems' proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others.</p> <p>Technical Safeguards include use of multifactor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls.</p> <p>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.</p> |

| Review and Comments                     |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
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| OpDiv Privacy Analyst Review            |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| Privacy Analyst Review Decision:        | Approved  | Privacy Analyst Review Date:                                                                                                                                                                                                                                                                                                                                                                                                          | 7/1/2026  |                |           |
| Privacy Analyst Review Comments:        |           | # of Days - PA Review:                                                                                                                                                                                                                                                                                                                                                                                                                | 0         |                |           |
|                                         |           | Note the Archer error associated 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. At this time, we are unable to update Archer to reflect the correct answer “Yes.” The ATO date is 12/19/2025. The FDA Archer Team is aware of this occurrence and is working on a solution. |           |                |           |
| SOP Review                              |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| SOP Review Decision:                    | Approved  | SOP Review Date:                                                                                                                                                                                                                                                                                                                                                                                                                      | 7/6/2026  |                |           |
| SOP Review Comments:                    |           | # of Days - SOP Review:                                                                                                                                                                                                                                                                                                                                                                                                               | 5         |                |           |
| Agency Privacy Analyst Review           |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| Agency Privacy Analyst Review Decision: | Approved  | Agency Privacy Analyst Review Date:                                                                                                                                                                                                                                                                                                                                                                                                   | 7/20/2026 |                |           |
| Agency Privacy Analyst Review Comments: |           | # of Days - APA Review:                                                                                                                                                                                                                                                                                                                                                                                                               | 14        |                |           |
|                                         |           | Reviewer: Godisgreat Peters<br>7/9/2026 This PIA is ready for SAOP review and approval.                                                                                                                                                                                                                                                                                                                                               |           |                |           |
| SAOP Review                             |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| SAOP Review Decision:                   | Pending   | SAOP Review Date:                                                                                                                                                                                                                                                                                                                                                                                                                     |           |                |           |
| SAOP Review Comments:                   |           | # of Days - SAOP Review:                                                                                                                                                                                                                                                                                                                                                                                                              | 0         |                |           |
| SAOP Signature                          |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| Date                                    | User      | Type                                                                                                                                                                                                                                                                                                                                                                                                                                  | Name      | Original Value | New Value |
| No Records Found                        |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| Supporting Document(s)                  |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| Name                                    |           | Size                                                                                                                                                                                                                                                                                                                                                                                                                                  | Type      | Upload Date    | Downloads |
| No Records Found                        |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| Comments                                |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |
| Question Name                           | Submitter | Date                                                                                                                                                                                                                                                                                                                                                                                                                                  | Comment   | Attachment     |           |
| No Records Found                        |           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                |           |