

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC AIMS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	FDA/OC
3 Title of System or Information Collection:	Agency Information Management System (AIMS)
4 Is this System or Information Collection new or is an existing one being modified?	No Change
5 Unique Project Identifier Number:	009-10-01-10-01-1010-00-404-142
6 System of Records Number:	09-10-0004 (FDA) Communications (Oral & Written) with the Public,
7 OMB Information Collection Approval Number and Expiration Date :	N/A
8 Other Identifying Number(s):	N/A

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC AIMS

- 9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

AIMS provides administrative tracking and electronic storage for several agency functions. The core data within AIMS is pulled from the agency ASAP system for staff, contractor and organizational data required for the applications. The core also contains any information that is shared by two or more of the AIMS modules. The modules are Correspondence (both internal generated and received from external sources), Freedom of Information (FOI), Federal Register (FR), Dockets Management, Advisory Committee, Ethics, Security Clearances and Interagency Consult Reviews. The system also has a records management application for all records tracked in the system. The module for Administrative Tracking and Electronic Document Storage of FOI requests, responses, and related correspondence is authorized by the Freedom of Information Act, (FOIA) 5 U.S.C. 552. The module for Ethics records is authorized by the Ethics in Government Act (PL 95-521) and the Ethics Reform Act of 1989, as amended (PL 101-194). The Civil Service Act authorizes the module for Security Clearances. The Federal Advisory Committee Act authorizes the module for Advisory Committee Records.

- 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

The Correspondence Staff, the Division of FOI and the Division of Dockets Management store names, address and e-mail addresses on individuals who submit correspondence and FOI requests or submit comments on FR published documents. The Correspondence Staff and the Division of FOI use the information to respond to correspondence and FOI requests. The Division of Dockets Management only stores the information with the record. The Ethics Staff tracks the filing status of each FDA employee, notification of filing requirements and receipt of the filing reports. The Security Clearances Staff stores the clearance requirements for both FDA and Contractor staff along with the approval track and renewal requirements. The other modules use FDA staff and contractor information only in the tracking of workflow and approval processes. Information in the FOI Tracking and Document Repository is obtained from letters submitted to the FDA from the public pursuant to the FOIA. The Agency only collects data necessary to identify and correspond with requesters such as requester's name, address, records requested, and records provided to requester. Information is used to process FOIA requests. AIMS uses role based security. Individuals only have access to the data that is required to perform their duties. Modules collect only the data that is required to respond to a request for information or to complete an agency function.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC AIMS

- 11 Explain why the information is being collected.** FDA receives approximately 24,000 FOI request per year. A tracking system is required to monitor the processing of requests. In addition the FOIA and the Ethics in Government Act have annual reporting requirements that are based on information collected in the system. The Security Clearance staff is responsible for maintaining the security levels for all FDA personnel and its contractors and must have a system for tracking security clearances.
- 12 Identify with whom the agency will share the collected information .** The only application that shares data with external sources is Security Clearances. The security clearance process goes through OMB. FOIA module information is shared with agency employees involved in the processing of FOIA requests. Certain information is available to the public as provided by the FOIA.
- 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.** Information is obtained from correspondence submitted by the FOI requesters and individuals that correspond with the agency or comment on a Federal Register notice . FDA's Public Information Regulations at 21 CFR Part 20 inform the public of the procedures for submitting FOI requests. Federal Register notices inform individuals of the procedures for commenting on a notice. In the case of security clearances and ethics, when an individual comes to work at FDA as an employee or contractor they are required to complete forms requesting the information. Forms contain notification statements informing the individuals of the purpose for collecting the information and the authority for collecting the information.
- 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)** No information is collected from children under age 13 on the Internet. With respect to FOIA requests, any individual can file a FOIA request, however, no information is collected on the Internet.
- 15 Describe how the information will be secured.** All data is stored on secure servers within the FDA operating infrastructure. All access is through user names and passwords that follow all HHS and FDA Security guidelines.
- 16 Describe plans for retention and destruction of data collected.** The retention and destruction is based on the NARA approved records retention schedule for each record or document type stored in the system. For the FOIA module, retention and destruction vary depending upon disposition of requests. Data may be retained from two to six years after final disposition of FOI requests and destroyed thereafter.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC AIMS

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| 17 | Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | 09-10-0004 (FDA) Communications (Oral & Written) With the Public 09-90-0058 (HHS) FOI Case Files and Correspondence Control Index OGE-1 (Office of Government Ethics) Financial Disclosure Reports & Other Ethics Programs OGE-2 (Office of Government Ethics) Confidential Statements of Employment & Financial Interest 09-90-0008 Conflict of Interest Records, HHS/OS/ASPER OPM/Central-9 Personnel Investigations Records |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Agency Information Management System (AIMS) |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC CAS

Question:

Response:

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| 1 | Date of this Submission (MM/DD/YYYY): | 2003-11-18 |
| 2 | HHS Agency (OPDIV): | FDA |
| 3 | Title of System or Information Collection: | Central Accounting System (CAS) |
| 4 | Is this System or Information Collection new or is an existing one being modified? | Existing system being maintained in steady state with decommissioning planned for December 2005. |
| 5 | Unique Project Identifier Number: | 009-10-01-01-01-1010-00-402-124 |
| 6 | System of Records Number: | 09-90-0024 |
| 7 | OMB Information Collection Approval Number and Expiration Date : | |
| 8 | Other Identifying Number(s): | |
| 9 | Provide an overview of the system or collection and indicate the legislation authorizing this activity. | The Central Accounting System is FDA's primary internal financial management system. The General Accounting Office certified it on June 27, 1974. It conforms to DHHS standards for accounting systems, including use of uniform transaction codes, account structure, and standardized data fields. CAS administratively controls FDA's spending authority. The system is a core financial system with a General Ledger, Accounts Payable and Accounts Receivable systems. The system produces internal financial reports and supports all external financial reports required by Congress, OMB, and Treasury. |
| 10 | Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort. | The Central Accounting System collects the names of FDA business travelers from another internal FDA system, the Travel Manager system. The information is received daily and enables the processing of obligations against budget authorities. CAS does not perform any other public or internal data collections. |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC CAS

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| 11 Explain why the information is being collected. | CAS collects the last name of the FDA business traveler associated with a travel order for system operation and accounting requirements associated with processing travel orders. |
| 12 Identify with whom the agency will share the collected information | CAS does not execute any further distributions of the collected information. |
| 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | FDA traveler name information is collected from daily travel transaction records from another internal FDA system. |
| 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | Not applicable, access to the FDA Central Accounting System is restricted to pre-authorized federal employees operating within a secure computing environment. |
| 15 Describe how the information will be secured. | The FDA Central Accounting System operates within a secure federal computing environment. Access to system data is restricted to pre-authorized federal employees after validated log on. |
| 16 Describe plans for retention and destruction of data collected. | FDA traveler name information collected by CAS from daily travel transaction records are subject to the financial record retention period of six years and three months. |
| 17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | 09-90-0024 |
| 18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D |
| 20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC ConsInfra

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	FDA
3 Title of System or Information Collection:	FDA Consolidated Infrastructure
4 Is this System or Information Collection new or is an existing one being modified?	New
5 Unique Project Identifier Number:	009-10-01-01-0301-00-404-139
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	FDA is moving towards long-term improvements in the structuring of IT services across centers aimed at facilitating greater integration in the delivery of programs and realizing significant cost savings. Efficiencies will be realized by consolidating the technology infrastructure services and standardizing on how IT service is provided. The consolidated infrastructure is described as local area networks, help desk and call center, email, voice and data services, desktop management and support, database and server management, and Internet/Intranet services.
10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.	FDA is collecting data for administration and e-mail purposes from and for the employees and contractors in the agency. External data is collected through e-mail from the FDA public website. No PII information is requested, but the public user may have chosen to furnish it.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC ConsInfra

- 11 Explain why the information is being collected.** FDA administrative data is used for locating, payroll and day-to-day administration of personnel activities. E-mail data is kept for communications purposes among employees and contractors within the agency, department and the public. Information collected through the FDA Internet site is voluntarily provided by the public to FDA, and is used by the FDA to respond to each inquiry or comment.
- 12 Identify with whom the agency will share the collected information .** FDA shares its e-mail data with the Department of Health and Human Services for the purpose of improving communications among all of the HHS employees. Information collected through the FDA Internet site is voluntarily provided to the FDA . No information collected through the FDA Internet site is disclosed, given, sold, or transferred unless it is required by law, or for law enforcement reasons. This information may also possibly be shared with other government agencies that have public health or consumer protection duties, attorneys or investigators involved in law enforcement or policy-making, and in limited circumstances, including requests from Congress or private individuals as required by law to disclose information submitted.
- 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.** Administrative data, collected by administrative officers for payroll and travel, is maintained in FDA administrative systems, and is reviewable by each employee for information accuracy. Personnel are reminded through e-mail to check the accuracy of the information and to contact the administrative officer for corrections. The public voluntarily provides any information collected through the FDA Internet site. The FDA Internet privacy policy statement clearly states what information FDA collects, how this information is used, and to whom it is provided. This privacy statement is accessible via the Internet at <http://www.fda.gov/privacy.html>.
- 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)** FDA Internet websites contain information specifically for children. Occasionally, the FDA will receive e-mail from a child. No PII information is requested, but the child public user may have voluntarily chosen to furnish it. If a child sends the FDA an e-mail inquiry or comment, the FDA will answer it, then delete the e-mail from its files.
- 15 Describe how the information will be secured.** Data is secured on servers within the FDA, or FDA-approved facilities. The servers are stored in physically and environmentally secure locations. There is no public access to these systems, and those employees who access the data do so through secure means.
- 16 Describe plans for retention and destruction of data collected.** The FDA data is collected and backed-up through processes that retain the integrity of the data on disks and tape media. Destruction of data is carried out in a systematic way when equipment or systems are retired at the end of the life cycle. All media is rendered unreadable before the media is retired.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC ConsInfra

- 17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. No, a system of records is not being created.
- 18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):
- 19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):
- 20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC DIDR

Question:

Response:

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| 1 | Date of this Submission (MM/DD/YYYY): | 2003-11-20 |
| 2 | HHS Agency (OPDIV): | FDA/OC |
| 3 | Title of System or Information Collection: | Demographic Information and Data Repository |
| 4 | Is this System or Information Collection new or is an existing one being modified? | New, initial concept phase |
| 5 | Unique Project Identifier Number: | (IT) 009 10-01-10-01 0304-00 110-030 |
| 6 | System of Records Number: | n/a |
| 7 | OMB Information Collection Approval Number and Expiration Date
: | n/a |
| 8 | Other Identifying Number(s): | n/a |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC DIDR

- 9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

The DIDR offers an Agency-wide knowledge management system for product labeling, review templates, study protocols and study data, built upon a foundation of interoperability standards for information submitted to the Agency. The Demographic Information and Data Repository (DIDR) will provide the data required for monitoring, risk-based analysis and reporting of sub-population differences in response. The DIDR will facilitate access to this much needed information through electronically enhanced business processes, specifically the evaluation of gender and other sub-population differences, and provide management tools for operational quality assurance such as those recommended in the 2001 GAO Report on Women's Health. The DIDR will consist of electronic information in a structured and standardized format, and tools to enhance analytic capabilities. This will support better access to data and information, improve risk-benefit assessments in the FDA and enhance risk management practices for drugs, biologics, foods and devices. The DIDR are a set of projects proposed in response to a Congressional mandate to develop a database focused on women's health activities. The Agency-wide data repository will hold product information, clinical study data/protocols, and review documents as the first elements targeted for inclusion in the repository. This triad of DIDR projects will provide the basis for development of a comprehensive institutional knowledge-based system focused upon enhancing access to and utilization of data that can be used to assess gender and other sub-population differences. This knowledge management system will help improve regulatory decision-making, facilitate quality assurance and enhance risk management of medical products for sub-populations. Congressional Mandate FY2002: The conferees are concerned that the FDA has paid insufficient attention to gender-based research. The conferees direct that the agency develop an agency-wide database focused on women's health activities to include demographic data on clinical trials. Congressional Mandate FY2003: The Committee strongly supports FDA's efforts to improve gender-based research, in part by encouraging women's participation in clinical trials and tracking demographic data about such participation. The Committee directs that FDA continue, at a minimum, the fiscal year 2002 level of funding for the Office of Women's Health and report to the Committee the Agency's progress in developing an Agency-wide data set focused on women's health activities before the fiscal year 2004 appropriations hearing.

- 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

The information will include clinical trial protocols, clinical trial data, Reviewer Templates and Product Labeling. These data are the minimum necessary to track participation of sub-populations in clinical trials and conduct research in women's health issues.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC DIDR

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| 11 | Explain why the information is being collected. | n/a |
| 12 | Identify with whom the agency will share the collected information | n/a |
| 13 | Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | n/a |
| 14 | State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 | Describe how the information will be secured. | n/a |
| 16 | Describe plans for retention and destruction of data collected. | n/a |
| 17 | Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | n/a |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC EASE

Question:

Response:

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| 1 | Date of this Submission (MM/DD/YYYY): | 2003-11-19 |
| 2 | HHS Agency (OPDIV): | FDA |
| 3 | Title of System or Information Collection: | Enterprise Administrative Support Environment (EASE) |
| 4 | Is this System or Information Collection new or is an existing one being modified? | Existing |
| 5 | Unique Project Identifier Number: | 009-10-01-10-01-1020-00-403-131 |
| 6 | System of Records Number: | 09-40-0010, 09-90-0018, 09-40-0001 |
| 7 | OMB Information Collection Approval Number and Expiration Date : | n/a |
| 8 | Other Identifying Number(s): | n/a |
| 9 | Provide an overview of the system or collection and indicate the legislation authorizing this activity. | EASE is an FDA-wide administrative system that provides essential personnel, organization and locator information, automates time and attendance, and provides ad hoc reporting through its associated RAM data warehouse. |
| 10 | Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort. | FDA personnel data is retrieved from DHHS Personnel Files (FDA only) for the purpose of providing corporate data to various FDA Systems, to provide management reports and to provide the basis to process civilian personnel time and attendance recording. Person location data is collected to provide HHS and FDA with location and email directories. FDA Non employee personnel data is collected to provide a basis for location and security purposes. Only those data elements required for the FDA applications is being maintained. |
| 11 | Explain why the information is being collected. | To provide Corporate data to FDA for management and security purposes. |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC EASE

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| 12 Identify with whom the agency will share the collected information | HHS is provided FDA civilian time and attendance data on a biweekly basis to process FDA payroll. Location data is provided to HHS for the HHS Employee Location System. |
| 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | HHS collects the Personnel Data. The Center Representatives, and the various roles involved with the specific data provide notification to the employees/non-employees upon request of the data. Information about the collection of data is providing within the users manuals and upon training. |
| 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | No information from children under the age of 13 is collected |
| 15 Describe how the information will be secured. | System security is based on Database and Application Roles, Organization and Data Element Access. The System is accessed only within the FDA Firewall via ID/ Password. |
| 16 Describe plans for retention and destruction of data collected. | Data is maintained historically for purposes of management reports. Core data is destroyed when no longer needed for verification of information contained in the system and when no longer required for reporting purposes. Time and Attendance data once sent to HHS is no longer required. However, it will be retained for a minimum of 6 years for reporting purposes. |
| 17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | 09-40-0010, 09-90-0018, 09-40-0001 |
| 18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D |
| 20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC EON

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-30
2 OPDIV:	FDA/OC
3 Title of System or Information Collection:	Emergency Operations Network (EON)
4 Is this system or information collection new or is an existing one being modified?	New
5 Does this system collect, maintain, and/or disseminate information in identifiable form (IIF)?	Y
6 Identify a point of contact to whom a member of the public can address questions concerning this information system and the privacy concerns associated with it.	Betty B. Dorsey
7 Unique Project Identifier Number:	009-10-01-02-01-0305-00-104-010
8 System of Records Number:	N/A
9 OMB Information Collection Approval Number and Expiration Date:	N/A
10 Other Identifying Number(s):	N/A

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC EON

- 11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.**

The Emergency Operations Network (EON) provides an Agency-wide system to fully support the enterprise for the full range of FDA emergencies through the implementation of two robust infrastructures, functional and technological, and the reengineering of the present emergency system. The development and incorporation of agency-wide guidance in the EON will ensure that the Agency response is uniform, consistent, and coordinated. EON will contain contact information for key FDA staff members, including home addresses, telephone numbers and email addresses. This data is needed to effectively and efficiently respond to evolving emergency situations. The authorizing legislation for EON includes the Food Drug & Cosmetic Act 903(b) and 711, the Bioterrorism Act (2002), and Homeland Security Presidential Directives.
- 12 Describe the information the agency will collect, maintain, or disseminate and how the agency will use the information. In this description, indicate whether the information contains IIF and whether submission is voluntary or mandatory.**

The EON project is in the development phase. EON will provide FDA contact data extracted from the publicly available DHHS employee directory website. For selected key individuals, this will be augmented with other contact information (home and other personal telephone numbers and email addresses) extracted from the FDA Redbook.
- 13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.**

After a single upload at the start of the project, FDA Redbook and DHHS employee directory data will be entered manually when the contact database is initially created. Updates and maintenance will be done manually. There are no automatic inputs/updates from other automated systems. This is the minimum necessary information needed to maintain required response missions for the EON.
- 14 Explain why the IIF is being collected, maintained, or disseminated.**

Information is needed to provide a readily accessible source of contact data for staff engaged in managing emergency situations where time is of the essence and manual acquisition of the data (from physical telephone books or rosters) is not adequate.
- 15 Identify with whom the agency will share the IIF.**

Information will be available only to authorized users of the EON system. Access to the system will be granted on an as-needed basis, depending on the nature of the emergency in question.
- 16 Describe how the IIF will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.**

Information will be extracted from the publicly available DHHS employee directory website and (for selected key individuals) from the FDA Redbook. No data will be collected directly from individuals and data will not be shared outside the EON environment. This use of the data is consistent with those for which it was originally collected, therefore no additional notice is considered necessary.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC EON

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| <p>17 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)</p> <p>18 Describe how the IIF will be secured.</p> <p>19 Describe plans for retention and destruction of IIF.</p> <p>20 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.</p> <p>21 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</p> <p>22 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</p> <p>23 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</p> | <p>No information on children will be collected.</p> <p>Access to the information is restricted to those engaged in emergency operations. Unique IDs and passwords will be used on all user accounts, and the system will be logically isolated from the rest of the FDA intranet. Access from the public internet is blocked by a firewall.</p> <p>Information will be retained for as long as it is needed for operational purposes and destroyed (purged) when no longer needed or current.</p> <p>FDA will either create a new system of records or modify an existing system to cover this activity.</p> <p>Betty B. Dorsey</p> <p>Lester M. Crawford, D.V.M, Ph.D.</p> <p>James J. Rinaldi</p> |
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HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FIRST

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-20
2 HHS Agency (OPDIV):	FDA/OC
3 Title of System or Information Collection:	SCIENCE FIRST
4 Is this System or Information Collection new or is an existing one being modified?	Existing one being modified
5 Unique Project Identifier Number:	009-10-01-10-01-2000-00-202-072
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	SCIENCE FIRST is a virtual agency-wide science center, consolidating scientific information from across the entire agency. SCIENCE FIRST contains tools and applications to support the agency's initiative to enhance science within the agency, the continuing goal of science-based regulatory decision-making, foster collaboration and communication between agency scientists and increase awareness of FDA research accomplishments. The regulation that applies to this system is the Government Paperwork Elimination Act (GPEA).

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FIRST

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| <p>10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.</p> | <p>The system collects and disseminates science-related and other pertinent regulatory information such as skills resources, research projects, scientific and regulatory publications, links to training and knowledge enrichment sources, and scientific data sources. This information will be used to support the agency's initiative to enhance science within the agency, the continuing goal of science-based regulatory decision-making, foster collaboration and communication between agency scientists, and increase awareness of FDA research accomplishments.</p> |
| <p>11 Explain why the information is being collected.</p> | <p>The system collects and disseminates science-related and other pertinent regulatory information to foster collaboration and communication among Agency employees</p> |
| <p>12 Identify with whom the agency will share the collected information</p> | <p>SCIENCE FIRST does not share the collected information</p> |
| <p>13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.</p> | <p>Information related to FDA employees is collected via an Intranet-based interface and from publicly available sources.</p> |
| <p>14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)</p> | <p>No information is collected from children under the age of 13.</p> |
| <p>15 Describe how the information will be secured.</p> | <p>SCIENCE FIRST is secured through the use of multiple layers of defense, including firewalls, network and application password protection, audit log reviews, and network intrusion detection</p> |
| <p>16 Describe plans for retention and destruction of data collected.</p> | <p>The collected data is held indefinitely</p> |
| <p>17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.</p> | <p>No, a system of records has not been created under section 552a of Title 5, United States Code (the Privacy Act).</p> |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FIRST

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| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | James J. Rinaldi |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | Mark B. McClellan, M.D., Ph.D |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FURLS

Question:

Response:

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| 1 | Date of this Submission (MM/DD/YYYY): | 2003-11-20 |
| 2 | HHS Agency (OPDIV): | Food and Drug Administration |
| 3 | Title of System or Information Collection: | FDA Unified Registration and Listing System |
| 4 | Is this System or Information Collection new or is an existing one being modified? | New |
| 5 | Unique Project Identifier Number: | 009-10-01-09-01-1030-00-114-043 |
| 6 | System of Records Number: | n/a |
| 7 | OMB Information Collection Approval Number and Expiration Date
: | 0910-0502 10/31/2006 |
| 8 | Other Identifying Number(s): | FDA Form Number 3537/3537a |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FURLS

- 9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

On June 12, 2002, President Bush signed The Public Health Security and Bioterrorism Act of 2002 (PL 107-188). This Act was written to enhance the nation's ability to prevent, identify and respond to bioterrorism. In the case of FDA, the Bioterrorism Act substantially expands the authority the FDA can bring to bear in regulating the food industry. Domestic and foreign food facilities (importing food into the United States) will be required to register with FDA. Information required includes : name and address of facility; U.S. agent if foreign facility; and emergency contact information in the event of a public health emergency. As a result of this Act, FDA has a very aggressive schedule for rulemakings and systems addressing registration of food facilities, record-keeping and prior notice of imported food shipments. The Food Facility Registration System required in the Act will allow FDA to compile an up-to-date list of relevant facilities and to rapidly identify and contact potentially affected facilities in the context of possible bioterrorism involving the food supply. However, FDA must accommodate a registration period 60 days in advance of the statutory deadline of December 12, 2003 to assure that the international system of food production and transport is not disrupted. While FDA regulators work diligently to put the required regulations in place, the aggressive timeframe mandated under law applies also to the development of the Food Registration system. Therefore, the Food Facility Registration Module of the FDA Unified Registration and Listing System was brought on-line on October 16, 2003. Currently, approximately 4,000 registrations are completed per day through this system.

- 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are required to register the facility with the FDA either through the paper process or through FURLS. The information currently collected by FURLS is specifically related to this Food Facility Registration. FURLS information fields closely match those identified in FDA forms 3537/3537a which were approved through legal council. The information is specifically related to contacts, emergency contacts, facility information as follows:

- Name, physical address, phone number of the facility
- Same information for the parent company, if the facility is a subsidiary
- All trade names the facility uses
- Food product categories (21 CFR 170.3)
- A statement certifying that the information submitted is true and accurate and submitter is authorized to register the facility
- Name and contact information of the person submitting the certification statement
- Name of foreign facility's U.S. agent and the agent's contact information
- Emergency contact information



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FURLS

- 11 Explain why the information is being collected.** This system is specifically identified in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and is a step toward protecting the public from a threatened or actual terrorist attack on the U.S. food supply.
- 12 Identify with whom the agency will share the collected information .** Per Sec. 1.243 (a) of the Final Interim Rule, the list of registered facilities and registration documents submitted under this subpart are not subject to disclosure. In addition, FDA does not disclose any personal information collected about facilities or facility contacts unless it is required by law or for law enforcement reasons. We only use personal identifying information to contact personnel in the facility in the event of an emergency of other regulatory need. FDA personnel involved in Food Registration, law enforcement or policy-making use the information provided. We may share this information with other government agencies that have public health or consumer protection duties such as the Department of Commerce.
- 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.** Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are required to register the facility with the FDA. Facilities are offered the opportunity to register via the Internet or through a paper or pdf form that they then mail, fax or e-mail to the FDA. A significant amount of information has been shared with facilities over the last year in terms of meetings, web documents, Q&A's, federal register notifications, opportunity for public comment, etc. A summary of all of this information can be found at <http://www.cfsan.fda.gov/~furlis/ffregfr.html> Because this information collection went through the OMB approval process, it was available for public comment and much of what is reflected in the system and paper form today is in response to these public comments.
- 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)** No information is collected from children under age 13. The owner, operator, or agent in charge of a facility is responsible for registering a facility. In the case of a foreign facility, the facility may designate a U.S. agent to register for them. A U.S. agent is a person physically located in the United States who is designated by a foreign food facility as its agent for purposes of FDA's registration requirements. The U.S. agent acts as a communications link between FDA and the foreign facility for routine communications. FDA will contact the U.S. agent when an emergency occurs unless the registration specifies another emergency contact person.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FURLS

- 15 **Describe how the information will be secured.** Though information pertaining to persons or facilities is maintained by the system, such as names, phone numbers, and facility addresses, the system contains little Privacy Act Information, or other information having a high confidentiality requirement. Other information processed, stored, or transmitted by the system that requires the most protection from unauthorized persons consists of registration numbers given to facility registrants, as well as registrants' password and logon information. The Account Management module handles the creation and administration of user accounts for access to all FDA registration and listing modules. For FURLS, the module allows general system users who submit food registrations and updates to create and maintain secure login accounts (the terms "general system user" and "registrant" will be used interchangeably). Users are authenticated by the Accounts Management system prior to accessing Food Facility Registration. The registration and listing module (FFRM) is responsible for enforcing specific access rules for users. Additionally, the Account Management module uses the business rules and infrastructure implemented by the Enterprise Administrative Support Environment (EASE) in creating and administering FDA Personnel user accounts. The FURLS project has personnel and physical/environmental security in place and an independent assessment of the FURLS application has been conducted. In addition to the logical security included in Accounts management, multiple layers of defense are in place to protect the transfer of data and information, and to assure against unauthorized access to code or data. Software and operating systems patches are in place and a hardening checklist has been followed on all servers.
- 16 **Describe plans for retention and destruction of data collected.** Complete submissions from facilities are maintained for a minimum of 10 years before destruction.
- 17 **Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.** The Privacy Act does not apply because the data is being maintained by Facility and not by individual name or personal identifiers.
- 18 **The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):** Betty B. Dorsey
- 19 **The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):** Mark B. McClellan, M.D., Ph.D.

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC FURLS

20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):

James J. Rinaldi



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC MDI

Question:

Response:

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| 1 | Date of this Submission (MM/DD/YYYY): | 2003-11-24 |
| 2 | HHS Agency (OPDIV): | FDA/OC |
| 3 | Title of System or Information Collection: | FDA MDI Security System Network |
| 4 | Is this System or Information Collection new or is an existing one being modified? | Existing |
| 5 | Unique Project Identifier Number: | 009-10-01-10-01-0308-00-401-121 |
| 6 | System of Records Number: | 09-10-0018 |
| 7 | OMB Information Collection Approval Number and Expiration Date : | n/a |
| 8 | Other Identifying Number(s): | n/a |
| 9 | Provide an overview of the system or collection and indicate the legislation authorizing this activity. | The FDA MDI Security System Network is comprised of card access, intrusion alarms and maps and is utilized to provide FDA Identification/Access cards for FDA facilities. This information is provided pursuant to Public Law 93-597 (Privacy Act of 1974), December 31, 1974 for individuals applying for FDA Security Card Keys. Federal Property Management Regulations, 41 CFR 101.20.301, authorize the maintenance of systems by Government agencies for identifying individuals as employees in order to restrict access to Federal buildings after normal working hours and to areas not open to the general public. |
| 10 | Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort. | Employees <input type="checkbox"/> names, dates of birth, social security numbers, height, weight, vehicle tag number, access level, building, room number and whether they are a contractor, guest worker, visiting scientist, etc. are required before issuing an FDA Identification/ Access Card which allows access to certain FDA facilities. |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC MDI

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| 11 Explain why the information is being collected. | This information is collected to ensure that only authorized FDA employees, contractors, visiting scientists, etc. are issued FDA Identification/Access Badges. |
| 12 Identify with whom the agency will share the collected information | Only authorized agency security representatives and the Physical Security Branch. |
| 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | The information is collected on the FDA 3391 form (FDA Card Access Request Form) and is required for FDA employees to get an FDA Identification/Access Card. The privacy act statement, authority, purposes used and effects of nondisclosure are indicated on the back of the form. |
| 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 Describe how the information will be secured. | Information is secured through different levels of passwords. |
| 16 Describe plans for retention and destruction of data collected. | Hard copies are maintained for a period of six months. Records in the system with picture are maintained indefinitely. |
| 17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | 09-10-0018 |
| 18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D |
| 20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC PMS

Question:

1 Date of this Submission (MM/DD/YYYY):

2 HHS Agency (OPDIV):

3 Title of System or Information Collection:

4 Is this System or Information Collection new or is an existing one being modified?

5 Unique Project Identifier Number:

6 System of Records Number:

7 OMB Information Collection Approval Number and Expiration Date
:

8 Other Identifying Number(s):

Response:

2003-11-07

FDA/OC

Property Management System

Existing

009-10-01-10-01-0307-00-402-128



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC PMS

9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

The FDA Property Management System (PMS) automates administrative management of accountable personal property equipment assets of the FDA throughout the life cycle from receipt to final disposition. Nearly all aspects of daily FDA business operations are supported by some form of accountable personal property equipment. A broad range of equipment items is managed in PMS, from testing devices to computer mainframes. Each asset item tracked in the system is a complete unit of equipment, durable in nature, with an expected service life of two or more years. Requirements for PMS are defined in the Joint Financial Management Improvement Program (JFMIP) document, JFMIP-SR-00-4, Federal Financial Management System Requirements, Property Management System Requirements issued in October 2002. A vast array of detailed information about assets users and contracts is required for effective property management. PMS provides a data repository of asset information as well as enabling asset security, inventorying, control, tracking, and movement. PMS is an internal effectiveness tool supporting Asset and Liability Management and Financial Management as specified in the Business Reference Model (v.2.0) of the Federal Enterprise Architecture

10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

Federal employee names and employee numbers are passed to the Property Management System from another internal FDA administrative system, the Enterprise Administrative Support Environment (EASE). The information is transferred weekly and enables the assignment of responsible employee names and numbers to each item of FDA personal property entered in PMS. The information is needed in PMS for property searches in conjunction with periodic equipment inventories. The FDA Property Management System does not perform any other public or internal personally identifiable information data collections.

11 Explain why the information is being collected.

The federal employee name and employee number information is being collected for system operation and federal personal property reporting requirements associated with the conduct of official FDA Government business.

12 Identify with whom the agency will share the collected information

The system does not share collected information outside of the federal government.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC PMS

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| <p>13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.</p> <p>14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)</p> <p>15 Describe how the information will be secured.</p> <p>16 Describe plans for retention and destruction of data collected.</p> <p>17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.</p> <p>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</p> <p>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</p> <p>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</p> | <p>PMS federal employee name and employee number is collected weekly from another internal FDA administrative system the Enterprise Administrative Support Environment (EASE). The information is used in PMS to match employees responsible for custody and/or use with records of accountable FDA property equipment assets. Receipt of the asset provides awareness that the employee has been assigned responsibility for the item.</p> <p>Not applicable, access to the FDA Property Management System is restricted to pre-authorized federal employees operating within the secure FDA computing environment.</p> <p>The FDA Property Management System operates within the secure FDA computing environment. Access to the system is restricted to pre-authorized federal employees after validated logons.</p> <p>Property item asset records including federal employee assignee PII information is retained for the useful life of the asset and subject to retention for a minimum of three years after final disposition of the asset.</p> <p>The internal, administrative tracking and management of accountable FDA personal property use of federal employee information in the Property Management System does not form a system of records as defined under the Privacy Act.</p> <p>Betty B. Dorsey</p> <p>Mark B. McClellan, M.D., Ph.D.</p> <p>James J. Rinaldi</p> |
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HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC PRISM

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-05
2 HHS Agency (OPDIV):	FDA/OC
3 Title of System or Information Collection:	PRISM Simplified Acquisition System
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-10-01-0306-00-405-143
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The Purchase Request Information System (PRISM) automates internal FDA procurement awards. The system benefits the agency through improved efficiencies in the acquisition process and use of reporting tools. PRISM was begun in response to Executive Order 12873 entitled Federal Acquisition, Recycling and Waste dated October 20, 1993, Part 4 Acquisition Planning and Affirmative Procurement Programs, Sec. 404 Electronic Acquisition System mandating the implementation of electronic commerce/electronic data exchange (ES/EDI) in acquisitions. The system is used exclusively by Federal employees and is not accessed by the public.

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC PRISM

- 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.
- For acquisitions, PRISM collects personally identifiable information about the names, office addresses, office telephone numbers and email addresses of federal employees. The records are of employees originating and approving purchase orders and delivery orders for FDA acquisitions. The federal employee information is collected at the time an acquisition order is originated or approved. The federal employee information is for system operation and federal procurement reporting requirements. Vendor names, telephone numbers, addresses, DUNS numbers, tax identification numbers and contacts information from the E-Government Central Contractor Registry System are also recorded in the PRISM database. The vendor information is for procurement award processing, vendor payment processing and federal reporting requirements. PRISM does not perform any other public or internal data collections.
- 11 Explain why the information is being collected.
- The information is being collected for system operation and federal procurement reporting requirements associated with the conduct of official FDA Government business.
- 12 Identify with whom the agency will share the collected information .
- PRISM shares collected information with other internal administrative management systems, but does not share collected information outside of the federal government.
- 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.
- PRISM federal employee information is obtained when employees complete necessary forms to be given system access. Vendor information is obtained from information provided by vendors to the E-Government Central Contractor Registry System.
- 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)
- Not applicable, system access is restricted to pre-authorized federal employees operating within the secure FDA computing environment.
- 15 Describe how the information will be secured.
- PRISM operates within the secure FDA computing environment. Access to PRISM is restricted to pre-authorized federal employees.
- 16 Describe plans for retention and destruction of data collected.
- All system records are subject to the procurement record retention period of six years and three months unless litigation is pending.

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC PRISM

- 17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.
- 18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):
- 19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):
- 20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):

The exclusively internal FDA procurement award tracking and reporting use of federal employee and vendor records maintained in PRISM does not form a system of records as defined under the Privacy Act.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC TM

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-07
2 HHS Agency (OPDIV):	FDA/OC
3 Title of System or Information Collection:	Travel Manager
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-01-01-2010-00-402-126
6 System of Records Number:	09-90-0024
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC TM

- 9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.**
- Reengineering of the travel process has been a key priority for the Food and Drug Administration (FDA). Most agency travel processes were manual. Administrative staff reductions and increasing travel regulation complexity made automation a critical need. Improvements were further mandated by the Joint Financial Management Improvement Program (JFMIP) in issuance of Travel System Requirements, JFMIP-SR-99-9, dated July 1999. JFMIP is a cooperative undertaking of the U.S. Department of the Treasury, the General Accounting Office, the Office of Management and Budget, and the Office of Personnel Management. Travel Manager combines automated travel regulations, government forms generation and electronic document processing into a powerful, easy-to-use software service. The system serves the travel needs of federal employees traveling on FDA business and non-employees sponsored for travel at FDA expense, e.g. invitational speakers, State or Local Government officials, investigators, regulators, etc. Only federal employees are provided direct access to TM. Non-employees traveling at FDA expense are categorized as Special Government Employees (SGE) and provided TM system support through a federal employee Document Preparer. In 2003, roughly one thousand or approximately 25% of FDA travelers were in the SGE category. TM has virtually eliminated FDA's manual administrative burden for both travel support and travel accounting with significant cost savings. TM is aligned with the Federal eTravel initiative for standardization and automation of travel processes.
- 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.**
- Personally identifiable information about FDA Travelers in Travel Manager is collected using an internal Travel Manager Account Request/ Permission Rights Form. The form is completed by all system users before access to system capabilities are granted. The FDA Traveler name, social security number and other travel related profile information is used to process travel orders and generate electronic funds transfer reimbursements of travel expenses. Travel Manager does not perform any data collections unrelated to the processing of travel orders or reimbursements of travel expenses.
- 11 Explain why the information is being collected.**
- Travel Manager collects information about FDA business travelers for purposes of processing travel orders, system operations and accounting operations associated with recording travel obligations and disbursements.
- 12 Identify with whom the agency will share the collected information.**
- Travel Manager shares collected information with other internal administrative management systems, but does not share collected information outside of the federal government.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA OC TM

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| <p>13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.</p> <p>14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)</p> <p>15 Describe how the information will be secured.</p> <p>16 Describe plans for retention and destruction of data collected.</p> <p>17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.</p> <p>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</p> <p>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</p> <p>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</p> | <p>FDA Traveler information is obtained for federal employees when employees complete necessary forms to be given system access. Information for non-federal employee travelers is obtained when necessary forms are completed for authorization of FDA sponsored travel.</p> <p>Travel Manager is used exclusively by federal employees in the conduct of FDA business and does not collect information from children under age 13 on the Internet .</p> <p>Travel Manager operates within the secure FDA computing environment. Access to the system is restricted to pre-authorized federal employees.</p> <p>All Travel Manager system records are subject to the financial record retention period of six years and three months.</p> <p>09-90-0024</p> <p>Betty B. Dorsey</p> <p>Mark B. McClellan, M.D., Ph.D.</p> <p>James J. Rinaldi</p> |
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HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA EDCS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-18
2 HHS Agency (OPDIV):	FDA/ORA
3 Title of System or Information Collection:	Electronic Document Control System (EDCS)
4 Is this System or Information Collection new or is an existing one being modified?	New
5 Unique Project Identifier Number:	009-10-01-08-02-0204-00-404-142
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA EDCS

9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

The Electronic Document Control System (EDCS), is a document management and workflow system developed to manage the Quality Management System (QMS), warning letters, acknowledgement letters and the complete regulatory packages for the Food and Drug Administration (FDA) Office of Regulatory Affairs (ORA). The objective of the EDCS is to:

- Develop an electronic information system for the management of documents using Documentum, an enterprise content management platform.
- Provide a centralized and standardized repository for all ORA units to develop, share and maintain all QMS and regulatory packages (ie, EIR, 483s and supporting documents), which will be determined by appointed ORA personnel.
- Reduce the time and effort required to manage and deliver QMS and regulatory documents, by implementing a system to control document creation and publishing enterprise-wide. This system is envisioned to provide the ability to route documents through an approval process (workflow), monitor the status of documents, and maintain versioning history.
- Improve the sharing of information and knowledge across various user groups and public, reducing replication of information and the work involved producing it.

10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

The EDCS is collecting two major categories of information. The Quality Management System (QMS) piece of the EDCS collects the Standard Operating Procedure (SOP) related documents in order to ensure the quality of the ORA products. These products include Investigation Operations Manual (IOM), Compliance Program Guidance Manual (CPGM), Import Bulletin, Import Alert and many other quality related documents produced by ORA. These QMS products will be imported into the system by the compliance officers. Another category of the information is the regulatory packages. The EDCS will provide the integrated regulatory packages; 1) complete reports, 2) complete regulatory actions and recommendations, 3) complete lab sample results. These regulatory packages will be populated into the system by investigators via the EDCS web front-end.

11 Explain why the information is being collected.

n/a

12 Identify with whom the agency will share the collected information

n/a



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA EDCS

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| 13 | Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | n/a |
| 14 | State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 | Describe how the information will be secured. | n/a |
| 16 | Describe plans for retention and destruction of data collected. | n/a |
| 17 | Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | n/a |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D. |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA ELEXNET

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-25
2 HHS Agency (OPDIV):	FDA
3 Title of System or Information Collection:	Electronic Laboratory Exchange Network (eLEXNET)
4 Is this System or Information Collection new or is an existing one being modified?	New
5 Unique Project Identifier Number:	009-10-01-08-01-1070-00-111-034
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	<p>The Electronic Laboratory Exchange Network (eLEXNET) was developed to facilitate secure information sharing among public health partners and collaboration among food safety experts. eLEXNET provides food safety officials with access to food test results for analytes of concern at the detail level and at the product or product industry level. eLEXNET is a seamless, integrated, secure network that provides multiple federal, state and local government agencies engaged in food safety activities with the ability to compare, communicate, and coordinate findings in laboratory analyses. The system enables U.S. health officials to assess risks, analyze trends and identify problem products. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods.</p>

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA ELEXNET

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| 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort. | eLEXNET currently allows food safety laboratories at all levels of government (federal, state, local) to share real-time food safety sample and analysis data on selected microbiological analytes. eLEXNET receives sample status and sample analysis summary, laboratory analytical methods and results, and laboratory conclusions from other systems within FDA, as well as from participating laboratories . All data collections are necessary to meet the goals of this system. |
| 11 Explain why the information is being collected. | n/a |
| 12 Identify with whom the agency will share the collected information | n/a |
| 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | n/a |
| 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 Describe how the information will be secured. | n/a |
| 16 Describe plans for retention and destruction of data collected. | n/a |
| 17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | n/a |
| 18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA ELEXNET

19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):

Mark B. McClellan, M.D., Ph.D.

20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):

James J. Rinaldi



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA FACTS

Question:

Response:

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| 1 | Date of this Submission (MM/DD/YYYY): | 0000-00-00 |
| 2 | HHS Agency (OPDIV): | FDA/ORA |
| 3 | Title of System or Information Collection: | Field Accomplishments and Compliance Tracking System (FACTS) |
| 4 | Is this System or Information Collection new or is an existing one being modified? | No Change |
| 5 | Unique Project Identifier Number: | 009-10-01-08-01-1010-00-110-032 |
| 6 | System of Records Number: | N/A |
| 7 | OMB Information Collection Approval Number and Expiration Date : | N/A |
| 8 | Other Identifying Number(s): | N/A |
| 9 | Provide an overview of the system or collection and indicate the legislation authorizing this activity. | FDA's inspection process, managed by FACTS, is responsible for the health and safety of the American Public by providing support to the overall FDA's mission for promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use. Legislation authorizing this activity is the Food Drug and Cosmetic Act. |
| 10 | Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort. | The FACTS system contains data about commercial firms and their business relationships, data, FDA decisions, manpower, procedures, establishments, commerce, compliance, enforcements, products, consumer complaints and FDA organizations. The FACTS database provides information on FDA performance to Congress and the OMB, and supports the Drug industry's PDUFA initiatives. This system also presents rapid review of current and past fieldwork assignments, results, and time/cost to accomplish in the Agency mission areas of regulation, surveillance, and compliance. |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA FACTS

- 11 Explain why the information is being collected.** Providing support to the overall FDA's mission for promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use.
- 12 Identify with whom the agency will share the collected information** . Facts shares collected information with the following systems: Lab data exchange between FACTS-OASIS (ORA), Data to FACTS Reports; OPAS (ORA), Assignment data to Turbo EIR (ORA), Firm profile data to ORA/DCIQA (Intranet/ Internet), Lab data to eLEXNET (ORA, CFSAN), Complaints & Adverse event data to CAERS (CFSAN), Firm profile data feed to CDER, Pre-approval inspection data exchange with EES (CDER), Firm data to eDRLS (CDER), Inspection data from MPRIS & CASS (CDRH), Personnel data from EASE (OC).
- 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.** The primary users of FACTS are FDA organizations (see above) that enter, update, retrieve, and otherwise manipulate the data contained in the FACTS database with the ORA Field Offices staff being the principal suppliers of FACTS data. The Centers then make extensive use of FACTS to communicate with the Field. The secondary users of FACTS include organizations and individuals external to the FDA that contributes industry information to the FACTS database. These include consumers, health care providers, state partners, state public health agencies, and other Federal agencies.
- 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)** Information will not be collected from children under age 13 on the Internet for FACTS
- 15 Describe how the information will be secured.** FACTS has built-in controls to grant or modify access to the relevant data based on the user role and District he or she belongs to with FACTS end users having only read only access to data from other district offices. For the FACTS/eSAF system there are three primary security zones. The three zones are 1) the Internet, 2) the Service Area Network, or Demilitarized Zone (DMZ), and 3) the Intranet or inner core. This approach separates the functions of border control, identification and authentication, and access control.
- 16 Describe plans for retention and destruction of data collected.** Data retention and destruction is conducted in accordance with published system security plans.

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA FACTS

- 17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.
- 18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):
- 19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):
- 20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):

A system of records is not being created under section 552a for Title 5.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MARCS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-24
2 OPDIV:	FDA
3 Title of System or Information Collection:	Mission Accomplishment & Regulatory Compliance Services (MARCS)
4 Is this system or information collection new or is an existing one being modified?	New
5 Does this system collect, maintain, and/or disseminate information in identifiable form (IIF)?	N
6 Identify a point of contact to whom a member of the public can address questions concerning this information system and the privacy concerns associated with it.	Betty B. Dorsey, FDA Privacy Act Officer
7 Unique Project Identifier Number:	009-10-01-02-01-0206-00-110-032
8 System of Records Number:	
9 OMB Information Collection Approval Number and Expiration Date:	
10 Other Identifying Number(s):	

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MARCS

11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

The major objectives of the MARCS program effort will be to:

- Provide better integration of related import, inspection, and enforcement business functions that now exist separately in the FACTS and OASIS systems
- Ensure timely and accurate decision-making regarding import restrictions
- Provide functionality to support Prior Notice, which will aid in the increased surveillance of imports
- Provide other functionality that is currently missing in both FACTS and OASIS. The major functional area that is not supported by either of these systems is integrated Work Planning. Much of the mission of ORA is directed and managed by the creation and execution of work plans that are administered and tracked at the regional and district level. Neither system provides a comprehensive capability to create nor track work plans. MARCS will remedy this deficiency.
- Improve system stability and reduce the risk that a minor change in functionality could cause a major system crash. Such a system failure would render the FDA incapable of verifying the current safety status of all regulated products, including foods, medications, and critical medical devices, such as pacemakers.
- Improve system performance and ease of use that is now limited because of the limitations of a terminal server-based architecture.
- Improve availability, and scalability to provide adequate support for increased functionality and an increase in the user bases.
- Provide a platform that can form the foundation for better support of remote, and particularly mobile, staff.
- Provide a single look and feel, and similar navigation, to users who regularly use both systems. The Bioterrorism Act of 2002 is the authorizing legislation for this activity.

12 Describe the information the agency will collect, maintain, or disseminate and how the agency will use the information. In this description, indicate whether the information contains IIF and whether submission is voluntary or mandatory.

The Mission Accomplishment and Regulatory Compliance Services (MARCS) System is a comprehensive redesign and reengineering of two core mission-critical systems at FDA: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operation and Administration Support System (OASIS). These systems are legacy systems that support the regulatory functions that primarily take place in FDA's field offices. OASIS primarily supports the review and decision-making process related to products imported into the U.S. FACTS supports the investigation, tracking of compliance, and laboratory operations related to domestic operations under FDA purview.

13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.

14 Explain why the IIF is being collected, maintained, or disseminated.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MARCS

- 15 Identify with whom the agency will share the IIF.
- 16 Describe how the IIF will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.
- 17 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)
- 18 Describe how the IIF will be secured.
- 19 Describe plans for retention and destruction of IIF.
- 20 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.
- 21 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):
- 22 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):
- 23 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):

Betty B. Dorsey FDA Privacy Act Officer

** Pending agency head approval **

James J. Rinaldi Chief Information Officer

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MIA

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-05
2 HHS Agency (OPDIV):	FDA
3 Title of System or Information Collection:	ORA Enterprise Portal
4 Is this System or Information Collection new or is an existing one being modified?	New
5 Unique Project Identifier Number:	009-10-01-08-01-0202-00-110-032
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MIA

9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

The ORA Enterprise Portal a multi-phased effort that will use Oracle Portal software to create an environment where users can, with a single sign-on, access multiple FDA systems. When fully implemented, the portal will provide:

- A web infrastructure that will support new applications under development at ORA, and be a platform for integrating older applications as they are migrated, or reengineered, into a web environment.
- A number of standard services as a part of its environment: workflow, personalization, secure role-based access to systems, PKI integration, content indexing and retrieval, and other standard portal features
- Process flow capability that will support import review functionality, allowing import reviewers to retrieve data from multiple databases without the manual Processes and cumbersome use of legacy applications that is now required.
- A comprehensive user environment for information management, including retrieval of data from all ORA systems, including the Data Warehouse (ORADSS).
- An environment tailored to the ORA work community's information needs. The environment can easily be customized to each user's role, providing links to supporting systems, web-sites, and any FDA information needed to support each user's daily information needs.
- The front-end to the Emergency Operations Network (EON), sharing technical resources and infrastructure with EON.

10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

The Portal will not collect or maintain data except for the minimum needed to establish a secure account ID. Data accessed through the portal may include:

- Data about the facilities that manufacture, store, process or ship FDA regulated products into the US.
- Data about importers, consignees, shippers, carriers, involved in importing and/or distributing imported FDA regulated products.
- Data about the size, contents, type of FDA regulated products entering the US.
- Data regarding inspections, reviews, investigations or past history (including recalls) of FDA products entering the US of those involved in their manufacture, etc.
- FDA approved standards for FDA regulated products. Most of this data already exists in FDA legacy systems and is currently used in processes used to review admissibility of imported foods.

11 Explain why the information is being collected.

The only privacy-related information maintained is that needed to establish authorized access.

12 Identify with whom the agency will share the collected information

This information will not be shared with anyone. Account information is subject to the highest levels of security at FDA.

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MIA

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| <p>13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.</p> | <p>Information is obtained when a potential user requests access and provides his/her name and FDA email address</p> |
| <p>14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)</p> | <p>No information is collected from anyone under age 13.</p> |
| <p>15 Describe how the information will be secured.</p> | <p>Information is contained in as part of the Portal security infrastructure with applied access controls.</p> |
| <p>16 Describe plans for retention and destruction of data collected.</p> | <p>Information is retained until a User leaves the FDA. Procedures have been established to notify the System Administrator when an authorized user resigns or retires. At that time the data is deleted.</p> |
| <p>17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.</p> | <p>Since the only data maintained inside the portal is data related to secure access, no system of records will exist. Information will never be retrieved about the user by either name or number.</p> |
| <p>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</p> | <p>Betty B. Dorsey</p> |
| <p>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</p> | <p>Mark B. McClellan, M.D., Ph.D.</p> |
| <p>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</p> | <p>James J. Rinaldi</p> |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MODEL

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-18
2 HHS Agency (OPDIV):	FDA
3 Title of System or Information Collection:	Field Work Force Planning System (FWFPS)
4 Is this System or Information Collection new or is an existing one being modified?	New
5 Unique Project Identifier Number:	009-10-01-08-02-0203-00-304-106
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The purpose of the Field Workforce Planning System (FWFPS) is to provide field managers with resources and output projections deemed necessary to carry out FDA's mission in the field.

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MODEL

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| 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort. | The information collected includes operations conducted by Field personnel such as inspections, investigations, sample collections, etc. The information is organized according to the type of personnel performing the operation(s) and enables field managers to organize and allocate work according to the program objectives and activities stipulated for the Workplan. FWFPS is an essential component of ORA's field work planning and resource allocation process. FWFPS uses standardized rules to develop each region, district and laboratory ceiling. It also summarizes the year's plan targets for inspections, sample collections and analyses, and other import and domestic regulatory activities that support FDA's five budget programs. FWFPS is necessary for each field organization to keep track of operational activity targets. It is also used to calculate field office personnel ceilings using consistent decision rules that support the funding instructions contained within the Congressional Budget each year. The data collected provides an effective means to prepare resource and organizational plans because it utilizes an efficient time reporting and operational organizational structure to prepare plans, report on field performance, and structure the field workforce in the most efficient means possible. |
| 11 Explain why the information is being collected. | n/a |
| 12 Identify with whom the agency will share the collected information | n/a |
| 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | n/a |
| 14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 Describe how the information will be secured. | n/a |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA MODEL

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| 16 | Describe plans for retention and destruction of data collected. | n/a |
| 17 | Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | n/a |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D. |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA OASIS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-26
2 HHS Agency (OPDIV):	FDA/ORA
3 Title of System or Information Collection:	Operational & Admin. System for Import Support (OASIS)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-08-01-1020-00-110-032
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	OASIS automated the re-engineered business processes the FDA utilizes for making its import admissibility determinations to ensure the safety, efficacy and quality of the foreign-origin products for which FDA has regulatory responsibility under the Federal Food, Drug and Cosmetic Act.
10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.	OASIS enables FDA to handle more efficiently and effectively the burgeoning volume of shipments (now over 8 million/year -- up by 50% in the last four years) of imported products.
11 Explain why the information is being collected.	n/a
12 Identify with whom the agency will share the collected information	n/a

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA OASIS

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| 13 | Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | n/a |
| 14 | State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 | Describe how the information will be secured. | n/a |
| 16 | Describe plans for retention and destruction of data collected. | n/a |
| 17 | Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | n/a |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D. |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA OPAS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	FDA/ORA
3 Title of System or Information Collection:	On-Line Program Analysis System (OPAS)
4 Is this System or Information Collection new or is an existing one being modified?	Existing one being modified.
5 Unique Project Identifier Number:	009-10-01-08-01-0201-00-301-092
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA OPAS

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| 9 Provide an overview of the system or collection and indicate the legislation authorizing this activity. | OPAS extracts employee accomplishment information from the ORA Field Accomplishments and Compliance Tracking System (FACTS). The extracted information refers to the employees' work activities by Operation, Firm, Location, Position Class, Program Code, and Number of Hours. This employee information is then counted and aggregated for each dimension (Operation, Location, Position Class, Program Code, Fiscal Year). Values are loaded into an Oracle Express multi-dimensional database for display to the OPAS users (Headquarters managers and analysts, and field managers). Work plan information is collected from the MODEL files, but MODEL stores no data for an individual employee. In the future, MODEL will be replaced with Field Workforce Planning System (FWFPS). OPAS does not display public information (i.e., names of Firms). Although this information is collected through FACTS, OPAS displays only counts of Firms in various categories (by Establishment Type, Industry Code, Location, and Fiscal Year). Legislations authorizing this activity are the Prescription Drug User Fee Act, the Federal Food, Drug, and Cosmetic Act, the Bioterrorism Act of 2002, Controlled Substances Act, and The Medical Device User Fee and Modernization Act of 2002. |
| 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort. | The Agency collects information about resources and the time it takes to address ORA mission activities. This information is used by the Division of Planning Evaluation Management (DPEM) to collect fees, provide necessary training for personnel, and to determine resource needs and funding requirements for ORA to enjoy success in its mission. The OPAS data presented to users are statistics derived from counting FACTS records and FWFPS data. |
| 11 Explain why the information is being collected. | n/a |
| 12 Identify with whom the agency will share the collected information | n/a |
| 13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | n/a |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA OPAS

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| 14 | State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 | Describe how the information will be secured. | n/a |
| 16 | Describe plans for retention and destruction of data collected. | n/a |
| 17 | Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | n/a |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D. |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA ORADSS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-11
2 HHS Agency (OPDIV):	FDA\ORA
3 Title of System or Information Collection:	ORA Reporting Analysis Decision Support System (ORADSS)
4 Is this System or Information Collection new or is an existing one being modified?	Yes
5 Unique Project Identifier Number:	009-10-01-08-01-1040-00-111-033
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	To fulfill its regulatory responsibility under the Federal Food, Drug & Cosmetic (FD&C) Act, the FDA uses the Operational and Administrative System for Import Support (OASIS) system to help make admissibility determinations to ensure the safety, efficacy and quality of the foreign-origin products for which the FDA has regulatory responsibility. Section 801(a) of the FD&C Act sets out procedures for imports under FDA's jurisdiction.
10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.	The ORADSS system uses information collected by the OASIS system. OASIS contains information related to FDA regulated products being imported into the United States
11 Explain why the information is being collected.	n/a

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA ORADSS

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| 12 | Identify with whom the agency will share the collected information | n/a |
| 13 | Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. | n/a |
| 14 | State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) | n/a |
| 15 | Describe how the information will be secured. | n/a |
| 16 | Describe plans for retention and destruction of data collected. | n/a |
| 17 | Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. | n/a |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D. |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA RES

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-12
2 HHS Agency (OPDIV):	FDA/ORA
3 Title of System or Information Collection:	Recall Enterprise System (RES)
4 Is this System or Information Collection new or is an existing one being modified?	n/a
5 Unique Project Identifier Number:	009-10-01-07-01-1011-00
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	n/a
8 Other Identifying Number(s):	n/a

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA RES

- 9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.

In 2000 the GAO audited CFSAN regarding food safety. As a result of this audit, GAO produced a report titled, "FOOD SAFETY: Actions Needed by USDA and FDA to Ensure that Companies Promptly Carry Out Recalls (GAO/RCED-00-195)," August 2000. In this report, GAO stated that the FDA needed to ensure that companies initiate and carry out recalls without delays, particularly of foods that may cause serious adverse health consequences. Specifically, GAO recommended that the FDA:

- Provide specific guidance to companies on time frames for quickly initiating and carrying out food recalls that involve potentially serious adverse health risks, including procedures to expeditiously notify their distribution chains and alert the public.
- Provide the public with timely access to recall information.
- Modify existing recall databases, as necessary, to include information on the timeliness of companies' recall activities to determine whether companies delay in initiating and carrying out recalls.

To comply with these recommendations, the ORA/OE/DCMO re-engineered the existing Recall prototype into the current RES project. RES makes it possible to collect recall information Agency wide, by allowing the Districts and Centers to enter recall data via the FDA Intranet. Public access to specific pieces of recall information is available via the Internet. In addition, the President's Management Agenda states "This administration's goal is to champion citizen-centered electronic government that will result in a major improvement in the federal government's value to the citizen." RES clearly supports this goal in that the driving factor to redesign the existing recall prototype is to provide the public with timely access to recall data.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA RES

- 10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

Almost all of the data captured through the RES application is non-personal and can be grouped into the follow categories: · Firm information · Product information · Center-specific information · Recall Event information · Recall Recommendation information · Recall Classification information · Recall Summary and Termination information Personally Identifiable Information (PII) is limited to the minimum amount needed for effective communication in the system. This communication has two aspects, internal and external. The internal aspect of the system uses the names and email addresses of the individual FDA employees who create or work with the records in the RES application. These needed pieces of PII, the employee's name and email address, come from the FDA's FACTS database, which is accessed through the individual's RES login codes. The user's name and email provides access to the user's profile information record in the RES database. These records contain information regarding each user's role, and the FDA Center with responsibility for the over sight of the recall activity. In addition to FDA employees, pieces of PII are also capture in regards to the reporting company, the name(s) of the company point(s) of contact, their email addresses, and company mailing addresses. These pieces of information are provided to FDA by the reporting company(s) for means of communication. The External use of PII is that the company involved in the recall provides the name and email address of a company representative so the public can make enquiries regarding the recall.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA RES

- 11 **Explain why the information is being collected.**
- The FDA is responsible for monitoring over 100,000 U.S. firms that manufacture or process products. FDA's Office of Regulatory Affairs (ORA) is focused on assuring that firms comply with FDA regulations when manufacturing products or process products in order to achieve consumer protection. The FDA's Investigations Operations Manual 2000 states that ORA's mission is to achieve effective and efficient compliance of regulated products through high quality, science-based work that results in maximizing consumer protection. Within ORA, the Recall Operations Staff (ROS) in the Office of Enforcement (OE), Division of Compliance Management and Operations (DCMO) serves as the Agency's focal point for all product recall activities. ROS is also responsible for providing policy, procedure, and direction to the FDA field and Center recall operations as dictated by the Food, Drug and Cosmetic (FD&C) Act. Recalls are an effective method of removing or correcting consumer products that are in violation of the laws administered by the FDA. In order to effectively collect and process recall information the FDA needs to communicate both internally and externally using email addresses and when needed postal addresses for the establishments involved in the recall process. The public also needs to be provided with an avenue of communication with establishment involved in the recall so they can obtain any additional information or guidance in regard to the recall.
- 12 **Identify with whom the agency will share the collected information**
- The only PII shared with the public is through the internet access to RES and this access limits PII to the name, email address, and business address of the establishment's public point of contact. This information is provided to facilitate consumers' questions to the establishment regarding the recall.
- 13 **Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.**
- Internally, users of the RES application must fill out request form in order to access the system. This requires the user name, email address, FDA Center of employment, and manager's approval. The user understands that this information is not shared out side of the FDA, but is used within the application to limit access and edit rights, and for email communication and tracking who is working on which recalls. Establishments involved in the recall process must provide contact information for communication purposes and it is understood that only the information regarding the external public point of contact will be released to the public once the recall is approved and information regarding the recall is released to the FDA internet site for public viewing. Released information is a subset of the recall information gathered by FDA during the recall process and PII is limited to the reporting establishment's public point of contact. External users of the RES information, the public, are not required to provide any personal information as access is opened to all through the FDA internet web site.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA RES

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| <p>14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)</p> <p>15 Describe how the information will be secured.</p> <p>16 Describe plans for retention and destruction of data collected.</p> <p>17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.</p> <p>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</p> <p>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</p> <p>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</p> | <p>No information in RES will be collected from children.</p> <p>All records containing PII are retained within a centralized database instance maintain by FDA/ORA/OIT in accordance with established FDA procedures and guidelines for database security</p> <p>All records within the RES application are electronic. RES is designed as repository for both current and past recall information. At this time a duration limit for record retention has not been established.</p> <p>The RES system of records is compliant under section 552a of Title 5, United States Code (the Privacy Act) as all personal information is limited to information needed in order to communicate within the RES application process, and the availability of such information is limited to the FDA employees involved in processing the RES records.</p> <p>Betty B. Dorsey</p> <p>Mark B. McClellan, M.D., Ph.D.</p> <p>James J. Rinaldi</p> |
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HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA TURBOEIR

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA/ORA
3 Title of System or Information Collection:	FDA Turbo EIR
4 Is this system or information collection new or is an existing one being modified?	Existing
5 Does this system collect, maintain, and/or disseminate information in identifiable form (IIF)?	Y
6 Identify a point of contact to whom a member of the public can address questions concerning this information system and the privacy concerns associated with it.	Betty B. Dorsey, FDA Privacy Act Officer
7 Unique Project Identifier Number:	009-10-01-02-01-1060-00-110-032
8 System of Records Number:	09-10-0002
9 OMB Information Collection Approval Number and Expiration Date:	N/A
10 Other Identifying Number(s):	009-10-01-08-01-1060-00-110-032

HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA TURBOEIR

- 11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.**
- The Turbo EIR Field Agent application provides a standardized database of citations, and assists the investigator in preparation of the FDA Form 483 and the Establishment Inspection Report (EIR). FDA field investigators annually conduct approximately 17,000 establishment inspections. A Food Drug and Cosmetic Act requirement of the inspectional process is to report (in writing) certain types of adverse observations to the management of the inspected firm at the conclusion of the inspection. About forty percent of all inspections result in the issuance of an FDA 483. The FDA 483 is the written report listing the adverse observations observed by the investigator. The investigators must also generate a comprehensive narrative for each inspection. These narratives are known as Establishment Inspection Reports (EIRs) and are commonly prepared with word processing software. Turbo EIR Field Agent provides onscreen guidance to the investigator for preparation of the EIR. Turbo on the Web is a web browser based application that allows FDA users to retrieve FDA 483 and EIR documents via the FDA intranet.
- 12 Describe the information the agency will collect, maintain, or disseminate and how the agency will use the information. In this description, indicate whether the information contains IIF and whether submission is voluntary or mandatory.**
- Turbo EIR Field Agent painlessly gathers data on the specific violations observed during the inspection and proceedings that transpire during the course of the inspection. Those data (and the FDA 483 items themselves) are then uploaded to a central database where they are available in the FDA for analysis and trending. The EIRs are also available online. The standardization inherent in Turbo EIR reduces inconsistency and lack of uniformity in the FDA 483 process. Specific personally identifiable information collected by Turbo EIR is names of establishment employees that participated in the FDA inspection. The collection of these names is to identify the most responsible person at the establishment and to note how establishment employees participated in the conduct of the inspection. These names are not used by the Turbo EIR system for data searches.
- 13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.**
- Specific personally identifiable information collected by Turbo EIR is names of establishment employees that participated in the FDA inspection. The collection of these names is to identify the most responsible person at the establishment and to note how establishment employees participated in the conduct of the inspection. These names are not used by the Turbo EIR system for data searches.
- 14 Explain why the IIF is being collected, maintained, or disseminated.**
- In addition to enforcing the Food Drug and Cosmetic Act, the information collected by Turbo EIR Field Agent is used to perform analysis and trending which in turn becomes a component in the development of Good Manufacturing Practices standards.



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA TURBOEIR

- 15 Identify with whom the agency will share the IIF. The information is shared with various compliance/management operational divisions (such as Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Devices and Radiological Health, Center for Veterinary Medicine) in the FDA that perform enforcement, analysis and trending.
- 16 Describe how the IIF will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared. Assigned an inspection, the investigator travels to the establishment to perform it. If the investigator observes adverse conditions they are linked to the FDA citation database in Turbo EIR Field Agent. Within Turbo EIR Field Agent the investigator is then able to provide specific information relating to each observation. When all observations and specifics are recorded Turbo EIR Field Agent prints the FDA 483. The investigator then meets with the management of the firm and explains the adverse observations recorded. At this point the firm's management has an opportunity to have their comments added to the FDA 483. At the end of the management meeting the investigator presents the final FDA 483 (with comments) to the firm's management and the inspection is complete. Afterwards the investigator using Turbo EIR Field Agent authors the Establish Inspection Report (EIR). An EIR is created for each inspection, even if a FDA 483 is not issued. The EIR is a comprehensive report of the inspection and contains information needed to support the Violation Letter process and of interest to FDA management.
- 17 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998) Not applicable, Turbo EIR does not collect information from children under age 13.
- 18 Describe how the IIF will be secured. The controls to secure information collected by Turbo EIR Field Agent are strong encryption techniques both locally and in the establishment of connections, access controls on the system and on the network where the system resides, detection and auditing of unauthorized access attempts and data verification routines.
- 19 Describe plans for retention and destruction of IIF. The current retention period is indefinite.
- 20 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained. 09-10-0002



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA ORA TURBOEIR

21 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):

Betty B. Dorsey FDA Privacy Act Officer

22 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):

** Pending agency head approval **

23 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):

James J. Rinaldi FDA Chief Information Officer



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA-CBER-EDoc Query

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-17
2 HHS Agency (OPDIV):	FDA/CDER
3 Title of System or Information Collection:	E-Doc Query (EDQ)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	
6 System of Records Number:	009-10-01-03-02-0203-00-110-032
7 OMB Information Collection Approval Number and Expiration Date :	N/A
8 Other Identifying Number(s):	N/A
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	<p>This system provides read-only access to digital assets (ex. Images, text, WORD, PDF, html) related to several other databases and network shared areas in CDER. The majority of the applications that can be viewed via this facility contain non-public drug review related information but not personal information. However this system does provide access to the Adverse Drug Reaction case reports. The Adverse Drug Reaction case reports contain little personal information but some adverse reaction data submitted by physicians, hospitals and the public do contain personal identifiers . The personal information is not contained in any standard reports and is not in searchable fields. Where it does exist, it includes the name and possibly the SSN of the individuals having adverse drug reactions. The Food, Drug and Cosmetic Act is the legislative authority for this activity.</p>



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA-CBER-EDoc Query

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| <p>10 Describe the information the agency will collect and how the agency will use the collected information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.</p> | <p>The Adverse Drug Reaction case reports are submitted to FDA by pharmaceutical firms, physicians, hospitals and the public. Each paper report is scanned in (images only - no OCR) and assigned a unique ID. The reports can only be accessed through this system by the unique ID code assigned to it. Only staff with access to AERS or the AERS DataMart will know what the unique IDs are for each of the reports. In addition, access to this system is restricted to those that have a 'need to know' based on their job responsibilities - primarily the Office of Drug Safety and Medical Officers. They cannot search by any other data fields aside from the date the report was received and the date the report was scanned.</p> |
| <p>11 Explain why the information is being collected.</p> | <p>No information is collected.</p> |
| <p>12 Identify with whom the agency will share the collected information .</p> | <p>This personal information is never shared. FOI staff screen all reports that go outside of the Center to assure that no sensitive or personal information is disclosed. Access to the information is strictly limited.</p> |
| <p>13 Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.</p> | <p>Adverse reaction information is submitted by the pharmaceutical industry as required by law. The pharmaceutical industry never submits privacy data. Physicians, hospitals and the public sometimes submit privacy data on case reports. Since the Agency does not request or use the privacy data, no notice or opportunity for comment is provided to subjects.</p> |
| <p>14 State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)</p> | <p>Not Applicable. No information is collected from children, or on the Internet.</p> |
| <p>15 Describe how the information will be secured.</p> | <p>Access to the data is highly restricted and only accessible by safety evaluators, reviewing medical officers, and compliance staff.</p> |
| <p>16 Describe plans for retention and destruction of data collected.</p> | <p>Published schedules for retention are followed.</p> |
| <p>17 Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice under which the records will be maintained.</p> | <p>No.</p> |



HHS Privacy Impact Assessment (PIA) Summary

OPDIV: FDA System Name: FDA-CBER-EDoc Query

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| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date): | Betty B. Dorsey |
| 19 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date): | Mark B. McClellan, M.D., Ph.D. |
| 20 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date): | James J. Rinaldi |

