

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: eCTD

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-20
2 HHS Agency (OPDIV):	FDA/CDER
3 Title of System or Information Collection:	Electronic Common Technical Document (eCTD)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-04-02-0204-00
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
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	This system contains no Privacy Act information. The EVS is an application designed to support the FDA's regulatory submission and review initiative as it relates to eCTD submissions. The EVS provides an efficient and flexible approach for receiving, processing, and viewing ICH eCTD submissions as well as establishing a central repository for related metadata. The Food, Drug and Cosmetic Act is the legislative authority for this activity.
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 NDAs are received from new drug sponsors on a variety of transport media, such as Digital Linear Tapes (DLTs), floppy diskettes, and Compact Disks (CDs). NDA submissions are checked for errors and copied to the EDR document repository; and reviewers are sent electronic mail (e-mail) notification of the submission's availability.

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: eCTD

- 11 Explain why the information is being collected.
- 12 Identify with whom the agency will share 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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): 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 CBER BIMS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA/CBER
3 Title of System or Information Collection:	Biologic IND (Investigational New Drug) Management System -BIMS
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)?	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:	009-10-01-02-02-1030-00-204-079
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
11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The Center for Biologics Evaluation and Research (CBER) is charged with protecting and enhancing public health through the regulation of biological products including blood, vaccines, therapeutics and related drugs and devices. This requires CBER to receive, review and act on INDs (Investigational New Drug), IDEs (Investigational Device Exemptions) and Master Files. Authority/Mandate: 21 CFR 312, 21 CFR 812 , 21 CFR 314.420

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER BIMS

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| <p>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.</p>   | <p>IND/IDE sponsor, investigator names and credentials, product details such as indications, content, clinical trials, FDA review team member names, review status, IND/IDE status, investigation sites addresses, business phone # and business addresses of sponsor contact. This is the minimum data required in order for the FDA review team to be able to correspond with the sponsors with any questions about the submitted application. After review of the data by the FDA privacy officer it has been determined that BIMS contains no IIF.</p> |
| <p>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</p>   | <p>N/A</p>   |
| <p>14 Explain why the IIF is being collected, maintained, or disseminated.</p>   | <p>N/A</p>   |
| <p>15 Identify with whom the agency will share the IIF.</p>  | <p>N/A</p>   |
| <p>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.</p> | <p>N/A</p>   |
| <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>N/A</p>   |
| <p>18 Describe how the IIF will be secured.</p>  | <p>N/A</p>   |
| <p>19 Describe plans for retention and destruction of IIF.</p>   | <p>N/A</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>N/A</p>   |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER BIMS

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 EDR

### Question:

### Response:

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|----|---|--|
| 1  | Date of this Submission (MM/DD/YYYY):   | 0000-00-00   |
| 2  | HHS Agency (OPDIV):   | FDA/CBER   |
| 3  | Title of System or Information Collection:  | CBER Electronic Document Room  |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Modified   |
| 5  | Unique Project Identifier Number:   | 009-10-01-02-01-1010-00  |
| 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  |
| 9  | Provide an overview of the system or collection and indicate the legislation authorizing this activity.   | The Electronic Document Room (EDR) is a collection of systems that e-business enables the regulatory process for industry and CBER. The EDR stores, retrieves, and distributes electronic submissions to reviewers. The EDR is integrated with the CBER regulatory databases to allow for advanced searches based on data in the CBER databases. The EDR automates processing of submissions and automatically sends notifications to reviewers. The EDR also serves as a repository for CBER generated final documents. |
| 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 system Meta data about submissions that allows for searching of submissions such as submission dates, product name, sponsor names, submission type, review office. The information is being used to allow users of the system to search for information or data in the system. Data collected is the data that the users of the system requested to be captured by the system.   |



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CBER EDR

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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):   | 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 CBER GTS

### Question:

### Response:

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|----|---|---|
| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-21  |
| 2  | HHS Agency (OPDIV):   | FDA/CBER  |
| 3  | Title of System or Information Collection:  | Gene Therapy System (GTS)   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | New   |
| 5  | Unique Project Identifier Number:   | 009-10-01-02-02-1100-00   |
| 6  | System of Records Number:   |   |
| 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 Gene Therapy System is a collection of gene therapy adverse events for patients, for protocols for an IND. Gene Therapy products are defined from cells, vectors and genes and are stored for an IND. Patients products, selected from the products for an IND, are identified with the dosages that the patient received. The products are given to patients through a site and route. The report and reporter information for the adverse event are also saved. Authority/Mandate: 21 CFR 312, 21 CFR 812, 21 CFR 314.420 |
| 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 will collect IND, protocol, product, patient, patient product, dosages, report, reporter, test and adverse event information. The information will be collected from adverse event and annual reports. The agency will use this information to determine relationships between adverse events and products used in protocols.  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER GTS

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| <b>11 Explain why the information is being collected.</b>  | The information is being collected to obtain answers quickly for gene therapy adverse events.   |
| <b>12 Identify with whom the agency will share the collected information .</b>   | The agency will answer questions to Congress and the public when question arise about gene therapy adverse events.  |
| <b>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.</b> | The information will be obtain from annual reports and adverse events sent to FDA from sponsors. These are mandatory reports the sponsors supply to FDA. It is extracted from FDA Form 1571, 1572 and from within the submissions itself. |
| <b>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)</b>   | No.   |
| <b>15 Describe how the information will be secured.</b>  | Information is secured via adapted industry standard authentication process and role-based privilege access method.   |
| <b>16 Describe plans for retention and destruction of data collected.</b>  | Retention schedule is indefinitely.   |
| <b>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.</b>   | No information is being collected that can personally identify patients.  |
| <b>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</b>   | Betty B. Dorsey   |
| <b>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</b>   | Mark B. McClellan, M.D., Ph.D.  |
| <b>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</b>  | James J. Rinaldi  |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER HCTERS

### Question:

### Response:

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| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-12   |
| 2  | HHS Agency (OPDIV):   | FDA, CBER  |
| 3  | Title of System or Information Collection:  | Human Cell and Tissue Establishment Registration System (HCTERS)   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Existing   |
| 5  | Unique Project Identifier Number:   | 009-10-01-03-02-1080-00-204-079  |
| 6  | System of Records Number:   |  |
| 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 system is used to register establishments that deal with Human Cell Tissue, Cellular, and Tissue-based products.   |
| 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. | HCTERS gets data from form FDA 3356 either paper forms or the electronic web-based version. Both versions satisfy the regulatory requirements of company identification, products, and function. Only the information required by the regulation is collected. |
| 11 | Explain why the information is being collected.   |  |
| 12 | Identify with whom the agency will share the collected information  | .  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER HCTERS

- 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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): 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 CBER NXD

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-17
2 HHS Agency (OPDIV):	FDA/CBER
3 Title of System or Information Collection:	National Xenotransplantation Database (NXD)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-02-02-1030-00-1010-00
6 System of Records Number:	
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.	FDA currently regulates xenotransplantation products as biologics. Animal cells, tissues, and organs intended for therapeutic use in humans are subject to regulation by the FDA under Sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262) and Section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321). In accordance with the statutory provisions governing biological products and drugs, a xenotransplantation product must be the subject of an IND or IDE application in compliance with 21 CFR part 312, 21 CFR Part 812, or of an approved PLA, NDA, BLA or PMA (510K) regardless of whether the finished product is shipped across state lines.

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER NXD

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 NXD collects seven main categories of information: Xenotransplantation facilities; Xenotransplantation patients; (does not contain any patient data) Xenotransplantation procedures; Adverse clinical events associated with xenotransplantation; Clinical follow-ups of recipients of xenotransplantation products; Animal health events/Herd health events; and Patient death reports. Personal patient information is intentionally excluded from the data collected to avoid loss of personal privacy.

11 Explain why the information is being collected.

12 Identify with whom the agency will share 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.

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)

15 Describe how the information will be secured.

16 Describe plans for retention and destruction of data collected.

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):

Betty B. Dorsey

## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CBER NXD

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 CBER RMS BLA

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-12
2 HHS Agency (OPDIV):	DHHS/FDA/CBER
3 Title of System or Information Collection:	Regulatory Management System for the Biologics License Application (RMS/BLA)
4 Is this System or Information Collection new or is an existing one being modified?	Modified
5 Unique Project Identifier Number:	009-10-01-03-02-1060-00-204-079
6 System of Records Number:	N/A
7 OMB Information Collection Approval Number and Expiration Date :	N/A
8 Other Identifying Number(s):	009-10-01-02-02-1020-00 BRMS (historical data accessible from BLA)
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	RMS/BLA supports CBER's Managed Review Process for the review and approval of applications for biological derived drugs and blood products (the BLAs) that are regulated by CBER. Submission Tracking Numbers (STNs) need to be assigned, information about BLAs, products, and facilities maintained and searchable, review milestone deadlines generated and reported, post-Approval commitments monitored and reported. IT solutions are essential in enabling CBER in meeting its obligations under PDUFA for the timely review of BLAs and tracking of post marketing commitments. RMS/BLA is integrated with DATS and EDR. Reviewers can pull up eSubmissions from the EDR from within RMS/BLA. Under authority of 21CFR601, 21CFR820 (for IVD test kits), and the Prescription Drug User Fee Act and later amendments to the Act.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER RMS BLA

- 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.
- 11 Explain why the information is being collected.
- 12 Identify with whom the agency will share 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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.
- Drug product and company names, product details such as indications, content, manufacturing facilities, manufacturing processes, FDA review committee member names, review status, licensed status, company and facility addresses, business phone # and business addresses of company representatives.
- FDA/CBER exists to review regulate biologic drugs and blood derived products. It reviews Biologic License Applications (BLAs) and approves these marketing applications per 21CFR600 and 601. The Center is required to track these BLA submissions, the review of these submissions, and the licensed products it regulates. The information that is captured and maintained in the RMS/BLA system is essential in allowing CBER to fulfill these obligations.
- Certain information related to the performance of CBER's review of BLA submissions is reported to Congress. Information on licensed products is reported to the public and shared with other federal agencies such as the CDC. There are no links to RMS/BLA data from outside the Agency. Presently, any information provided outside the agency is through formal reporting.
- All information in RMS/BLA is provided by the applicants (regulated drug companies ) of BLA submissions. It is extracted from FDA Form 356H and from within the submissions itself. Other information is added to this from CBER generated actions such as the act of FDA licensing a product or issuing a letter or memo.
- No.
- Information is secured via a adapted industry standard authentication process and role-based privilege access method.
- Retention schedule is indefinitely.
- No



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER RMS BLA

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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               |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER RMS DATS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-12
2 HHS Agency (OPDIV):	FDA/CBER
3 Title of System or Information Collection:	Regulatory Management System/ Document Accountability and Tracking Systems (RMS/DATS)
4 Is this System or Information Collection new or is an existing one being modified?	Modified
5 Unique Project Identifier Number:	009-10-01-03-02-1060-00-204-079
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.	RMS/DATS supports the Document Control Center staff with receipt and routing of manufacturer submissions to reviewers and incoming and outgoing communications. These include IND, BLA, NDA, 510(k), PMA, and Labeling submissions. DATS functionality includes the logging of shipment information, data entry of regulatory application information, support for document routing and circulation through the Center, support for inventory controls and management, and the generation of various reports and queries. The DCC, and therefore DATS, is the first step in the process of managed review. DATS assigns and owns the receipt dates of submissions, which are used in the generation of review performance milestones, required under PDUFA and MDUFMA. Authority under 21CFR312, 314, 601, 812, 820 and the Prescription Drug User Fee Act as amended by the FDA Modernization Act.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER RMS DATS

- 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. Drug product and company names, sender firm names, submissions types, and courier identification numbers such as UPS or FedEx numbers for received packages.
- 11 Explain why the information is being collected.
- 12 Identify with whom the agency will share 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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): 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 CBER RMS DATS

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 CBER RMS LRS

### Question:

### Response:

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| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-12   |
| 2  | HHS Agency (OPDIV):   | FDA/CBER   |
| 3  | Title of System or Information Collection:  | Regulatory Management System/ Lot Release System (RMS/LRS)   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Modified   |
| 5  | Unique Project Identifier Number:   | 009-10-01-02-02-1070-00  |
| 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  |
| 9  | Provide an overview of the system or collection and indicate the legislation authorizing this activity.   | RMS/LRS supports CBER's oversight of sample lots in support of licensure and surveillance of products that are regulated by CBER. RMS/LRS also fulfills bioterrorism requirements for the tracking of test samples to the labs. The system conforms to the BLA model and interfaces with RMS/BLA system. The nature of Lot Release requires that LRS be flexible enough to allow the assignment of a Lot to a Product/ Establishment relationship that may not be licensed or pending. The system consists of three types of forms: Data Entry or Update, Report, and Maintenance. |
| 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. | Drug product and company names, product testing protocols, manufacturing processes, inventory and tracking of samples to be tested are collected. Names of FDA laboratory personnel who test the samples.  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CBER RMS LRS

- 11 Explain why the information is being collected.
- 12 Identify with whom the agency will share 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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): 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 CDER ADIMS

### Question:

### Response:

- |    |   |  |
|----|---|--|
| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-17   |
| 2  | HHS Agency (OPDIV):   | FDA/CDER   |
| 3  | Title of System or Information Collection:  | Automated Drug Information Management System (ADIMS)   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | New  |
| 5  | Unique Project Identifier Number:   | 009-10-01-03-01-0302-00-110-032  |
| 6  | System of Records Number:   |  |
| 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.   | This system allows reviewers to track review data electronically and provides an electronic repository of internally generated reviews and review-related documents. It will also be a vehicle for submission of information regarding drug applications. The Food, Drug and Cosmetic Act is the legislative authority for this activity. This system contains no Privacy Act information. |
| 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. | All information comes from drug applications submitted by industry and contains no Privacy Act information. Most of the data is entered manually into databases and is available only to authorized CDER employees.  |
| 11 | Explain why the information is being collected.   |  |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER ADIMS

- 12 Identify with whom the agency will share 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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):

Betty B. Dorsey

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

James J. Rinaldi

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER AERS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	FDA/CDRH
3 Title of System or Information Collection:	CDRH Adverse Events Reporting System
4 Is this System or Information Collection new or is an existing one being modified?	Existing system, not being modified
5 Unique Project Identifier Number:	009-10-01-05-02-1010-00-110-032
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.	This system stores and processes information about adverse events or malfunctions related to medical devices. The collection of this data is conducted under the authority of the Safe Medical Devices Act of 1991.

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER AERS

**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 for this system provides details of specific adverse events and malfunctions related to medical devices. The data consists of a summary description of the event being reported, identifies the device and its manufacturer, some general patient and medical information, the location of event, and codified analysis of the event by the device manufacturer. This level of reporting provides enough data to generate adverse event statistics and provides enough detail for qualified event analysts to identify events requiring more extensive investigation, either as an individual event or as part of a systematic evaluation of the safety of specific groups of devices. Certain patient-specific information is collected, such as patient age or birth date, weight, sex, and a non-standard patient identification number used by a user facility. Reporting instructions specifically instruct the reporting hospitals, device manufacturers, device distributors, and any voluntary reporters not to include patient names, names of attending medical personnel, social security numbers, drivers license numbers or other personally identifiable information in response to specific questions or to imbed this information in descriptions of events. References to patient names and attending medical personnel are replaced with generic terms such as "the patient", "the doctor", etc. The patient data is never released to the public and is not used to track patients. It collected solely to provide a complete picture of the adverse event.

**11 Explain why the information is being collected.**

This data is collected to monitor the safety of medical devices in use in the United States. Every effort is made to determine the safety and efficacy of medical devices prior to their being marketed in the United States. These issues are addressed in the pre-market requirements for bringing a device to market. However, determination of device safety is based upon clinical trials, and the historical experience with similar devices. Once a device is introduced into widespread general use, previously unidentified safety issues may become known. The adverse event reporting process is intended to provide the FDA with a mechanism to monitor the frequency and severity of medical device related adverse events which could cause the safety of device to be re-evaluated, requiring changes to the device, its labeling, or even removal of the device from the market.

**12 Identify with whom the agency will share the collected information**

Information about performance of devices is shared with the public, and may be shared with other governmental agencies, both foreign and domestic. Patient information is not shared. The location of events is not shared.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER AERS

- 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 OMB-approved paper forms. Provisions exist to receive reports by fax and approved similes of the approved government form. For emergency reporting, provisions exist to receive an adverse event report by phone. The Safe Medical Devices Act defines which organizations are required to report. The OMB-approved forms translate the reporting requirements contained the SMDA into discrete data elements. There are instructions that accompany the forms, which explain how to complete and return them to FDA. In addition, voluntary reporting is encouraged within the medical community by those who are not legally required to report adverse events. Web based voluntary submittal processes are being developed within HHS for various component agencies that collect different kinds of adverse event data. Web based mandatory reporting processes are in early stages of design and development.
- 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 is not collected on the Internet at this time. No information is collected from children.
- 15 Describe how the information will be secured.
- Persons accessing the data must be authorized, present a valid ID, and be authenticated. Only FDA and selected HHS oversight employees are granted accounts. Within the production environment, assigned privileges determine account access. The system is not directly accessible outside the FDA network
- 16 Describe plans for retention and destruction of data collected.
- In the past, the paper forms were retired to federal storage facilities. Currently forms are being stored as digital images. All paper records and computer data is retained indefinitely. Data can be archived and destroyed based on the Federal Records Retention schedule. To date, FDA has chosen to retain all of the information.
- 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 system of records is being created.
- 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 CDER AERS

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 CDER COMIS

### Question:

### Response:

- |    |   |  |
|----|---|--|
| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-10-27   |
| 2  | HHS Agency (OPDIV):   | FDA/CDER   |
| 3  | Title of System or Information Collection:  | Center-wide Oracle Management Information System (COMIS)   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Existing   |
| 5  | Unique Project Identifier Number:   | 009-10-01-03-02-0210-00-110-032  |
| 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.   | COMIS is a legacy system that primarily contains tracking information about products under review. The data is non-public information and it's strictly controlled. It contains no Privacy information with the exception of the module known as the Bioresearch Monitoring Information System (BrmIS). This module contains identification of clinical investigators along with identifying information. The database is used for investigatory purposes and is therefore exempt from the Privacy Act. Because this database contains individual names of investigators and personal identifiers, access to it is strictly limited. Food, Drug and Cosmetic Act is the legislative authority for this activity. |
| 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 is submitted as part of New Drug Applications. The information is for investigatory purposes and is therefore exempt from the Privacy Act.   |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER COMIS

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|--|---|
| <b>11 Explain why the information is being collected.</b>  | The information is collected for investigatory purposes only.   |
| <b>12 Identify with whom the agency will share the collected information</b><br>.  | The non-public information is not shared with anyone.   |
| <b>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.</b> | The information is obtained via the FDA 1571, Claimed Exemption from a New Drug; i.e., Investigational New Drug. Clinical investigators provide the information as part of the submission   |
| <b>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)</b>   | No.   |
| <b>15 Describe how the information will be secured.</b>  | The Privacy information is not shared with anyone. Access to it is strictly controlled. Access is only granted to staff members of the Division of Scientific Investigations in CDER/FDA. Access is only granted on request of the program and after approval by the CDER Information Systems Security Officer. |
| <b>16 Describe plans for retention and destruction of data collected.</b>  | Required retention schedules are followed.  |
| <b>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.</b>   | The BrmIS module, which is the only part of COMIS containing personal identifiers, is exempt under Title 21, vol1, section 21.61(f). A specific exemption was provided because of the investigatory nature of the system.   |
| <b>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</b>   | Betty B. Dorsey   |
| <b>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</b>   | Mark B. McClellan, M.D., Ph.D.  |
| <b>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</b>  | James J. Rinaldi  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER DFS

### Question:

### Response:

- |    |   |   |
|----|---|---|
| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-21  |
| 2  | HHS Agency (OPDIV):   | FDA/CDER  |
| 3  | Title of System or Information Collection:  | Division File System (DFS)  |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Existing  |
| 5  | Unique Project Identifier Number:   | 009-10-01-04-02-0209-00-110-032   |
| 6  | System of Records Number:   |   |
| 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.   | This system contains no Privacy Act information. DFS provides document management tracking, archiving, electronic signature, and search capabilities for internally generated review documents. The Food, Drug and Cosmetic Act is the legislative authority for this activity. |
| 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. | No data is collected this is an internal document management system.  |
| 11 | Explain why the information is being collected.   |   |
| 12 | Identify with whom the agency will share the collected information  |   |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER DFS

- 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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): 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 CDER DrugSafety

### Question:

### Response:

- |    |   |   |
|----|---|---|
| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-17  |
| 2  | HHS Agency (OPDIV):   | FDA/CDER  |
| 3  | Title of System or Information Collection:  | Drug Safety   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Existing  |
| 5  | Unique Project Identifier Number:   | 009-10-01-03-01-1010-00-110-032   |
| 6  | System of Records Number:   |   |
| 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.   | This is not a Privacy Act System of Record. This system contains little personal information but historically adverse reaction data submitted by physicians, hospitals and the public that contained personal identifiers and were keyed into the system. That practice was halted in 2002. 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. |
| 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 data is minimal and incidental and should not have been entered into the system and is no longer entered. Personal information sometimes appears on case reports completed and submitted by physicians, hospitals and the public. This personal information in the system is never shared. All reports that go outside of the Center are screened by FOI staff to assure that no sensitive or personal information is disclosed.  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER DrugSafety

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|--|---|
| <b>11 Explain why the information is being collected.</b>  | No information is collected.  |
| <b>12 Identify with whom the agency will share the collected information</b>   | This personal information is never shared. All reports that go outside of the Center are screened by FOI staff to assure that no sensitive or personal information is disclosed. Access to the information is strictly limited.   |
| <b>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.</b> | 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. |
| <b>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)</b>   | Not Applicable.   |
| <b>15 Describe how the information will be secured.</b>  | Access to the data is highly restricted and only accessible by safety evaluators, reviewing medical officers, and compliance staff.   |
| <b>16 Describe plans for retention and destruction of data collected.</b>  | Published schedules for retention are followed.   |
| <b>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.</b>   | No.   |
| <b>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</b>   | Betty B. Dorsey   |
| <b>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</b>   | Mark B. McClellan, M.D., Ph.D.  |
| <b>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</b>  | James J. Rinaldi  |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER EES

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-10-27
2 HHS Agency (OPDIV):	FDA/CDER
3 Title of System or Information Collection:	Establishment Evaluation System (EES)
4 Is this System or Information Collection new or is an existing one being modified?	Collection new or is an existing one being modified?
5 Unique Project Identifier Number:	009-10-01-03-02-0203-00-110-032
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.	This system contains no Privacy Act information. It contains non-public information concerning drug manufacturing site inspections and associated FDA conclusions and recommendations. Food, Drug and Cosmetic Act is the legislative authority for this activity.

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER EES

- 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.
- Through EES, the agency collects the following types of information: drug application and supplement numbers, drug manufacturer information (name, manufacturing site address), manufacturing site inspection request, inspection tracking information (e.g., scheduled, completed), ORA district office and CDER Office of Compliance recommendations based on inspection outcome. CDER drug application reviewers use this information while making decisions about approval/non-approval of drug applications. ORA field personnel also use this information to help determine whether or not imported drugs should be admitted into the country. EES captures a minimum of site inspection tracking and outcome information needed in order to assist FDA personnel in performing their jobs. The data is relatively high-level, and does not include the details of site inspection reports.
- 11 Explain why the information is being collected.
- 12 Identify with whom the agency will share 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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER EES

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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. |                                |
| 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 CDER IMTS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA/CDER
3 Title of System or Information Collection:	Industry Meeting Tracking System (IMTS)
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)?	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:	009-10-01-04-01-0302-00-110-032
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 CDER IMTS

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|--|--|
| <p>11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.</p>  | <p>The Industry Meeting Tracking System supports the scheduling of meetings between agency personnel and drug industry. IMTS allows CDER management to monitor performance against Prescription Drug User Fee Act (PDUFA) goals for industry-requested meetings and track meeting workload. In addition, IMTS supports tracking information for meetings that FDA requests with external constituents and also within the FDA internal organizations. The Food and Drug Administration Modernization Act (FDAMA) and the Prescription Drug User Fee Act (PDUFA III) are the legislation authorizing this activity.</p> |
| <p>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.</p>   | <p>In conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992, in November 1997 (PDUFA 2), the FDA agreed to specific performance goals (PDUFA goals) for the management of meetings between sponsors and applicants of PDUFA products. IMTS supports the scheduling of meetings between agency personnel and drug industry. IMTS allows CDER management to monitor performance against PDUFA goals for industry-requested meetings and track meeting workload. The system collects, maintains and/or disseminates no IIF.</p>  |
| <p>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</p>   | <p>N/A</p>   |
| <p>14 Explain why the IIF is being collected, maintained, or disseminated.</p>   | <p>N/A</p>   |
| <p>15 Identify with whom the agency will share the IIF.</p>  | <p>N/A</p>   |
| <p>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.</p> | <p>N/A</p>   |
| <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>N/A</p>   |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER IMTS

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|----|--|--|
| 18 | Describe how the IIF will be secured.  | N/A  |
| 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. | N/A  |
| 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 CDER POCA

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA
3 Title of System or Information Collection:	Phonetic Orthographic Computer Analysis System (POCA)
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)?	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:	009-010-01-03-02-211-00
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
11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The system calculates the similarity of proposed proprietary names to proprietary names on the market. Confusion of names that are too similar leads to drug errors. The legislative authority to regulate proprietary drugs names is derived from the Federal Food Drug and Cosmetic Act section 502. This is further expanded on in 21 Code of Federal Regulations (CFR) 201.10 (5).

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER POCA

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| <p>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.</p>   | <p>The agency collects drug names that are already on the market. Before approval any new proprietary drug names are compared to the list of marketed proprietary drug names and evaluated for drug safety in light of possible drug errors caused by similar names. All proprietary names on the market are collected along with any proposed new names. This is the minimum information that is needed to ensure drug safety in drug proprietary names. There is no IIF collected.</p> |
| <p>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</p>   | <p>N/A</p>   |
| <p>14 Explain why the IIF is being collected, maintained, or disseminated.</p>   | <p>N/A</p>   |
| <p>15 Identify with whom the agency will share the IIF.</p>  | <p>N/A</p>   |
| <p>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.</p> | <p>N/A</p>   |
| <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>N/A</p>   |
| <p>18 Describe how the IIF will be secured.</p>  | <p>N/A</p>   |
| <p>19 Describe plans for retention and destruction of IIF.</p>   | <p>N/A</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>N/A</p>   |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER POCA

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 CDER PREATS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA
3 Title of System or Information Collection:	Pediatric Research Equity Act Tracking System (PREATS)
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:	009-10-01-03-02-0211-00
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
11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The Pediatric Research Equity Act Tracking System (PREATS) supports the task of tracking all pediatric waivers, deferrals and completed studies. The Pediatric Research Equity Act requires conduct of pediatric studies for certain new and marketed drugs and biological products in the pediatric population. Users must indicate the whether studies are waived, deferred or completed for the applications subject to this requirement and follow-up on any action taken on applications under the authority of this Act.

## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CDER PREATS

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| <p>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.</p>   | <p>In order for the Agency to carry out the tasks that were set forth under PREA, a tracking mechanism was necessary to capture the required information. Therefore a Pediatric Research Equity Act Tracking System (PREATS) was developed accomplish the task of tracking all pediatric waivers, deferrals and completed studies for applications subject to PREA. This system will improve the efficiency and timeliness of pediatric drug development and review and enable the users of the system, OCTAP and the review division Project Managers, to better track and manage the actions taken on pediatric drug applications. In addition, the system allows users to enter new Pediatric information, research on pediatric information and report effectively and accurately to Congress. By having the Project Managers input waivers, deferrals and completed studies into the tracking system, the Agency will be to answer inquiries from Congress and others. The system contains no IIF.</p> |
| <p>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</p>   | <p>N/A</p>  |
| <p>14 Explain why the IIF is being collected, maintained, or disseminated.</p>   | <p>N/A</p>  |
| <p>15 Identify with whom the agency will share the IIF.</p>  | <p>N/A</p>  |
| <p>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.</p> | <p>N/A</p>  |
| <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>N/A</p>  |
| <p>18 Describe how the IIF will be secured.</p>  | <p>N/A</p>  |
| <p>19 Describe plans for retention and destruction of IIF.</p>   | <p>N/A</p>  |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER PREATS

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| 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. | N/A  |
| 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 CDER SPL

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA
3 Title of System or Information Collection:	Structure Product Labeling (SPL)
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)?	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:	009-10-01-02-01-0303-00-110-032
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 CDER SPL

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| <p>11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.</p>  | <p>The FDA Structure Product Labeling project will provide an environment to receive and store labeling Content and information From Pharmaceutical companies. The system will also provide reviewers with the ability to retrieve, review, compare, edit and approve labeling changes online. The SPL project directly supports FDAs role in developing uniform data standards for the use of the electronic health record. This project also directly supports the FY 2003 FDA Strategic Action Plan. The legislation authorizing this project is the FDA Modernization Act and the Prescription Drug User Fee Act.</p>   |
| <p>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.</p>   | <p>Within the proposed FDA SPL project the Agency will use the system and the collected information as listed below: · Manufacturers submit labeling content and content changes to FDA in a standard electronic format · FDA receives labeling and listing changes from manufacturers and imports the information into an electronic labeling repository · FDA processes the labeling content and changes using SPL review and workflow management tools that access the electronic repository · FDA exports up-to-date SPL to the NLM on a daily basis · NLM disseminates the medication information to healthcare information suppliers who make it available to the public.</p> |
| <p>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</p>   | <p>N/A</p>  |
| <p>14 Explain why the IIF is being collected, maintained, or disseminated.</p>   | <p>N/A</p>  |
| <p>15 Identify with whom the agency will share the IIF.</p>  | <p>N/A</p>  |
| <p>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.</p> | <p>N/A</p>  |
| <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>N/A</p>  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDER SPL

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| 18 | Describe how the IIF will be secured.  | N/A  |
| 19 | Describe plans for retention and destruction of IIF.   | N/A  |
| 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. | N/A  |
| 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 review **               |
| 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 CDRH eRAD

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	FDA/Center for Devices & Radiological Health
3 Title of System or Information Collection:	eRadHealth
4 Is this System or Information Collection new or is an existing one being modified?	Existing, being modified
5 Unique Project Identifier Number:	009-10-01-05-01-0201-00-110-032
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	0910-0025, expires 11/30/03 (extension requested, Federal Register Notice dated October 7, 2003)
8 Other Identifying Number(s):	n/a



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH eRAD

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

The eRadHealth project is an automated knowledge management system to monitor and assure safety of man-made radiation from electronic products, administered by the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). The system provides a mechanism for exchange of technical data on radiation-emitting electronic products. The data and records are needed by FDA and State governments to make decisions on safety and radiation controls to reduce health risks, and to take actions to protect the public from radiation hazards presented by electronic products. The eRadHealth system is being developed to replace the existing paper files and 33 year-old tracking data system. It provides a means for preparing, submitting, accepting, storing, retrieving, reviewing, and replying to radiation safety product data and reports using electronic formats. The system consists of an electronic submission module for customers, a loader/security module, a database with search and query tools, a reviewer module, and a data compilation and display for customers and stakeholders. The system is authorized by the Radiation Control for Health and Safety Act of 1968, now Sections 532-542 of Electronic Product Radiation Control of the Food, Drug, and Cosmetic Act (U.S.C. 360ii-ss).

**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 data collected consists of radiation emissions; product operational characteristic and safety performance; manufacturing, quality assurance and radiation testing programs; locations of products; and product corrections. The following privacy information may be included: Public: name/age/gender/number of persons exposed to radiation during an adverse event, type of injury/complaint incurred during adverse event, and name/location/contact information of individuals reporting an adverse event; Employee: name/title/location/contact information of responsible individuals in regulated industry, and name/organization of FDA employees and State employees involved in submitting or reviewing data. The use of data is both relevant and necessary. Work processes and use conditions are documented and verified prior to requesting submission of data. All data supports the mandates and authorities under the Radiation Control for Health and Safety Act.

**11 Explain why the information is being collected.**

The FDA, States, and a few other Federal agencies need data to determine risk of exposure to the public and workers of radiation from electronic products. Those agencies and regulated industry also need data to make decisions about how and when products need to be corrected to protect public health and safety or the public needs additional safety information to encourage actions to reduce or eliminate radiation exposures.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH eRAD

- 12 **Identify with whom the agency will share the collected information**
- .
- Data on product locations are shared with States, so they may conduct radiation emission and product safety tests in partnership with FDA. Data on radiation emissions and radiation controls are shared with State Radiation Control Programs and Federal agencies, such as Transportation Security Administration, Department of Defense, National Institute for Occupational Safety and Health, Federal Aviation Administration, and National Aeronautics and Space Administration, for making risk management determinations. Data on manufacturers and importers and the compliance status of their products are shared with U.S. Customs so they can efficiently determine admissibility into U.S. commerce or refusal of foreign-made products.
- 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.**
- 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.
- 15 **Describe how the information will be secured.**
- Information is secured and controlled by limiting access to authorized users based on work assignments directly related to the specific data. By providing physical safeguards such as building guards and locked rooms and cabinets where data is stored or used and limiting access to authorized persons having current security clearance. By providing procedural safeguards such as requiring users to attend regular training and sign security agreements to protect personal and proprietary information from the public and unauthorized personnel and by technical safeguards including personal identifiers, periodic expiration of authentication mechanisms, system capture of the user identifier and time with all data changes, multiple audit trails, and regular examination of the anomaly monitors.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH eRAD

- 16 **Describe plans for retention and destruction of data collected.** Retention and destruction of data follows the CDRH Data Retention Plan dated February 2003. Paper documents are shredded and computer tapes erased and demagnetized after: 18 years for radiation safety product reports, 20 years for microform copies of laboratory test results and general correspondence, 25 years for other microform copies, 25 years for compliance case files, 7 years for annual reports, 6 years for exemption/variance requests, field test forms or assembler certification forms, and 5 years for adverse event reports and product defect actions.
- 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.** A system of records is not being created for this project because it does not purposely retrieve data by personal identifiers.
- 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 CDRH Image2000

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	FDA/CDRH
3 Title of System or Information Collection:	Image 2000
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-05-01-1030-00-110-032
6 System of Records Number:	
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.	<p>Under the Medical Device Amendments of 1976, manufacturers of medical devices including but not limited to x-ray machines, pace makers and breast implants, are required to submit applications to the FDA for approval to ensure that these products are safe, effective, and labeled properly before they become available on the market . The Image 2000 system is a document management system that is used as a storage and archival repository of all pre- and post market surveillance information including premarket submissions, decision letters, and correspondence, as well as adverse event reports and supplemental documentation. Under the 1976 medical device amendments to the Food, Drug, and Cosmetic act, the Food and Drug Administration is mandated to collect and analyze manufacturer data related to the safety and efficacy of medical devices before they may be marketed in the US.</p>



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH Image2000

- 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.**
- Paper and electronic submissions of technical and administrative data, letters, and reports from regulated industry, and FDA employees are collected. This information is used to decide whether the device is safe, effective, and properly labeled before allowing the manufacturer to market their product or products. In addition, the FDA's final decision letter and any correspondence or supplemental information is stored with the original submission information.
- 11 Explain why the information is being collected.**
- The information contained in Image 2000 represents the official record of these submissions from manufacturers. This includes Premarket Notifications 510(k), Premarket Approvals (PMAs), Investigational Device Exemptions (IDEs), labeling data, medical device reporting, and establishment registration and medical device listing forms. In addition, all FDA decision letters and any supplemental information requested from the manufacture are stored in Image 2000. This information is scanned and indexed using OCR technology to assist CDRH reviewers with all pre and post market surveillance of medical devices. CDRH policy requires that official records be maintained for a period of 30 years.
- 12 Identify with whom the agency will share the collected information .**
- The information contained within the Image 2000 system is available only to FDA employees that obtain a CDRH user account. However, under the Freedom of Information Act, information contained within Image 2000 can be requested for review. These requests are obtained through the CDRH Office of Systems and Management, which redact any personal or proprietary information before sending a FOI-releasable copy of the submission to the requestor.
- 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.**
- Currently, the FDA receives submission information in either electronic or paper form from the device manufacturers. Once received, the submission is entered into a tracking database separate from the Image 2000 system. At this time, CDRH employees are notified of the submission and the original paper submission is scanned into the Image 2000 system and is available for review or the electronic version is indexed and scanned for OCR (optical character recognition) which allows the user to conduct key word searches on the entire submission. Under the Freedom of Information Act, the public may request a copy of the submission information contained within the Image 2000 system. However, prior to releasing this information, the submission records are reviewed by the CDRH Office of Compliance to redact any non-releasable data. The submission file is then sent to the manufacturer for pre-disclosure review. It is then the responsibility of the manufacture to further redact any information that is not releasable to the public. Once a pre-disclosure form is received from the manufacture and any PII is redacted from the submission, the report will be forwarded to the FOI requestor.



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CDRH Image2000

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| <b>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)</b>                 | No information is collected from children under age 13.   |
| <b>15 Describe how the information will be secured.</b>  | The Image 2000 is located on the FDA/CDRH network and is only available to authorized FDA employees who must provide valid identification and be authenticated.   |
| <b>16 Describe plans for retention and destruction of data collected.</b>  | Currently, the retention period is 30 years and the data is backed up nightly. Official copies of paper documents are shredded and computer tapes are erased and demagnetized at the end of the retention period. The procedures are documented in the CDRH Records Retention Plan dated February 2003. |
| <b>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.</b> | The FDA Privacy Act counsel advised that only systems that purposely collect, store data by, or retrieve data by personal identifiers are subject to the provisions of the Act. The Image 2000 system does not meet these conditions, so a system of records has not been published.                    |
| <b>18 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</b>   | Betty B. Dorsey   |
| <b>19 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency Head (sign and date):</b>   | Mark B. McClellan, M.D., Ph.D.  |
| <b>20 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the Agency CIO (sign and date):</b>  | James J. Rinaldi  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH MEDSUN

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-05
2 HHS Agency (OPDIV):	FDA/Center for Devices & Radiological Health
3 Title of System or Information Collection:	Medical Product Surveillance System (MedSun)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-05-02-1020-00-110-030
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	0910-0471, July 31, 2004
8 Other Identifying Number(s):	n/a

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH MEDSUN

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

The Medical Product Surveillance Network (MedSun) is an Internet-based system under which health-care facilities have volunteered to submit reports of adverse events involving medical devices in that facility. Participating facilities, representing hospitals, nursing homes, outpatient treatment and diagnostic centers, each designate a person(s) to submit these reports. Under section 519 of the Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 360(i)), FDA is authorized to require: manufacturers to report medical device related deaths, serious injuries, and malfunctions; and user facilities (hospitals, nursing homes, ambulatory surgical facilities and outpatient diagnostic and treatment facilities) to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA) amended Section 519(b) of the Food, Drug and Cosmetic Act (the act) (21U.S.C. 360I(b)). This amendment mandated the replacement of universal user facility reporting by a system that is limited to a subset of user facilities that constitutes a representative profile of user reports for device related deaths and serious injuries. FDA has implemented MedSun as a pilot program to implement FDAMA. Participating sites fulfill their adverse event reporting obligations by participating in MedSun.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH MEDSUN

**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 related to adverse events occurring with the use of medical devices. This includes some very general information about the patient involved in the event: age or date of birth; weight; and sex. No personal patient identifiers are collected in the report that could directly identify the patient, i.e. no patient name or social security number is collected. The reporting facility assigns an identifier to the report that will not identify the patient. Only the minimum data necessary about the patient to determine the safety and effectiveness of the device is collected. Information about the device is collected: manufacturer information (name and address); and device identifiers, such as brand name and serial number. This information is the minimum needed to contact the manufacturer to determine the degree of manufacturer follow-up that is taking place related to the event. Information about other aspects of the medical care that could have affected the safe and effective use of the medical device is collected, such as other devices or therapies being used at the time of the event. Information about tests that may have been performed following the event, which may assist in determining the role of the device, is collected. This is the minimum information to determine the role of the medical device and the role of other contributing factors to an adverse event. The name and address of the reporting institution is collected along with the name, work address, and email address of the reporter from that institution. This information is required for FDA to follow-up with the reporter to obtain any needed additional information about the event.

**11 Explain why the information is being collected.**

FDA is the regulatory agency responsible for the safety and effectiveness of medical products including medical devices and radiological products. Important questions about medical devices, such as those concerning user experience, durability, and rare effects may not be answered until after the device has been marketed. To protect the public health, FDA must be able to rapidly collect information pertaining to adverse events associated with medical devices after they have been marketed. As noted in answer to question #1, FDA is required to obtain information about problems with medical devices from user facilities. MedSun is a pilot program, which collects device information from a subset of facilities that are required to report to FDA.



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CDRH MEDSUN

- 12 Identify with whom the agency will share the collected information .
- Only FDA analysts and scientists have the necessary identification and authentication mechanisms to review the reported information to determine problems with the use of medical devices. Under 519 of the Food Drug, and Cosmetic Act, FDA may only share this information with the device manufacturer who manufactured the device discussed in the report; with employees of the Department of Health and Human Services; with the Department of Justice; or with duly authorized committees and subcommittees of the Congress. No personal identifying information is shared with the public (under the Freedom of Information Act).
- 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 MedSun program recruits hospitals (and associated home care agencies, outpatient treatment and diagnostic centers) and nursing homes to participate in this Internet-based reporting program. Each participating facility provides at least two MedSun representatives who are authorized by FDA to access the reporting form on a secure Internet site. Once these MedSun representatives are authenticated on the web server, they may complete the website's reporting form with information concerning problems that have occurred in their facilities with the use of medical devices. As part of the reporting process, the site collects the reporter's name and email address. The reporters may access their own reports but cannot access any information sent in by any other reporting site. The reporters attend a three-hour training and orientation session where all aspects of the program are discussed with them. They also receive written information about the rules of disclosure (rules of disclosure, described in # 3, above, are defined by statute for the mandatory reports □ Section 519 of the Food Drug and Cosmetic Act - and by regulation for the voluntary reports □ 21 CFR, Part 20). This is not a new data collection. The Internet site is a web version of the paper 3500A Mandatory Reporting form (OMB NO: 0910-0291; expiration date 3/31/05) with a few additional questions (not personal identifying information), that reporters are not required to answer. Participating sites are required to report incidents involving death or serious injuries, and are encouraged to voluntarily report potential for harmful events. This Internet program is OMB NO: 0910-0471 (expiration date: 07/31/2004). Part of this OMB clearance process included a 60-day time frame for 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. Only designated, authorized, and authenticated users have access to the site.



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CDRH MEDSUN

- 15 **Describe how the information will be secured.** The designated reporters at the reporting facilities use end-to-end encryption to submit data to the Internet site, which resides behind a firewall. All reporters and users of the system agree to Rules of Behavior. Users of the system must be authorized and authenticated. Access to information is determined by assigned level of access such that designated reporters from each participating site may view their own reports, but may not view reports sent from any other facility. FDA and contractor users must be authorized and provide proper identification and authorization to access the data for analysis purposes. All users sign a non-disclosure agreement.
- 16 **Describe plans for retention and destruction of data collected.** The National Archives and Records Administration have cleared plans for data retention and destruction on September 24, 2002 (#N1-088-027). Record retention for the data files in the database stipulate that there is an annual cutoff every year and the records for that year will be deleted thirty years after the date of cutoff.
- 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. This system is not a system of records under the Privacy Act.
- 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 CDRH MPRIS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	FDA/CDRH
3 Title of System or Information Collection:	Mammography Program Reporting and Information System (MPRIS)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-05-01-1010-00-204-079
6 System of Records Number:	09-10-0019
7 OMB Information Collection Approval Number and Expiration Date :	0910-0309, 02/29/2004
8 Other Identifying Number(s):	n/a

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH MPRIS

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

On October 27, 1992, the United States Congress amended the Public Health Service Act by enacting Public Law 102-539, the Mammography Quality Standards Act (MQSA) of 1992 (42 U.S.C. 263b). The Act was reauthorized on October 9, 1998. The MQSA amended Part F of Title III of the Public Health Service Act (The PHS Act) by adding a new section requiring that a comprehensive statutory mechanism for certification and inspection of all mammography facilities in the United States (except facilities of the Department of Veterans Affairs) be established. After October 1, 1994, under MQSA, all facilities are: required to be accredited by an approved accreditation body; certified by the FDA; and inspected annually in order to legally provide mammography services in the United States. FDA is also responsible for monitoring and tracking inspection compliance. To respond to the responsibilities of implementing the MQSA for the approximately 10,000 FDA-certified facilities in the U.S., the FDA established the Division of Mammography Quality and Radiation Programs (DMQRP) in the Center for Devices and Radiological Health. The Mammography Program Reporting and Information System provide information technology support for the business function.

- 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 Food and Drug Administration maintains a System of Records: 09-10-0019, "Mammography Quality Standards Act (MQSA) Inspector Profile System, HHS/FDA/CDRH" (formerly the "Mammography Quality Standards Act (MQSA) Training Records"). This system of records is used to provide FDA with information about the training, certification, recertification, and performance of MQSA inspectors for the purpose of implementing the Mammography Quality Standards Act of 1992. The category of records kept in the system also includes audits and evaluations of the inspector's field performance, and inspector continuing education. The amount of information recorded on each individual is only that which is necessary to accomplish the purpose of the system. Records of continuing education and evaluations of an inspector's field performance are added as the information becomes available. Authorized users are FDA employees and contractors responsible for training the individuals who will inspect mammography facilities, and personnel in the Division of Mammography Quality and Radiation Programs (DMQRP) who will compile and analyze the test and personal data of the students.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH MPRIS

**11 Explain why the information is being collected.**

The United States Congress amended the Public Health Service Act by adding a new section requiring that a comprehensive statutory mechanism for certification and inspection of all mammography facilities in the United States (except facilities of the Department of Veterans Affairs) be established. After October 1, 1994, under MQSA, all facilities are: required to be accredited by an approved accreditation body; certified by the FDA; and inspected annually in order to legally provide mammography services in the United States. FDA is also responsible for monitoring and tracking inspection compliance. In addition, the MQSA, in part, directs the Secretary of Health and Human Services (FDA, by delegation) to establish a program to qualify, train, and monitor the performance of State and Federal MQSA inspectors. All information is collected in order to fulfill the requirements of the MQSA.

**12 Identify with whom the agency will share the collected information**

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Disclosure may be made to a congressional office from the records of an individual, in response to an inquiry from the congressional office made at the request of that individual. Disclosure may be made with the individual's supervisor since MQSA inspections are a significant part of many inspectors' job. This disclosure includes an inspector's performance while conducting inspections, in addition to performance in training classes, since it is an important element of information to help the supervisor determine employee assignments as well as the level of supervision needed. Disclosure may be made to contractors for the purpose of collecting, compiling, aggregating, analyzing, or refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records.

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH MPRIS

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.

Individuals on whom the record is maintained and training and performance records pertaining to that individual. The individual provides such information before training begins, and after they have signed a Privacy Act consent form that describes the reasons for collecting the data and the routine uses of it. The Division of Mammography Quality and Radiation Programs generate information about certification renewal or withdrawal in-house. Sources of information about field performance could include the inspector's supervisor, as well as any investigation of an inspector's performance as a result of an inspector's performance as a result of complaints by a mammography facility. An individual may learn if a record exists about him or her upon written request, with notarized signature if request is made by mail, or with identification if request is made in person, directed to: FDA Privacy Act Coordinator (HF1-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Record access procedures: Same as notification procedure. Requests should also reasonably specify the record contents being sought. The individual may also request an accounting of disclosures that have been made of their record, if any.

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



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CDRH MPRIS

- 15 **Describe how the information will be secured.** Authorized users are only Personnel of the Division of Mammography Quality Reporting Program who are engaged in the training and supervision of the individuals who inspect mammography facilities; FDA personnel who compile and analyze the test, personal data, continuing education, and work performance of the inspectors; the supervisors of those personnel; and contractors hired by FDA to implement the training program. All records (such as diskettes, computer listings, or documents) are kept in a secured area, locked rooms, and locked building. End users and system professionals continue to receive regular training in information systems security and have signed an agreement indicating their cooperation with FDA policies. Users are further instructed on system security during training sessions for this application and in accordance with the Privacy Act. Users of personal information in the performance of their duties have been instructed to protect personal information from public views and from unauthorized personnel. All reports containing confidential data are marked ``confidential". CDRH SOP requires that all reports containing confidential information be shredded before disposal. All users have individual identifiers and regularly expiring, complex passwords. Application level access controls are enforced and all users are assigned access based on their needs and authority. Upon a job change, a user's authorization is reviewed and changed as necessary. All changes to data, as well as the time of change and the user's identifier are captured. All data entered online is edited and checked.
- 16 **Describe plans for retention and destruction of data collected.** Records are retained for five years after the certified MQSA inspector leaves government service. At the end of five years, in individual's paper records are shredded and automated records are erased.
- 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.** System Number: 09-10-0019 Title: Mammography Quality Standards Act (MQSA) Inspector Profile System, HHS/FDA/CDRH (currently a system alteration is under review)
- 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 CDRH Premarket

### Question:

### Response:

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| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-19   |
| 2  | HHS Agency (OPDIV):   | FDA/Center for Devices and Radiological Health   |
| 3  | Title of System or Information Collection:  | CDRH Pre-Market Tracking   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Existing   |
| 5  | Unique Project Identifier Number:   | 009-10-01-04-02-1050-00  |
| 6  | System of Records Number:   |  |
| 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.   | This system collects information about the receipt, review process, and review outcome of medical device pre-market submissions received by the FDA. Medical device pre-market submissions are mandated by the 1972 medical device amendments to 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 information collected for this system is primarily a computer record of the receipt of a pre-market submission for a medical device. Information identifying the device, the applicant, the submitter, the manufacturing site, and the intended use of the device are taken from the pre-market submission. Most of the data in the system is administrative data, detailing the FDA review process, generated by FDA, and is not data from the pre-market submission. Submitters do provide the names of contact individuals. These individuals are contacted, as necessary, to answer questions, provide additional information, and facilitate the prompt review of the submission. |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH Premarket

- 11 Explain why the information is being collected.
- 12 Identify with whom the agency will share the collected information  
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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.
- 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)
- 15 Describe how the information will be secured.
- 16 Describe plans for retention and destruction of data collected.
- 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): 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 CDRH RLS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-19
2 HHS Agency (OPDIV):	Food and Drug Administration/Center for Devices & Radiological Health
3 Title of System or Information Collection:	Medical Device Establishment Registration and Device Listing Process
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-04-02-1030-00
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	0910-0387, March 31, 2005
8 Other Identifying Number(s):	n/a
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	Section 510 of the Food, Drug and Cosmetic Act as amended authorizes and requires the Food and Drug Administration to collect information on all medical device establishments that market medical devices in the United States. The act requires that medical device establishments register their physical location, and to list the devices manufactured or processed at this physical location with FDA. The act specifies that all collected information is FOI-releasable. This system is a collection of databases that store information that FDA regulated medical device establishments are required to submit to comply with the reporting requirements specified in 21 CFR 807. The information is retained forever in a combination of historical tables and current data files.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH RLS

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| <b>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.</b>  | The information collected identifies the name and physical location of the establishment, the establishment's owner or operator, an Official Correspondent, other business trading names, and who the United States agent is. The information collected identifies what category of device is manufactured or processed at a registered establishment. The Official Correspondent and United States agent are business contacts. FDA collects their name, company name, address, phone and fax numbers, and e-mail address. This information is not considered to be personal privacy information since it is solely used to contact the regulated establishment regarding FDA matters. Extensive analysis of the burden of collecting this information, has limited the data collected to the information that FDA needs to carry out its regulatory responsibility to inspect and monitor the compliance of medical device establishments. |
| <b>11 Explain why the information is being collected.</b>  | n/a  |
| <b>12 Identify with whom the agency will share the collected information</b><br>.  | n/a  |
| <b>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.</b> | n/a  |
| <b>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)</b>   | n/a  |
| <b>15 Describe how the information will be secured.</b>  | n/a  |
| <b>16 Describe plans for retention and destruction of data collected.</b>  | n/a  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CDRH RLS

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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. | n/a  |
| 18 | The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):   | Medical Device Establishment Registration and Device Listing Process |
| 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 CFSAN CAERS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-17
2 HHS Agency (OPDIV):	FDA/CFSAN
3 Title of System or Information Collection:	CFSAN Adverse Events Reporting System (CAERS)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-06-01-1020-00-110-030
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
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	CAERS goal is to improve consumer protection with safety assessments on adverse food events. It also tracks what products and ingredients may be harmful and conveys this information to industry and consumer complainants. CAERS provides a centralized-comprehensive means for the timely capture, evaluation, and mitigation of adverse event reports involving foods, cosmetics and dietary supplements. This information is an integral aspect of the Agency's program to monitor and identify potential public health issues that may be associated with the use of a particular product already in the market place. Given today's heightened sensitivity to bio-terrorism, early identification is critical and essential to protect the public health and safety.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN CAERS

- 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.**
- Consumers or patients that experience injury/illness and report a complaint (Adverse Events) alleging that it is due to a product regulated or monitored by Center for Food Safety and Applied Nutrition (CFSAN). These voluntary adverse event complaints are received from various sources, including consumers, other government agencies, Congress on behalf of their constituents, trade associations, etc. Complaints of adverse events for foods, cosmetics and dietary supplements are received in written format, FDA □ MedWatch 3500, by telephone or a visit (reference Field Management Directive FMD-119.). Adverse event reports and other related medical information obtained through field investigation/follow-up is made available for medical officers to review for potential terrorism activity or analyze for potential public health risk for CFSAN regulated products.
- 11 Explain why the information is being collected.**
- CAERS is part of CFSAN□s Strategic Plan□s - Strategic Goal 3.5: Reduce the health risks associated with food and cosmetic products by preventing human exposure to hazards, monitoring product quality and correcting problems that are identified. Adverse event reporting is included as an essential program under this goal. Once food and cosmetic products are commercially available to consumers, it is important to monitor and evaluate adverse events associated with the consumer use of these products. As part of this mission, CFSAN performs post-market surveillance by assembling and monitoring adverse events resulting from the use of the following: · cosmetics, · traditional foods, · food and color additives, · Generally Recognized as Safe (GRAS) ingredients, · special nutritional products including dietary supplements, · medical foods, and · infant formulas While a small portion of these products has mandatory pre-market approval, pre-market notification, and/or post-market surveillance requirements, most of these products, notably dietary supplements, have no such requirements.
- 12 Identify with whom the agency will share the collected information**
- Information processed and stored in the CAERS surveillance repository is made available indefinitely for medical officers to review for potential terrorism activity or analyze for potential public health risk for CFSAN regulated products. Additionally, information is also shared based in accordance with the Freedom of Information Act (FOIA) and Congressional requests.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN CAERS

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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>CAERS does not collect information from individuals, therefore correspondence activities with the source of information, FACTS and MedWatch is not applicable. Agency Interconnection Agreements have been established to ensure secure information exchange and management.</p> <p>This system does not collect information from individuals or children under the age of 13.</p> <p>Access to information contained within CAERS is restricted through policy guidelines that govern implementation of password and other restrictions designed to limit access to role-based functions.</p> <p>The data contained in this application are held indefinitely. Information is not eliminated.</p> <p>n/a</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 CFSAN COLORS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA
3 Title of System or Information Collection:	Colors Certification System
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)?	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:	009-10-01-05-02-0202-00
8 System of Records Number:	N/A
9 OMB Information Collection Approval Number and Expiration Date:	OMB 0910-0216, 08/2004
10 Other Identifying Number(s):	Form FDA 3000
11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The Colors Certification system supports Colors Certifications in accordance with CFR Title 21, Parts 70 and 73. Colors Certification data is exported to the CFSAN web servers so that seventeen industrial users may view data on their own petitions. Requestors for Color certification will have access only to their own data on a separate public web site. All other data is restricted to the Office of Cosmetics and Colors.



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN COLORS

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| <b>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.</b>   | The CFSAN and FDA staff uses this data to enforce Section 721, Subpart B of the Food and Drug Act. The information collection is necessary to ensure the name and location of the color manufacturer, where the color additive is being stored, and how the color was made. The information contain no IIF. |
| <b>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</b>   | N/A   |
| <b>14 Explain why the IIF is being collected, maintained, or disseminated.</b>   | N/A   |
| <b>15 Identify with whom the agency will share the IIF.</b>  | N/A   |
| <b>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.</b> | N/A   |
| <b>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)</b>   | N/A   |
| <b>18 Describe how the IIF will be secured.</b>  | N/A   |
| <b>19 Describe plans for retention and destruction of IIF.</b>   | N/A   |
| <b>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.</b>   | N/A   |
| <b>21 The Privacy Analysis Worksheet and PIA Summary have been reviewed and endorsed by the OPDIV Privacy Contact (Sign and Date):</b>   | Betty B. Dorsey FDA Privacy Act Officer   |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN COLORS

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 CFSAN FARM

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-17
2 HHS Agency (OPDIV):	FDA/CFSAN
3 Title of System or Information Collection:	Food Additives Regulatory Management (FARM)
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-06-01-1010-00-110-032
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	· 0910-0016 Food Additive Petitions <input type="checkbox"/> Expiration: 10/31/2003
8 Other Identifying Number(s):	n/a



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN FARM

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

The FARM Project's electronic information management system is designed to support the electronic processing, review, maintenance, and reporting for food ingredient submissions. This includes the management of food and color additive petitions, Food Contact Notifications (FCNs), Generally Recognized as Safe Notices (GRNs) and Biotechnology Consultations (BNFs), by providing modern electronic information management tools necessary for the food ingredient reviewers and managers to maximize their productivity. FARM allows reviewers to spend more time reviewing submissions, since they spend less time searching for, processing, and sharing information. FARM also allows reviewers to utilize state-of-the-art analytical and search tools to support safety reviews, evaluations, and decisions. FARM is currently able to support industry electronic submission of food ingredient submissions and correspondence in a consistent/standard electronic format further improving efficiencies for industry and the FDA. Freedom of Information (FOI) requests and other communications disclosing information to industry and consumers are done electronically through the FARM System. The FARM system provides:

- Efficient desktop information retrieval and processing
- Workload management
- Step-by-step tracking capability for all aspects of the submission and review processes
- Analytical tools on the desktop to link all information pertinent to the review
- Expanded capability to access online scientific databases
- Capability to capture the data necessary to compare performance of base-line system, established in FY 2001, against performance levels/metrics of the previous five years.

- 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 FARM System collects information from the food industry on ingredients that are added to or will come in contact with food for human consumption. The information that industry submits to the agency contains chemistry, toxicology, environmental, nutritional, microbiological, and other relevant data. Information collected by the FARM System consists of data required to perform the safety review of food ingredients under the Federal Food Drug and Cosmetic Act and Regulations in Part 21 CFR Sections 71 & 170-190. These regulatory documents describe the data required from industry for the Food Contact Notification (FCN), Generally Recognized as Safe Notice (GRN), and Bioengineered Foods Consultation (BNF) processes. All notices and notifications must contain appropriate and sufficient scientific data and information to support the safety review process. The agency collects only the information provided for under the Federal Food, Drug and Cosmetic Act and in the corresponding regulations in 21 CFR 71-199.



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CFSAN FARM

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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):   | 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 CFSAN LACF

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-12-01
2 HHS Agency (OPDIV):	FDA/CFSAN
3 Title of System or Information Collection:	Low Acid Canned Foods
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-06-02-1020-00-110-032
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.	The LACF system, when completely implemented, will give low acid canned foods processors the ability to register data in accordance with CFR Title 21, Parts 108.25, 108.35, 113, and 114. In Phase I, the current implementation, only the CFSAN and FDA Field personnel involved in enforcement activities will have access to the software and data.
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.	In accordance with CFR Title 21, Parts 108.25, 108.35, 113, and 114, the data collected is reviewed by technical staff to determine if the LACF-related product is commercially sterile to prevent a potential health hazard. The CFSAN and FDA staff uses this data to enforce CFR Title 21, part 108 regulations.
11 Explain why the information is being collected.	n/a

## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CFSAN LACF

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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 CFSAN MILK

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA/CFSAN
3 Title of System or Information Collection:	Milk Shippers
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)?	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:	009-10-01-05-02-0202-00
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
11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The Government Paperwork Elimination Act (GPEA) requires that State inspectors submit data on milk shippers to the FDA/CFSAN administrators.

## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CFSAN MILK

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| <p>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.</p>   | <p>Once the CFSAN Milk Shippers administrator approves the submitted certificate, the approved Certificate information will be available to the public through Internet access and listed monthly on the IMS (Interstate Milk Shippers List). The system collects completed information in the OMB approved FDA form: Interstate Milk Shippers report (2359i), Single Service Certification (2359d), Check Rating report( 2359h) and Single Service Audit(2359c) to accomplish this effort. No IIF is collected.</p> |
| <p>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</p>   | <p>N/A</p>   |
| <p>14 Explain why the IIF is being collected, maintained, or disseminated.</p>   | <p>N/A</p>   |
| <p>15 Identify with whom the agency will share the IIF.</p>  | <p>N/A</p>   |
| <p>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.</p> | <p>N/A</p>   |
| <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>N/A</p>   |
| <p>18 Describe how the IIF will be secured.</p>  | <p>N/A</p>   |
| <p>19 Describe plans for retention and destruction of IIF.</p>   | <p>N/A</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>N/A</p>   |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN MILK

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 CFSAN Shellfish

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2004-08-25
2 OPDIV:	FDA/CFSAN
3 Title of System or Information Collection:	Shellfish Shippers
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)?	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:	009-10-01-05-02-0202-00
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
11 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The Government Paperwork Elimination Act (GPEA) requires that State inspectors submit data on shellfish shippers to the FDA/CFSAN administrators.



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA CFSAN Shellfish

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| <p>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.</p>   | <p>Once the CFSAN Shellfish Shippers administrator approves the submitted certificate, the approved Certificate information will be available to the public through Internet access and listed monthly on the ICSSL (Interstate Certified Shellfish Shippers List). The system collects completed information in the OMB approved FDA form 3038 to accomplish this effort. No IIF is collected by this system</p> |
| <p>13 Explain how the IIF collected, maintained, and/or disseminated is the minimum necessary to accomplish the purpose for this effort.</p>   | <p>N/A</p>  |
| <p>14 Explain why the IIF is being collected, maintained, or disseminated.</p>   | <p>N/A</p>  |
| <p>15 Identify with whom the agency will share the IIF.</p>  | <p>N/A</p>  |
| <p>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.</p> | <p>N/A</p>  |
| <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>N/A</p>  |
| <p>18 Describe how the IIF will be secured.</p>  | <p>N/A</p>  |
| <p>19 Describe plans for retention and destruction of IIF.</p>   | <p>N/A</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>N/A</p>  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN Shellfish

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 CFSAN VCRP

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-12-01
2 HHS Agency (OPDIV):	FDA/CFSAN
3 Title of System or Information Collection:	Voluntary Cosmetics Registration System
4 Is this System or Information Collection new or is an existing one being modified?	Existing
5 Unique Project Identifier Number:	009-10-01-06-02-0201-00-110-032
6 System of Records Number:	n/a
7 OMB Information Collection Approval Number and Expiration Date :	OMB □ 0910-0027 and 0910-0030, 10/2005
8 Other Identifying Number(s):	Forms FDA 2511, 2512, 2512a and 2414
9 Provide an overview of the system or collection and indicate the legislation authorizing this activity.	The voluntary Cosmetics Registration Program system is a web-based system allowing the cosmetics industry to obtain a registration number for manufacturing establishments and cosmetic product formulations. The Cosmetics Registration system supports the Cosmetics Industry in accordance with CFR Title 21, Parts 710 and 720. The CFSAN and FDA staff uses this data to enforce Sections 601 and 602 of the Food and Drug Act. Registration data is exported to the CFSAN web servers so that cosmetics registrants may view their own data.

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN VCRP

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| <b>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.</b>  | The voluntary Cosmetics Registration Program system is a web-based system allowing the cosmetics industry to obtain a registration number for manufacturing establishments and cosmetic product formulations by electronically requesting it using their web browser. Once the registration number is approved, they will also be able to submit and edit product and ingredient information in a similar manner, i.e. using web-based Forms 2512 and 2512a. The program is voluntary. Companies are requested to provide the physical location of their manufacturing establishments so they may be inspected for good manufacturing practices. Participants are also requested to provide information on their cosmetic product formulations which aids the agency in determining what ingredients are being used in cosmetic products and what preservative systems are being used to protect the integrity of the product. |
| <b>11 Explain why the information is being collected.</b>  | n/a  |
| <b>12 Identify with whom the agency will share the collected information</b><br>.  | n/a  |
| <b>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.</b> | n/a  |
| <b>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)</b>   | n/a  |
| <b>15 Describe how the information will be secured.</b>  | n/a  |
| <b>16 Describe plans for retention and destruction of data collected.</b>  | n/a  |



# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CFSAN VCRP

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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. | 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 CVM DERS

<u>Question:</u>	<u>Response:</u>
1 Date of this Submission (MM/DD/YYYY):	2003-11-20
2 HHS Agency (OPDIV):	Center for Veterinary Medicine
3 Title of System or Information Collection:	Drug Experience Reporting System
4 Is this System or Information Collection new or is an existing one being modified?	Modified
5 Unique Project Identifier Number:	009-10-01-07-02-1020-02
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.	DERS is a collection of data about adverse drug events and marketing history required by law from sponsors holding marketing authorizations for animal health products.
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.	DERS summarizes details of the adverse drug events in animals, amount of products marketed by distributors during the reporting period, labels used in marketing the products, other promotional material, and contains contact information for the firm submitting the information.
11 Explain why the information is being collected.	Contact information collected amounts to Rolodex type information that facilitates communication with the firm by phone and by mail addressing.
12 Identify with whom the agency will share the collected information	The information is not shared with other agencies.

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CVM DERS

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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>Contact information is collected as a matter of course through material submitted by the firms. The contact information is minimal and of the kind that would require no special consent.</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 or through the Internet.</p>  |
| <p>15 Describe how the information will be secured.</p>  | <p>Access to information is regulated by username, password, and role assignments. The FDA firewall protects the information from public intrusion.</p>  |
| <p>16 Describe plans for retention and destruction of data collected.</p>  | <p>There are no plans for retention and destruction of data maintained. The data is updated as needed and backups are frequent.</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>A system of records is not being created under section 552a of Title 5, United States Code (the Privacy Act).</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 CVM STARS

### Question:

### Response:

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|----|---|---|
| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-20  |
| 2  | HHS Agency (OPDIV):   | Center for Veterinary Medicine  |
| 3  | Title of System or Information Collection:  | Submission Tracking and Reporting System  |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Existing  |
| 5  | Unique Project Identifier Number:   | 009-10-01-07-02-1010-00-110-032   |
| 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.   | STARS is a collection of data about submissions from sponsors in support of marketing authorization for animal health products.                   |
| 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. | STARS summarizes details of the request for marketing authorization and contains contact information for the firm submitting the information.     |
| 11 | Explain why the information is being collected.   | Contact information collected amounts to rolodex-type information, which facilitates communication with the firm by phone and by mail addressing. |
| 12 | Identify with whom the agency will share the collected information  | The information is not shared with others.  |

# HHS Privacy Impact Assessment (PIA) Summary

## OPDIV: FDA System Name: FDA CVM STARS

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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>Contact information is collected as a matter of course through material submitted by the firms. The contact information is minimal and of the kind that would require no special consent.</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 or through the Internet.</p>  |
| <p>15 Describe how the information will be secured.</p>  | <p>Access to information is regulated by username, password, and role assignments. The FDA firewall protects the information from public intrusion.</p>  |
| <p>16 Describe plans for retention and destruction of data collected.</p>  | <p>There are no plans for retention and destruction of data maintained. The data is updated as needed and backups are frequent.</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>A system of records is not being created under section 552a of Title 5, United States Code (the Privacy Act).</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 NCTR MGSS

### Question:

### Response:

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| 1  | Date of this Submission (MM/DD/YYYY):   | 2003-11-17  |
| 2  | HHS Agency (OPDIV):   | FDA/NCTR  |
| 3  | Title of System or Information Collection:  | MultiGeneration Support System (MGSS)   |
| 4  | Is this System or Information Collection new or is an existing one being modified?  | Existing  |
| 5  | Unique Project Identifier Number:   | 009-10-01-09-02-1010-00-202-069   |
| 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 Multi-Generation Support System (MGSS) is an IT resource used to collect and store data for long-term animal toxicology studies. The mission of the National Center for Toxicological Research (NCTR) is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs .   |
| 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 MGSS collects data required by toxicology studies. It collects animal data such as weights, food/water consumption and clinical observations; it collects data such as compound, treatment group and route of administration; and it collects data about the environment in which the experiment takes place such as cage conditions and placements. These data are required to conduct peer-reviewed scientific research and for the analyses and scientific papers based on the research. |



## HHS Privacy Impact Assessment (PIA) Summary

### OPDIV: FDA System Name: FDA NCTR MGSS

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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):   | 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              |

