

### **06.3 HHS PIA Summary for Posting (Form) / FDA CDER Adverse Event Reporting System [System]**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 7/1/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-03-01-1010-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CDER Adverse Event Reporting System (AERS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Jeanette Somerville

**10. Provide an overview of the system:** Drug Safety (Adverse Event Reporting System-AERS) is a computerized information database designed to support the FDA's post marketing safety surveillance program for all approved drug and therapeutic biologic products. The ultimate goal of Drug Safety (AERS) is to improve the public health by providing the best available tools for storing and analyzing safety reports.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether**

**submission of personal information is voluntary or mandatory:** The system does not require collection of any IIF data for successful submission. However, some physicians, hospitals, or public may voluntarily submit IIF data, for example, social security numbers and patient names.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]**) Voluntary reporters have the option to report or not, to include their IIF or not, and if included, to select a check box requiring that the data be redacted when shared with anyone else. There will be a consent page on spontaneous reports explaining the process to the reporter. Mandatory reports are created by the importer/manufacturers and include what IIF may be known to them. They can likewise express the patient's consent to sharing IIF through the same checkbox method. The consent form will specifically include all future uses, and will direct the user to the FDA web page that will detail any change in expected use of the data.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The security plan as it relates to the implementation has not yet been written, but there will be non-functional requirements that mandate such security. There is an administrative and technical control by use of password and user identification and the system will be located at a secure facility.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/27/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDER Document Archiving, Reporting, and Regulatory Tracking System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/8/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-020200110 246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CDER Document Archiving, Reporting and Regulatory tracking System (DARRTS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Julieann Dubeau

**10. Provide an overview of the system:** CDER is responsible for tracking, reporting, and maintaining an archival record of the drug and biological products submitted to the FDA for review. The center reports to Congress on a number of issues, including performance on Prescription Drug User Fee Act of 1992 (PDUFA) related goals. To fulfill the mission and goals of CDER, DARRTS will provide a flexible, integrated, web-based system that will:

- Support the drug review and biologic review product tracking process;
- Provide administrative and regulatory reporting capabilities; and
- Improve the process by removing design components that result in work-arounds in the current system.

DARRTS is a component of CDER's overall initiative to move toward a fully electronic submission receipt, processing, and management system. DARRTS, which will be implemented in phases, will replace CDER's current systems supporting the receipt, management, and reporting of information about clinical investigational and marketing submissions for human drugs and therapeutics.

According to NIST SP 800-18, DARRTS is considered a Major Application (MA). Major Applications (MAs) are systems that perform clearly defined functions for which there are readily identifiable security considerations and needs.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether**

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):** DARRTS shares information with other operating divisions within FDA to facilitate the receipt, management, and reporting of information about clinical investigational and marketing submissions for human drugs and therapeutics. The information is business data only (not personal).

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** DARRTS will replace CDER's current systems supporting the receipt, management, and reporting of information about clinical investigational and marketing submissions for human drugs and therapeutics. The email collected and disseminated is for submission of firm information or for a company representative in the line of duty.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes currently in place.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within DARRTS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within DARRTS.

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/8/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDER Electronic Listing [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** Not Applicable

**1. Date of this Submission:** 11/4/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** N/A

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CDER Electronic Listing

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Ida Milner

**10. Provide an overview of the system:** The Center for Drug Evaluation and Research (CDER), Electronic Listing (eList) system supports the FDA's overarching mission to safeguard and promote the health of the public. Several business missions fuel this project. First is the provision of a means for industry to begin submitting product listing and registration electronically in XML format. XML format is compatible with Health Level-7 (HL-7), which is becoming a healthcare standard.

eList employs a technological environment enabling the FDA to electronically and reliably generate up-to-date Structured Product Labeling (SPL) format labeling for all drug products marketed in the United States. SPL file information contains the following medication data:

- How to use medication - dosing recommendations and monitoring use
- When to use medication - indication, clinical effects (e.g., interactions and adverse events), activity (e.g., mechanism of action), other information about the use of the medication
- Description of the medication - names, ingredients, strength, appearance, dosage form
- How the medication is supplied - name, package type, quantity
- Distributor of the medication

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether**

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** eLIST serves as a central data holding place for drug registration and listing. The information collected including manufacturer, registration information including register number, FEI number, company name and address etc. and drug listing information include ingredients of the drug, package of the drug, and the usage of the drug.

The information collected will be used for the purpose of validation and the purpose of drug label publish (to the public)

The information are collected by mandate.

The vendor point of contact information is redacted from the system before it goes to the public.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/8/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDER Legacy Refresh Systems [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 11/16/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CDER Legacy Refresh Systems

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Tiffany Lovelace

**10. Provide an overview of the system:** In July of 2009, DARRTS 3.0 (NDA and ANDA tracking) was rolled out. Some COMIS tracking systems were absorbed into DARRTS, some were retired, and some continued to operate as before, but were upgraded to an Oracle 10g platform running on a Solaris in UNIX. The latter systems, 15 in number, are collectively referred to as LX. These systems track such information as products, advertising submissions, registration and listing, site inspections, and flow of volumes to drug reviewers.

LX includes the systems listed below.

Group One: Systems with access control based network account and Active Directory status, using User Access table records (not Oracle roles) to control level of access

ADMIS – Advertising Management Information System

BrMIS – Bioresearch Monitoring Information System

DADS – Developers and Distributors System

DPRF – Drug Product Registration and Filing

DQRS – Drug Quality Registration System

DRLS – Drug Registration and Listing System

GC – General Counsel Tracking System

INVAS – IND/NDA Volume Accountability System

MACMIS – [DDMAC] Correspondence Management Information System

MEDEX – Medwatch Expedited Reporting Tracking System

User FLX – User FLX Tracking System

Group Two: Systems with access control based on individual Oracle account, using Oracle roles to control level of access

CIS – Clinical Investigator System

INVAS-OC -- IND/NDA Volume Accountability System for the Office of Compliance

PATEXCL – Patent and Exclusivity Tracking System

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** CDER LX does not store, process or collect PII.

In July of 2009, DARRTS 3.0 (NDA and ANDA tracking) was rolled out. Some COMIS tracking systems were absorbed into DARRTS, some were retired, and some continued to operate as before, but were upgraded to an Oracle 10g platform running on a Solaris in UNIX. The latter systems, 15 in number, are collectively referred to as LX. These systems track such information as products, advertising submissions, registration and listing, site inspections, and flow of volumes to drug reviewers.

LX includes the systems listed below.

Group One: Systems with access control based network account and Active Directory status, using User Access table records (not Oracle roles) to control level of access

ADMIS – Advertising Management Information System

BrMIS – Bioresearch Monitoring Information System

DADS – Developers and Distributors System

DPRF – Drug Product Registration and Filing  
DQRS – Drug Quality Registration System  
DRLS – Drug Registration and Listing System  
GC – General Counsel Tracking System  
INVAS – IND/NDA Volume Accountability System  
MACMIS – [DDMAC] Correspondence Management Information System  
MEDEX – Medwatch Expedited Reporting Tracking System  
User FLX – User FLX Tracking System

Group Two: Systems with access control based on individual Oracle account, using Oracle roles to control level of access

CIS – Clinical Investigator System  
INVAS-OC -- IND/NDA Volume Accountability System for the Office of Compliance  
PATEXCL – Patent and Exclusivity Tracking System

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:**

**PIA Reviewer Name:** Joe Albaugh

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 1/5/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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### **06.3 HHS PIA Summary for Posting (Form) / FDA CDER Special Products Online Tracking System [System]**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 1/31/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-020200110 246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Special Products Online Tracking System (SPOTS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Michael Folkendt

**10. Provide an overview of the system:** SPOTS is a web application which supports the tracking of all ingredients (active or inactive with certain specific exceptions) derived from plant (except highly purified compounds), animal, microorganism and recombinant technology used in pharmaceutical products that are the subject of a CDER NDA, ANDA, or IND.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The SPOTS application is

used by the drug product quality review staff primarily located in the Office of New Drug Quality Assessment (ONDQA), Office of Biotechnology Products (OBP), and the Office of Generic Products (OGD). All three offices are located under the Office of Pharmaceutical Science (OPS). The Office of New Drug Quality Assessment is the Business owner and administrator for this system.

The SPOTS application primary role is a database used to track applications that contain, or use as part of the manufacture, animal-derived, plant-derived, or biotech-generated ingredients. The reviewers add to the database as they review applications that meet the SPOTS criteria. The application also generates reports on an as needed basis.

All Product Quality Users are given CREATE (i.e., data entry) privileges. Before the new data is committed, it must first be reviewed by an administrator. Other CDER users are given Search only access. No personnel outside of CDER have access to the SPOTS system. The SPOTS system does not contain PII.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Joe Albaugh (Acting)

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/8/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDER Substance Registration System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 10/23/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-01-0303-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** CDER Substance Registrations System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Alex Schultz

**10. Provide an overview of the system:** The Substance Registration System (SRS) combines the features of the Substance Registration System (SRS) and Center Ingredient Dictionary (CID) application within a modern application environment that efficiently integrates software from MDL Information Systems within a J2EE environment. This system provides enterprise-wide integration with other FDA applications.

SRS enables FDA to efficiently, effectively, and reliably maintain unique identifiers for substances in drugs, biologics, foods, and devices, and make them available for use in health information systems.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** SRS enables FDA to efficiently, effectively, and reliably maintain unique identifiers for substances in drugs, biologics, foods, and devices, and make them available for use in health information systems. The information contain in SRSID does not contain PII data.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/30/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Center Electronic Submissions [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 10/12/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-5030-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** 5344

**7. System Name (Align with system Item name):** FDA CDRH Center Electronic Submissions (CeSub)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Paul Fisher

**10. Provide an overview of the system:** 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 Center for Devices and Radiological Health (CDRH) receives and reviews thousands of submissions from regulated industry and consumers seeking FDA approval to market new devices and products, as well as to track changes and adverse events related to approved products. These submissions traditionally have been scanned into the electronic document management system "Image 2000". The CeSub project is based mostly upon the Image 2000 knowledge and document management system, and it adds functionality to permit the receipt and review of electronic submissions.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**

Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** 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. The information contained in CeSub represents the official record of 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 manufacturer are stored in the CeSUB Image 2000 repository. Data within the system may include the submitter's name and contact information.

21 CFR 1002.7 gives FDA authority to define what information we want in a reporting guide. CDRH determined that contact information must be provided.

21 CFR 1002.7 requires a signature by the submitter because a responsible individual must be identified. Having that person's name in printed form so it is legible is necessary. Similarly 1002.10 requires the name of the manufacturer - since companies can have similar names, address information is required to uniquely identify the manufacturer. The location of manufacturing facilities is also specifically required.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Information contained within this system is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as

intended, and producing the desired result of protecting all information within the CDRH Center Electronic Submissions system.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 10/14/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Mammography Program Reporting Information System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 11/22/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-4060-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** 0910-0309

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CDRH Mammography Program Reporting and Information System (MPRIS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Timothy Haran

**10. Provide an overview of the system:** Under the Mammography Quality Standards Act (MQSA), all mammography facilities must 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. Likewise, mammography facility medical personnel must also meet qualification standards.

FDA's Center for Devices and Radiological Health (CDRH) employs the Mammography Program Reporting and Information System (MPRIS) to maintain inspection data and facility information, and, manage the inspection and reporting process. Information in MPRIS is shared with authorized FDA employees and contractors, and with the Centers for Medicare and Medicaid Services (CMS). The information provided to CMS is limited to facility certification data and does not include personally identifiable information (PII).

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**

Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**

N/A. PII is shared only with authorized FDA employees and contractors; it is not disclosed outside FDA. PII in MPRIS is not matched against PII in other systems, and no other organization or systems are dependent on the PII in MPRIS. Because MPRIS is not subject to the Privacy Act, there are no formal notification processes in place. Individuals who have questions or complaints, or wish to correct their PII (contact info, ID number) may contact system or program management

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The information collected in the Mammography Program Reporting and Information System (MPRIS) includes the name and physical location of each mammography facility, along with the facility mailing address, telephone and facsimile numbers, the types and number of mammography equipment in use, and PII consisting of the names of facility personnel, including official contacts for accreditation, billing, and compliance matters.

The facility information is collected by FDA inspectors, FDA-approved accreditation bodies, and by State inspectors working under contract to FDA, in the course of mandatory annual facility inspections. This information is required by, and used in keeping with, the provisions of the MQSA and related FDA regulations (21 CFR Part 900) to contact the regulated facility regarding FDA matters, to determine their certification status, to schedule inspections, and to determine the compliance of the facility and facility personnel with the MQSA and related regulations.

The CDRH Division of Mammography Quality and Radiation Programs (DMQRP) also collects information in MPRIS regarding the State inspectors working under contract with FDA. This data is obtained from State authorities at the time of contract signing, and it is limited to publicly-available information, including PII consisting of inspector name, office address, and office telephone and facsimile number. This information is not specifically mandated by statute but is required in order for FDA to contact inspectors and provide technical support, equipment, and policy guidance when necessary

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) MPRIS is not subject to the Privacy Act and the Act's requirement to provide notice statements on information forms does not apply. System users are advised at log in to the system that it is for use by authorized personnel only, that system use may be monitored and that by using MPRIS they consent to monitoring.

If FDA's privacy policies and practices change, the effected individuals will be notified electronically by email directly to the individuals, to the facility, and/or to the State office(s) through which FDA contracts with the State inspectors.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**

Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within MPRIS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within MPRIS

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 11/28/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Medical Safety Network [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 8/31/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-1020-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** OMB 0910-0471

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CDRH Medical Product Safety Network (MedSun)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Marilyn Flack

**10. Provide an overview of the system:** The Medical Product Safety Network (MedSun) is an Internet-based system. Healthcare facilities use MedSun to voluntarily submit reports of adverse events involving medical devices regulated by FDA. Participating facilities include hospitals, nursing homes, outpatient treatment and diagnostic centers and home health agencies. Each facility designates a person(s) to submit these reports. Each reporter is authenticated at the MedSun system web server, and each reporter has access only to their facility's data. This data is transferred in real time to database servers. No data is stored on the website. Submitted data is then analyzed by FDA employees to gain a perspective on postmarket problems related to medical devices.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
The name and contact information for each reporter is not shared with the public, but is shared

with the manufacturer and others in FDA so follow-up questions may be directed to the appropriate reporter.

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** Healthcare facilities such as hospitals, nursing homes, outpatient treatment and diagnostic centers voluntarily provide information concerning adverse events involving medical devices. This information includes data about the device and the reported event, and a limited amount of PII consisting of the name, work mailing address, work telephone number, and work email address of the facility's designated reporting individual.

For events involving death or serious injury, regulations (21 CFR 803) require the submission of event reports including the specified PII. Otherwise, the submission of this PII is voluntary and not required by statute or regulation. FDA requires this information for operational purposes in order to identify problem trends with specific devices and facilitate corrective action by the manufacturer. Reporter name and professional contact information in MedSun is shared with the manufacturer and others in FDA so that follow-up questions may be directed to the appropriate reporter.

Patient information is not collected in or passed through MedSun. No collected or disseminated data can be traced to a patient. FDA shares redacted reports on a public web site in order to inform the public about device and health issues. These redacted reports display only the event description, device manufacturer name, and the name and model number of the device.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]**) In the event that FDA makes major changes to the MedSun system, FDA will contact each participating facility and reporter to inform them of the change and provide an opportunity to withdraw from the program, or review and sign an updated participation form advising them how the submitted information will be used or shared.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**

Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** We meet all mandated administrative, technical, and physical control requirements for Major Applications

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Stephen Veneruso

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/31/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Traction [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 3/10/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** Not Applicable

**5. OMB Information Collection Approval Number:** Not Applicable

**6. Other Identifying Number(s):** Not Applicable

**7. System Name (Align with system Item name):** CDRH Traction

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Paul Fisher

**10. Provide an overview of the system:** Traction is a collaborative tool which stores all text-based information in a database file providing a place to create and share documents or data which is called a journal. The journal is a SQL-based database which is managed using commands developed by the vendor, Traction Software. These commands are included in the Traction install package and are executed by a local FDA Traction System Administrator when maintenance is needed. Database maintenance is not needed on a regular basis. All non-text based data (documents, spreadsheets, attachments) is stored directly on the host server and can be accessed at a server level.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
Not Applicable

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether**

**submission of personal information is voluntary or mandatory:** Traction is a collaborative tool which stores all text-based information in a database file providing a place to create and share documents or data which is called a journal. The journal is a SQL-based database which is managed using commands developed by the vendor, Traction Software. These commands are included in the Traction install package and are executed by a local FDA Traction System Administrator when maintenance is needed. Database maintenance is not needed on a regular basis. All non-text based data (documents, spreadsheets, attachments) is stored directly on the host server and can be accessed at a server level.

Once a user has logged into the application, they will navigate to their team/department's workspace. At this time, they can choose to create a new article (similar to email in composition), comment on an article (continuing a conversation), or upload documents to the shared folders portion of their workspace. As new content is added, the journal will be updated with new content and links to documents which are stored in the application. Traction does not contain PII and no PII is voluntary or mandatory for submission to the Traction tool.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Not Applicable

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Frederick Sadler

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 4/5/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN CFSAN Adverse Event Reporting System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 8/31/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-4100-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** Yes. A System of Records Notice (SORN) is currently in development with system number to be assigned.

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Adverse Event Reporting System (CAERS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Debra Street

**10. Provide an overview of the system:** CAERS is part of CFSAN's Strategic Plans - 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.

CFSAN is responsible for assuring a safe and wholesome food supply as well as safe cosmetics for the United States' consumers. As part of this mission, CFSAN performs post-market surveillance (CAERS) by collecting 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 have mandatory pre-market approval, pre-market notification, and/or post-market surveillance requirements, most of these products, notably dietary supplements, have no such requirements. CFSAN's primary source of information about

these products and post-market surveillance is collected through voluntary adverse event reporting handled by CAERS.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
Internal FDA systems

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The mission of the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) is to assure the safety and wholesomeness of the nation's dairy products, plant foods, beverages, seafood, dietary supplements, cosmetic products, infant formula, medical foods, food and color additives, and all ingredients that come into contact with foods (CFSAN regulated Products). Among CFSAN's priority activities supporting this mission is performing post-market surveillance including but not limited to collecting, monitoring, and analyzing adverse event reports and product complaints, which are alleged to be related to CFSAN regulated products. Virtually all of reports of the adverse events and product complaints are voluntary submissions from consumers, health professionals, and other interested parties. The very rare exception to voluntary submission is the mandatory reporting required for firms that manufacture infant formula when a death of an infant has been associated with their product. Reports are captured and processed and enter the CFSAN Adverse Event Reporting System (CAERS) through several routes (FDA's Field Accomplishments and Compliance Tracking System (FACTS), FDA's MedWatch Program, and direct mail, e-mail, or phone messages to CAERS). Voluntary IIF information may be included in the system. However, records are not retrievable by a typical IIF; instead, an agency-assigned CAERS case number is given to the case when information is entered into CAERS. The CAERS data is used as a basis for enforcement and regulatory action on CFSAN regulated firms and products to help perform the mission described above.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Controls and safeguards are in development in tandem with the System of Records Notice.

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/3/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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### **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN CFSAN Automated Research Tracking System [System]**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 12/7/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-0202-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Automated Research Tracking System (CARTS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Simmy Yau

**10. Provide an overview of the system:** CARTS enables the Center for Food Safety and Applied Nutrition (CFSAN) to manage its research efforts more economically, effectively, and transparently; and it now serves as the Center's principal research program coordination and communications tool through which we assess and report on the current status of our research portfolio, provide information on resource utilization, and help to ensure research program accountability. CARTS greatly facilitates the Center's ability to communicate information about all of our research activities with stakeholders both inside and outside the Agency.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** CARTS records all information on research conducted within CFSAN and in collaboration with external organizations. The information is gathered from scientists and managers and includes the nature and scope of the research itself, administrative and organizational information, and the names of individual scientists.

The PII collected in CARTS is limited to the name and affiliation of the collaborating scientists. Submission of this information is not statutorily mandated, but is operationally required in order to efficiently track and coordinate collaborative research programs in support of FDA's overall mission.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]** CARTS is not subject to the Privacy Act and there is no existing formal notification process. If FDA's privacy practices change or FDA changes its collection, use, or sharing of PII data in the system, the individuals whose PII is in the system will be notified in the most efficient and effective form available and appropriate to the specific change(s). This may include establishing a formal process involving written and/or electronic notice. Alternatively, notification will be made by informal processes such as email directly to the individuals effected.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Access to CARTS is restricted to authorized FDA users with accounts in CARTS and/or Business Objects who can only access CARTS information via the FDA intranet.

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 12/9/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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### **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Color Certification [System]**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 2/18/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-0505-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** OMB 0910-0216 (Exp. 2/28/2011)

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Colors Certification System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Adam Rixey

**10. Provide an overview of the system:** The Colors Certification System supports batch certification of color additives in accordance with CFR Title 21, Parts 70, 74, 80, and 82. Colors Certification data is exported to the CFSAN web servers so that twenty-one industrial users may view data on their own certification requests (the remaining eleven requestors certify only one or two samples per year and have not chosen to participate in the online system at this time). 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.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this**

**description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The information collected 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.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 2/25/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Food Applications Regulatory Management [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 5/17/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-4050-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Food Applications Regulatory Management (FARM)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Ziyad, JoAnn

**10. Provide an overview of the system:** The FARM system is an end-to-end electronic information management system that manages and validates the receipt, processing, storage, routing, tracking, and reporting of food ingredient information collected from the food industry. It manages information regarding food ingredients that are added to or will come in contact with food for human consumption and ingredients that are consumed as dietary supplements. The information that industry submits to the agency contains chemistry, toxicology, environmental, nutritional, microbiological, and other relevant safety-related 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, the Dietary Supplement and Health Education Act (DSHEA), the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), and related FDA regulations set out in the Code of Federal Regulations at 21 CFR 71 and 170-190. These legal authorities describe the data required from industry for the Food and Color Additive Petitions, Food Contact Notifications (FCN), Generally Recognized as Safe Notices (GRN), New Protein Consultations, Bioengineered Foods Consultations (BNF) for the Office of Food Additive Safety, New Dietary Ingredient 75 Day Notices, and 30 Day Structure Function Label Notices for the Office of Nutrition, Labeling and Dietary Supplements. All petitions, notices, and notifications must contain appropriate and sufficient scientific data and information to support the safety review process.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether**

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The FARM system contains information submitted by the food industry on ingredients that are added to or will come in contact with food. All petitions, notices, and notifications must contain appropriate and sufficient scientific data and information to support the safety review process.

The FARM system contains a minimal amount of PII which is required in order to contact industry business personnel. The names and business phone numbers collected are not used to retrieve information from the FARM system. The agency collects only the information provided for under the Federal Food, Drug and Cosmetic Act (FFDCA) and corresponding regulations (21 CFR 71-199), the Dietary Supplement and Health Education Act (DSHEA), and the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 5/17/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Interstate Milk Shipper [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 5/20/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** TBD

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Interstate Milk Shippers

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Kevin Smith

**10. Provide an overview of the system:** The Interstate Milk Shippers system is an online web-based system which allows electronic submission of Interstate Milk Shipper (IMS) forms directly through the Internet. The system enables State Rating Officers (or Consultant in the case of foreign single-service sources) and FDA Regional Milk Specialists to process and submit the Interstate Milk Shippers Report (form 2359i), the Interstate Milk Shipper Check Rating Report (form 2359h), and the Single Service Certification forms (form 2359d). The 2359i forms are submitted electronically to the FDA Regional Milk Specialist, who reviews the forms and submits them to the CFSAN IMS administrator for review and approval, followed by immediate publication on the IMS list through the Internet. State Milk Shippers Rating Officers no longer need to submit the paper form to the FDA but still have the option for paper submission. Only required personnel and officials are granted access to the application. Such access is controlled and reviewed regularly by IMS administrators. The scope of user access is restricted by the roles assigned to each user. Not all IMS documents are accessible to users. The roles define which document or sections of the document they can read or modify. Such restriction is important to maintain the accuracy and reliability of the data.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass**

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** State Regulatory Agencies, in cooperation with the National Conference on Interstate Milk Shipments (NCIMS), require mandatory reporting of names of interstate milk shippers and their ratings. Reported data includes the extent of the national testing activities, the analytical methods used, the nature and extent of the animal drug residues identified, and the amount of contaminated milk that was removed from the human food supply. The system encompasses all milk, including “Grade A” and “non-Grade A”, commonly known as manufacturing grade milk. “Grade A” milk represents approximately 95% of the milk supply in the United States and is regulated by State Regulatory Agencies in collaboration with the NCIMS.

As part of the regulatory process, State Rating Officers and Laboratory Evaluation Officers conduct regular ratings of interstate milk shippers, single service container fabricators, and milk laboratory evaluations, and submit the appropriate reporting forms to the Dairy and Egg Safety Branch of FDA’s Center for Food Safety and Applied Nutrition (CFSAN). Up-to-date firm data and rating information for milk shippers, laboratories, and manufacturers of single service milk containers is thereby maintained in the IMS List.

PII in this system is limited to the names and titles of FDA and State officials that are included as standard elements of the report forms submitted in the evaluation and approval process. Submission of this information is not mandated by statute but for operational and administrative purposes it is a required element of the report forms.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/30/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Low Acid Canned Foods [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 8/31/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-0505-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Low Acid Canned Foods (LACF)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Michael Mignogna

**10. Provide an overview of the system:** The LACF system gives 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, only CFSAN and FDA Field personnel involved in enforcement activities had access to the software and data. The Phase II implementation provides Domestic industry the ability to submit products' processes as well as monitor all submissions. When full implementation takes place, all foreign and domestic LACF facilities will have the ability to engage in online access and monitoring of a facility's products' processes.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** In accordance with CFR Title 21, Parts 108.25, 108.35, 113, and 114, the data collected is reviewed by technical staff to provide proof that the LACF-related product is commercially sterile to prevent a potential health hazard.

The CFSAN and FDA staff use this data to enforce CFR Title 21, part 108 regulations.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/1/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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### **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Priority-Based Assessment of Food Additives [System]**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 2/18/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-0505-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Priority-Based Assessment of Food Additives (PAFA)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Mary LaVecchia

**10. Provide an overview of the system:** PAFA gathers administrative, chemical, and toxicological information on over 3000 food substances directly added to food. In addition, limited information is collected on approximately 3500 food additives that may migrate into food through packaging or the like. This information is used as background material for regulatory review, research projects, and serves to answer Freedom of Information requests in an efficient manner. PAFA data is used to seed the tools used for preliminary Structure Activity Relationship (SAR) analysis when new substances are submitted to the Agency for approval.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** PAFA is used to maintain administrative, chemical, and toxicological information on over 2000 of approximately 3000 substances directly added to food, including substances regulated by the U.S. Food and Drug Administration (FDA) as direct, "secondary" direct, and color additives, and Generally Recognized As Safe (GRAS) and prior-sanctioned substances so that toxicological profiles can be produced for the ingredients added to the food supply. It is a source of information for post-market surveillance of food additives.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 2/25/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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### **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Resource Reporting System Via Project [System]**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 3/9/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-0202-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Resource Reporting System Via Project (RSVP)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Charles Sabatos

**10. Provide an overview of the system:** RSVP is a user-friendly time reporting system that provides data concerning personnel resources planned and expended to support the business processes of the Center for Food Safety and Applied Nutrition (CFSAN) offices and divisions. The application supports over 1200 users and is accessed only through the CFSAN Intranet.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** RSVP does not collect,

maintain, or disseminate any PII and users do not submit any personal information. RSVP only collects the total number of hours worked or on leave for each employee per pay period. Users can only access their own pay period totals in order to allocate hours to the specific projects they worked on. CFSAN uses this information for personnel resource tracking and planning.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 3/17/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Seafood HACCP [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 9/12/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** TBD

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Seafood Hazard Analysis and Critical Control Point

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** William R. Jones

**10. Provide an overview of the system:** Commercial seafood processors develop their plans of food safety controls to identify and prevent potential health hazards with their products. These controls comprise the processing firm's hazard analysis and critical control point (HACCP) program. CFSAN's Seafood HACCP application provides the means both to capture the controls and to evaluate each processing firm's performance with respect to its HACCP program. FDA field inspectors enter data directly into the Seafood HACCP application through the CFSAN Intranet. Then CFSAN's Office of Food Safety (OFS) evaluates each processing firm's performance in complying with its controls and generates a series of summarized reports. This evaluation process enables OFS management to evaluate the performance of processing firms as well as determine industry trends with respect to compliance and regulatory activities. The Seafood HACCP application also allows OFS to meet the Center's post-market, scientific, and business process goals in the area of seafood safety. HACCP plans are generally protected, and withheld from release subject to FOIA exemption (b)(4). The Seafood HACCP database is accessed through the Intranet. The database and server are protected by logical controls.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass**

**through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system captures firm data regarding seafood processors and their HACCP programs. This information enables FDA to evaluate each processing firm's performance in complying with its HACCP program.

The Agency performs HACCP compliance inspections of domestic and foreign fish and fishery products processing facilities. These inspections ensure that these processors implement a system of preventive controls, in addition to ensuring compliance with more traditional regulatory requirements, such as the Current Good Manufacturing Practice Regulation. The HACCP system tracks the implementation of HACCP plans and sanitation controls needed as part of the inspection of the processor's entire HACCP system.

PII in this system is limited to the names of FDA and State inspectors that are included as standard elements of the report forms submitted in the evaluation and approval process. Submission of the inspector names is not mandated by statute but is required in order to administer inspections.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to

ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/12/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Shellfish Shippers [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 5/13/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** TBD

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Shellfish Shippers

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Kevin Smith

**10. Provide an overview of the system:** FDA and State regulatory agencies, foreign nations, and the molluscan shellfish industry participate in the National Shellfish Sanitation Program (NSSP). Each participant identifies its certified shellfish processors to FDA on Form FDA 3038, the Interstate Shellfish Dealer's Certificate. FDA uses this information to compile the Interstate Certified Shellfish Shippers List, (ICSSL) a monthly publication that lists certified shellfish processors. This list is used to identify and exclude shellfish processed by uncertified processors.

FDA's Shellfish Shippers System has an online electronic data submission component that enables the State Control Authority (SCA), Shellfish Shipper inspectors and administrators to securely submit FDA form 3038 directly via the Internet. Submitters also have the option to provide a hard copy form 3038 to the FDA.

FDA maintains the form 3038 Certificate information in a centralized CFSAN (Center for Food Safety and Applied Nutrition) database. After the CFSAN Shellfish Shippers Administrator reviews and approves the submitted Certificate data, the Certificate information is entered into the system database and the certification information is made available to the public on the ICSSL.

The ICSSL displays: certified shellfish business name, city/town, state/country, and business's shellfish function (e.g., reshipper, shucker-packer); a list of FDA regional offices with contact names, office address, office phone and fax numbers, office email; and, State and country shellfish regulatory official contact information including the name of the official, title, office address, office phone and fax number, and office email address.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system collects shellfish industry firm data and certification information as part of FDA Form 3038 submitted by the firms. This information includes the business contact information for the certified shellfish entity, inspection date, certificate number and date of certification, state inspector name, SCA designee name, and the date of submission to FDA. This information is used by food control officials, seafood industry and other interested persons and is published monthly in the ICSSL, a primary tool for authorities to differentiate between certified and uncertified shellfish processors. The personal information collected in the system is a required element of form 3038 and does not include any PII beyond the names and titles of the state inspectors and SCA or SCA designee.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from

the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 5/17/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Small Business Nutrition Labeling Exemption [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 5/18/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** TBD

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Small Business Nutrition Labeling Exemption (SBNLE)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Rene Miguel Amaguana

**10. Provide an overview of the system:** The Federal Food, Drug, and Cosmetic Act requires packaged foods and dietary supplements to bear nutrition labeling unless they qualify for an exemption. A small business that produces a low-volume product may submit a Small Business Nutrition Labeling Exemption (SBNLE) Notice form stating it qualifies for an exemption from FDA's nutrition labeling requirements. The exemption applies if the business employs fewer than 100 full-time equivalent employees and fewer than 100,000 units of that product are sold in the United States in a 12 month period. The exemption is not available for products with regard to which a health or nutrition claim is made.

The SBNLE system facilitates this process; it enables FDA to centrally gather information related to companies seeking an exemption.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The SBNLE system contains information submitted by businesses seeking an exemption. To receive an exemption, businesses must submit a form requiring the firm type, name, mailing address, phone number, email address, time period for the exemption, number of employees, volume of product sold, and the name, title, and work phone number for the firm contact person. SBNLE also retrieves information from other FDA systems. It retrieves information from the Field Accomplishments and Compliance Tracking System (FACTS) database to automatically determine a company type (such as manufacturer or importer) based upon their Federal Employer Identification (FEI) number. SBNLE retrieves FDA employee data from the Enterprise Administrative Support Environment (EASE) system to automatically and securely log on authorized users. The only personally identifiable information (PII) collected via the SBNLE system is contact and authorization information for FDA employees involved in the exemption process and contact information for the small business employees involved in requesting an exemption.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** No

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Sarah Kotler

**Sign-off Date:** 6/9/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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### **06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Voluntary Cosmetics Registration Program [System]**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 8/31/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-0505-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** OMB 0910-0027 (Exp. 11/30/2007) and OMB 0910-0030 (Exp. 12/31/2008)

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CFSAN Voluntary Cosmetics Registration System (VCRP)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Donald Havery

**10. Provide an overview of the system:** The Voluntary Cosmetics Registration Program (VCRP) 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, i.e. completing Form 2511, 2512/12a, or 2514, over the Internet.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether**

**submission of personal information is voluntary or mandatory:** 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.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/1/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CTP Electronic Submissions [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 8/29/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** OMB No. 0910-0650; 0910-0654

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CTP Electronic Submissions

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** David Curtis

**10. Provide an overview of the system:** In order to meet the provisions of the Tobacco Act, specifically sections 905, 904(a)(1) and 904(a)(4), the Industry may submit registration and product listing, ingredient listing and health documents data. These submissions may be submitted via the eSubmitter application, through the FDA Electronic Submissions Gateway (ESG), physically on CD, or paper. Certain business requirements for the eSubmissions project will streamline the submissions process and better equip the Center for Tobacco Products (CTP) to manage and regulate the tobacco Industry.

Feature 1 - Provides a means to load/record submissions received via ESG, CD and paper.

Feature 2 - Provides a means to track and review all submissions received.

Feature 3 - Provides a means to store the submissions and all documents associated with the submission.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system collects information about tobacco products, their ingredients and where they are made. Information is used to make scientific and regulatory decisions regarding these products and the tobacco industry. No PII data is collected.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/9/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CTP Menthol Document Analysis Tool [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 1/4/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Menthol Document Analysis Tool

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Deborah Sholtes

**10. Provide an overview of the system:** This tool is a document management, search, retrieval, cataloging, indexing, and analysis tool for menthol tobacco documents submitted by the tobacco industry. The contractor will use a file server, a database, a search engine, and a web interface as an integrated tool within an enhanced security intranet environment. The tool will fulfill the need to code and abstract 400 GB of documents on menthol cigarettes provided by the tobacco industry. The tool will allow CTP Office of Science and the Tobacco Products Scientific Advisory Committee (TPSAC) to meet its obligation under Section 907 (e) of the Family Smoking Prevention and Tobacco Control Act to provide recommendations on menthol cigarettes no later than March 23, 2011.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** This tool is a document management, search, retrieval, cataloging, indexing, and analysis tool for menthol tobacco documents submitted by the tobacco industry. These documents include information on tobacco firm processes for manufacturing, marketing, and researching mentholated tobacco products. The tool will fulfill the need to code and abstract 400 GB of documents on menthol cigarettes provided by the tobacco industry. The tool will allow CTP Office of Science and the Tobacco Products Scientific Advisory Committee (TPSAC) to meet its obligation under Section 907 (e) of the Family Smoking Prevention and Tobacco Control Act to provide recommendations on menthol cigarettes no later than March 23, 2011.

The information contained in the system is not related to individuals. There is no personally identifiable information collected, maintained or disseminated by this system. The information within the system is limited to tobacco products and tobacco firm processes.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Deborah Sholtes

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 1/4/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CTP Tobacco Inspection Management System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** Significant System Management Changes

**1. Date of this Submission:** 11/4/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** Not Applicable

**6. Other Identifying Number(s):** Not Applicable

**7. System Name (Align with system Item name):** FDA CTP Tobacco Inspection Management System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Sophia Donaldson

**10. Provide an overview of the system:** The Tobacco Inspection Management System (TIMS) is designed to support the business processes of the Office of the Commissioner related to the collection and organization of inspectional data from retail locations. This data will be collected utilizing a mobile device application and/or paper process, and will be transmitted to a database housed on the FDA extranet. Assignment management, retail establishment management, and data validation tasks shall be conducted from a front-end web application through the FDA extranet.

Within TIMS, the Mobile Device Management System (TIMS MDM) will support the management of FDA-issued mobile devices used to collect and organize data related to the inspection of tobacco retail locations. The TIMS MDM system communicates with the mobile devices via the FDA extranet and provides the ability to remotely manage Configuration Profiles, gather a full device inventory including installed applications, distribute applications and settings based on smart groups, and generate auditing reports.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass**

**through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** FDA will use the Tobacco Information Management System (TIMS) to collect information related to inspections of businesses engaged in the sale of tobacco products and inspections of tobacco advertising and labeling. The purpose of the system is to facilitate the administration of inspections (e.g., track inspection work flow, distribution and completion), and to maintain information for potential use as evidence of violations.

The collected information will include the legal or trade name of the business, the business address, and the name and address of the owner. It will also include general information regarding the sale of tobacco products to minors and the advertising and labeling of tobacco products. As part of the inspection, state inspectors may take photographs of tobacco products, advertisements and packaging which will be submitted to TIMS and used as evidence of violations by the business. TIMS will not contain photographs of people or items that identify individuals.

TIMS will contain limited information about individuals. The system will contain an inspector name and inspector identification number for administrative purposes, but no other information about the inspector. In the event of a sale of tobacco to a minor, the name of the store clerk may be included as part of inspection information included in TIMS. TIMS will not contain any other information about a clerk.

Submission of the PII processed in TIMS is not mandated by statute or regulation but is required for operational and administrative purposes.

Within FDA, the TIMS application will have an internal-facing component in which FDA employees will review submitted inspection data and determine whether legal action is warranted against any offending business.

The Mobile Device Management (MDM) element of TIMS will not collect or contain PII. MDM will collect only technical data related to each FDA-issued mobile device including an inventory of applications on a device, and security and configuration settings installed on the device.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g.,**

disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Users voluntarily provide their name and/or inspector ID for the self-evident purpose of performing their duties. TIMS users are advised at the login screen that they are accessing a U.S. Government information system, their system usage may be monitored, recorded, and subject to audit, unauthorized use of the system is prohibited and subject to criminal and civil penalties, and that use of the system indicates consent to monitoring and recording.

If FDA's privacy practices change or FDA changes its collection, use, or sharing of PII data in the system, the individuals whose PII is in the system will be notified in the most efficient and effective form available and appropriate to the specific change(s). This may include establishing a formal process involving written and/or electronic notice. Alternatively, notification will be made by informal processes such as email notice to the individuals effected.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**

Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

#### ***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 11/7/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CVM Animal Drugs @ FDA (ADAFDA Greenbook) [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 12/22/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** TBD

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** CVM Animal Drugs @ FDA (ADAFDA)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Margaret Zabriski

**10. Provide an overview of the system:** ADAFDA is the FDA-internal Administrative Portal for entering and maintaining information about approved animal drugs, for monthly porting to the FDA publicly accessible website, also called Animal Drugs @ FDA.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system only collects information on animal drugs and does not contain any PII

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Dr. Eric Perakslis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/1/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA CVM Corporate Database Portal [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 12/29/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-09-02--4070-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA CVM Corporate Database Portal

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Margaret Zabriski

**10. Provide an overview of the system:** The Corporate Database Portal (CDP & CDP-Web) consists of these eight modules under one portal used throughout CVM: STARS, DERS, DPL, BIMO, MIFS, ATR, CDLM and NARMS RM. The CDP modules support the pre-market, post-market safety, product quality, administrative, food safety, drug indexing, bioresearch monitoring, and compliance business processes. The Fiscal Allocation System (FAS) is used to track expenditures to the team level and to reconcile OFM accounting. FAS provides the management officers with the ability to track calls placed against a VISA or MOD. The Compliance Log System (LOG) used by the Division of Compliance consists of 3 modules. The Correspondence Tracking module tracks correspondence received by the Division and provides various pending, completed, and overdue reports. The Regulatory Action module tracks regulatory actions taken against a company/person. Various types of reports are available. The Export Certificate Logging module tracks information related to requests for animal drug and animal food/feed export certificates.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system contains information on pre-market animal drugs and feeds (applicant holder, active ingredients, indications for use, species, etc), post-market safety animal drugs & feeds (adverse drug events, drug experience reports, etc), animal drug products & establishments, time reporting, animal drug research monitoring (clinical investigators, contract research labs, manufacturing sites), correspondence contacts, export certificates, regulatory actions, etc.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Tim Stitley

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/30/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA NCTR Research Management [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/1/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-1330-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA NCTR Research Management System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Beth Harrison

**10. Provide an overview of the system:** The NCTR's mission is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs. This research includes in-vivo, in-vitro and in-silico experiments that consume significant NCTR resources.

In order to maximize return on investment, NCTR must manage its resources carefully. To do this efficiently and effectively, NCTR has implemented a protocol tracking and approval process and an activity based costing regimen which requires significant data collection and reporting. The Research Management System (RMS) provides the essential tools for gathering these data and for providing the necessary decision support mechanisms used to allocate available resources to new and ongoing research efforts. No PII is needed or collected.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The RMS collects data required by its protocol approval and tracking efforts as well as the data needed to conduct activity based costing functions. Types of data collected include protocol review and approval information, document production and publishing, cost factors, specific training requirements, FTE availability and resource (labor hour and dollar) costs estimated for and consumed in support of specific projects (protocols). Individual's names or other PII are not involved.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Fred Sadler

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/2/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA NCTR Research Support [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/1/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-1331-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA NCTR Research Support System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Beth Harrison

**10. Provide an overview of the system:** The Research Support System (RSS) is an IT resource used to collect and store data for toxicology studies. It collects subject and experiment data from the introduction of an animal into the NCTR environment by purchase or birth, through the experiment process, and concludes with the data collected from micro-pathological examination of its tissues. NCTR's mission is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether**

**submission of personal information is voluntary or mandatory:** The RSS 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. It also collects gross- and micro-pathology data. These data are required to conduct peer-reviewed scientific research and for the analyses and scientific papers based on the research.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Fred Sadler

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/2/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Agency Information Management System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/26/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-10-01-1010-00-404-142

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-10-0004 (FDA) Communications (Oral & Written) with the Public, 09-90-0058 (HHS) FOI Case Files and Correspondence Control Index, OGE-1 (Office of Government Ethics) Financial Disclosure Reports & Other Ethics Programs, OGE-2 (Office of Government Ethic

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Agency Information Management System (AIMS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Rosie Whitcraft

**10. Provide an overview of the system:** AIMS provides administrative tracking and electronic storage for several agency functions. The core data within AIMS is pulled from the agency ASAP and EASE system for staff, contractor, and organizational data required for the applications. The core also contains any information that is shared by two or more of the AIMS modules. The modules are Correspondence (both internal generated and received from external sources), Freedom of Information (FOI), Federal Register (FR), Dockets Management, Advisory Committee, Ethics, Passports, Records Case Management, Office Moves, Awards, eArrive, Security and Fellowship Program. The system also has a records management application for all records tracked in the system.

The module for Administrative Tracking and Electronic Document Storage of FOI requests, responses, and related correspondence is authorized by the Freedom of Information Act, (FOIA) 5 U.S.C. 552. The module for Ethics records is authorized by the Ethics in Government Act (PL 95-521) and the Ethics Reform Act of 1989, as amended (PL 101-194). The Civil Service Act authorizes the module for Security Clearances. The Federal Advisory Committee Act authorizes the module for Advisory Committee Records.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the**

**individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
AIMS access is restricted. To the extent users across FDA components require read/view access to perform their duties, the specified PII is shared outside the Office of the Commissioner. PII in AIMS is not shared outside HHS/FDA.

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** FDA receives approximately 24,000 FOI requests per year. A tracking system is required to monitor the processing of requests. In addition the FOIA and the Ethics in Government Act have annual reporting requirements that are based on information collected in the system. The Passport staff is responsible for obtaining and maintaining the government-issued passports for all FDA personnel. The eArrive and Fellowship applications collect data on new employees and non-employees in order to bring them on-board and provide them both physical and IT access to FDA property. eArrive supplies data to the Security application. eArrive, Security and Passport contain PII information. Both SSN and DOB are mandatory for the processing of passports and obtaining security clearances in FDA. The information is mandatory if the individual wants to obtain a Government passport and if they want to be able to work at a FDA facility and access the FDA network.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.])** If a major change or use of data occurs users are notified via email notification or FDA-wide email. FOIA information is obtained from correspondence submitted by the FOI requesters and individuals that correspond with the agency or comment on a Federal Register notice. FDA's Public Information Regulations at 21 CFR Part 20 inform the public of the procedures for submitting FOI requests. Federal Register notices inform individuals of the procedures for commenting on a notice. For Passports, eArrive and Security elements, all information is collected on OMB approved forms that contain notification statements informing the individuals of the purpose for collecting the information and the authority for collecting the information. For Fellowship program participants, information is collected on an online form with a notification statement informing the individuals of the purpose for collecting the information and the authority for collecting the information.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within AIMS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within AIMS.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Stephen Veneruso

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 10/28/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Consolidated Infrastructure [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/7/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-02-01-01-0301-00-404-139

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Consolidated Infrastructure

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Stephen Veneruso

**10. Provide an overview of the system:** FDA is moving towards long-term improvements in the structuring of IT services across centers which is aimed at facilitating greater integration in the delivery of programs and realizing significant cost savings. Efficiencies will be realized by consolidating the technology infrastructure services and in the standardization of how IT service is provided.

The consolidated infrastructure is described as local area networks, help desk and call center, voice and data services, desktop management and support, database and server management, and Intranet services.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The Consolidated Infrastructure (CI) is not designed to collect, maintain, or disseminate information. The CI is intended to provide a secure and reliable computing environment in which other FDA applications and information systems can be hosted.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/8/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Electronic Submissions Gateway [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/7/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-0501-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Electronic Submissions Gateway (ESG)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Michael Fauntleroy

**10. Provide an overview of the system:** The purpose of the FDA Electronic Submissions Gateway (FDA ESG) is to provide a centralized, secure, Agency-wide solution for receiving electronic regulatory submissions. The FDA ESG will also be used to transmit regulatory data and information to other Government Agencies. The FDA ESG is essentially a component of a communications system, collecting information from multiple sources, then forwarding that information to a file server where the appropriate FDA system can retrieve the information. Information is stored within the FDA ESG on a limited basis in support of integrity and availability procedures. The FDA ESG owns none of the data that passes through its components. The data are "owned" by the supported applications. Thus, the FDA ESG is providing a supporting service to these applications as opposed to performing an FDA mission-specific function. The FDA ESG project will help the FDA achieve its legal mandate under the Prescription Drug User Fee Act (PDUFA) for eliminating paper transactions in favor of electronic submissions and processing. The FDA ESG was a specific goal of PDUFA III.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**

No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The FDA ESG collects two sets of data. The first set of data is collected from external Transaction Partners to create user accounts within the FDA ESG to support the transmission of regulatory documents. The accounts are owned by a corporate entity. The corporate entity supplies the name, phone number and email address for a primary and secondary contact person. This information is used by the FDA ESG when necessary to resolve technical issues. The second set of data is meta-data about each regulatory submission and includes time of submission, user account, transmission protocol, message id, and file name. This information is used by the Agency to track the submission and aid in file recovery.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/8/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Emergency Operations Network [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 10/12/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-08-01-0305-00-104-010

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Emergency Operations Network (EON)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Wayne Gorski

**10. Provide an overview of the system:** The Emergency Operations Network (EON) provides an Agency-wide system to fully support the enterprise for the full range of FDA emergencies through the implementation of two robust infrastructures, functional and technological, and through the reengineering of the present emergency system. The development and incorporation of agency-wide guidance in the EON will ensure that the Agency response is uniform, consistent, and coordinated.

The authorizing legislation for EON includes the Food Drug & Cosmetic Act 903(b) and 711, the Bioterrorism Act (2002), and Homeland Security Presidential Directives.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** EON handles data regarding emergency incidents including information about the nature of the incident and personally identifiable information (PII) consisting of contact information for FDA personnel. With regard to PII, EON provides FDA contact data extracted from the publicly available DHHS employee directory website. Submission of this data to EON is not specifically mandated by statute or regulation. However, it is required for operational purposes in order to effectively administer the system and coordinate emergency response actions.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Notification and consent as to the collection and use of contact information occurs as part of the hiring process for personnel placed in emergency response positions.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within the Emergency Operations Network Incident Management System (EON IMS) is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within EON IMS. It complies with Federal Information Security Management Act (FISMA) requirements for access controls to safeguard information from unauthorized access.

#### ***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Stephen Veneruso

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 10/28/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Enterprise Administrative Support Environment [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 7/13/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-10-01-1020-00-403-131

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-90-0018

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Enterprise Administrative Support Environment (EASE)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Rosie Whitcraft

**10. Provide an overview of the system:** EASE is an FDA-wide administrative system that provides essential personnel, organization, and locator information, automates time and attendance, and provides ad hoc reporting through its associated data warehouse.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
The Program Support Center (PSC) is provided the Social Security Number (SSN) and system Sequence ID for use with its Integrated Time and Attendance System (ITAS) single sign-on function. Location and email information is provided to various FDA Scientific, Regulatory and Administrative systems. The reporting warehouse houses all information and is made available for reporting based on Role access to various information.

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The information collected in EASE includes PII gathered from personnel in order to securely and effectively administer FDA systems and programs. The submission of this information to HHS is mandatory. FDA personnel data is retrieved from HHS Personnel Files (FDA only) for civilian and Commissioned Corps personnel, for the purpose of providing corporate data to various FDA Systems, and to provide management reports. Person location data is collected to provide HHS and FDA with location and email directories. Data regarding non-employee FDA personnel such as contractors is collected to provide a basis for location and security purposes. The agency maintains only those data elements required for FDA applications. PSC ITAS employee timecard and leave data (FDA only) is received each pay period, stored in the EASE database and loaded into the RAM data warehouse for reporting purposes.

EASE collects the following PII data for FDA civilian personnel, Commissioned Corps personnel assigned to FDA, and non-employee personnel working at FDA: legal name, date of birth, home address, Social Security Number (SSN), citizenship information, and for non-citizens the Green Card, Passport or Visa number.

PII data for FDA civilian personnel and non-employee personnel working at FDA is collected through an EASE application module, eArrive. eArrive is the front end data entry application for processing new employees and non-employees into FDA and creates their EASE record.

EASE receives electronic updates nightly from the HHS Human Resource system (EHRP) with official data on all active FDA civilian personnel. The primary key between EHRP and EASE is the SSN. EASE does not send data to EHRP.

EASE receives electronic updates nightly from the Commissioned Corps personnel system. The primary key is the SSN. EASE does not send data to the Commissioned Corps system.

EASE exchanges data electronically each night with ITAS (Integrated Time and Attendance System). ITAS is part of EHRP and is owned by PSC. The primary key is the SSN. EASE sends a file of active FDA civilian personnel to ITAS on a nightly basis. Every two weeks, EASE receives a file relating to payroll from ITAS.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) HHS collects the Personnel Data. The Center Representatives, and the various individuals involved with the specific data collection and use

provide notification to the employees and non-employees at the time the data is requested. Information about the collection of data is provided within the user manuals and in the course of training.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**

Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within EASE is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within EASE.

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Nipa Shah

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/30/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Facility Management System**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 8/10/2009

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-10-02-1040-00-401-119

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Facility Management System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Don Demers

**10. Provide an overview of the system:** Facility Management System is an integrated solution to further provide better services/information to all Centers and ORA on any facility related issue, such as designing, planning, leasing, or operation.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** This system will allow the Office of Real Property Services, Office of Shared Services, to maintain a comprehensive

database to better serve all Centers/ORAs on their needs related to space design, planning, and any alteration projects within the Food and Drug Administration.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** John R. Dyer

**Sign-off Date:** 8/22/2008

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC FDA Unified Registration and Listing System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/7/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-10-01-1030-00-114-043

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** OMB 0910-0502

**6. Other Identifying Number(s):** FDA Form Number 3537/3537a

**7. System Name (Align with system Item name):** FDA OC Unified Registration and Listing System (FURLS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Michael Maldony

**10. Provide an overview of the system:** The Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) was designed with the purpose of ensuring the protection of the United States from acts of bioterrorism. A significant safety measure that must be taken as a part of this mission applies to the protection of the nation's food supply against the threat of intentional contamination. To support this effort the Bioterrorism Act requires that the FDA develop a system for registering food facilities. The system designed by the FDA to fulfill this requirement is a FDA major application, the FDA Unified Registration and Listing System (FURLS). FURLS is a web-based system that will allow users worldwide to register with the FDA. The FURLS system can be accessed through the FDA website 24/7/365. Upon accessing the site, a user is then able to register with the FDA. The majority of FURLS users are account holders who utilize FURLS to register their food facilities. The remaining users are comprised of FDA Personnel who are able to use the FURLS system to gain access to the facilities' registration information.

Section 510 of the Food, Drug and Cosmetic (FD&C) Act and 21 CFR part 207, inter alia, requires persons (e.g. manufacturers, repackers, and relabelers) upon first engaging in the manufacture, preparation, propagation, compounding, or processing of human drugs, veterinary drugs, and biological products, with certain exceptions, to register their establishments. FURLS users consist of:

Individuals required by law or authorized by an establishment to initiate and/or maintain a registration with the FDA (general system users/external users),

Authorized FDA Personnel, and

Authorized FDA Contractor personnel who may support system operations after deployment.

F-URLS has seven basic modules to support its facility registration mission: Drug Facility Registration Module (DFRM), Food Facility Registration Module (FFRM), Devices Registration and Listing Module (DRLM ), Online Account Administration (OAA), Message Processor - Enterprise Service Bus (MP-ESB) that support communications integration between F-URLS modules, Alert System that sends alerts or other high priority communications to selected registrants, and the F-URLS Scheduler that allows time-dependent events to be programmatically initiated. Currently, FURLS is adding a new module, Shell Egg Producer Registration Module (SEPRM). In addition, F-URLS provides facility registration support to other FDA components such as the Low Acid Canned Foods (LACF) system. Other FDA systems may similarly make use of the F-URLS OAA. All such system interfaces are identified in Section 3.8

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** F-URLS is a web-based system that will allow users worldwide to register with the FDA. The F-URLS system can be accessed through the FDA website 24/7/365. Upon accessing the site, a user is then able to register with the FDA. The majority of F-URLS users are account holders who utilize F-URLS to register their food facilities. The remaining users are comprised of FDA Personnel who are able to use the F-URLS system to gain access to the facilities' registration information.

The data processed by the system is as follows:

(Italics implies information optional):

· User/Registrant's Name and Facility Name (Parent Company Name if facility is a subsidiary)

- Facility Address (Parent Company Address if facility is a subsidiary)
- Preferred Mailing Address
- User's email address
- User's telephone number
- User's fax number
- User's answer to a verification question for password
- User's password
- Emergency contact name
- Emergency contact title
- Emergency contact office phone
- Emergency Contact Cell Phone
- Emergency contact email address
- Facility trade name(s)
- Seasonal start/end dates
- Establishment type
- Storage type (appears if establishment type was Warehouse/Holding Facility)
- General Product Category, (appears if establishment type was NOT Warehouse/Holding Facility)
- Statement certifying that all information submitted is true and accurate
- Registration and PIN Numbers
- Firm Establishment Identifier (FEI) Numbers
- For foreign food facilities only: U.S. Agent name, address phone number, email address, and fax number.

To accomplish the functions mentioned above, F-URLS will initially include two modules: Food Facility Registration Module (FFRM) and the Account Management module. Additionally there are interfaces that will be described in part I of this section.

#### Account Management Module

The Account Management module handles the creation and administration of user accounts for access to all FDA registration and listing modules. For F-URLS, the module allows general system users who submit food registrations and updates to create and maintain secure login accounts (the terms "general system user" and "registrant" will be used interchangeably). Users will be authenticated by the Accounts Management system, defined below, prior to accessing F-URLS. The registration and listing module (FFRM) is responsible for enforcing specific access rules for users. Additionally, the Account Management module uses the business rules and infrastructure implemented by the Enterprise Administrative Support Environment (EASE) in creating and administering FDA Personnel user accounts. More information on the interface with EASE can be found in part I of this section. This avoids duplication when managing FDA user accounts and allows FDA users the ability to use their EASE account to access multiple

registration and listing modules. More specific information pertaining to the Account Management Module and its use cases can be found in the System Requirements and Design Document (SRDD).

#### Food Facility Registration Module (FFRM)

The Food Facility Registration Module is essentially the element of the system that meets the requirements of the Bioterrorism Act of 2002, which required that FDA develop a system for registering food facilities. This module will allow users with accounts established through the Account Management module to register their food facility with the FDA. FFRM will prompt each registrant to enter information pertaining to their facility such as the address of the facility, the facility trade name, the establishment type, and the general product category.

In addition to gathering facility information, the FFRM can generate a request to process a mailing. There are four types of cor

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

#### *PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/8/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Financial Reporting System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** Significant System Management Changes

**1. Date of this Submission:** 12/5/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Financial Reporting System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Amy Kramer

**10. Provide an overview of the system:** FDA has restructured its internal financial systems and standardized related business processes to better integrate with HHS's Unified Financial Management System (UFMS) and related financial processes. The resulting system is FDA's Financial Reporting System (FRS), which is composed of two interrelated applications: Hyperion, a Planning system, and the Business Intelligence Reporting System (BIRS), also referred to as OBIEE because it utilizes Oracle Business Intelligence Enterprise Edition Plus. These applications replace the Asset Management System (AMS) and Central Accounting System (CAS).

BIRS is a comprehensive suite of business intelligence tools and infrastructure. BIRS generates management reports to bring greater business visibility and insight to a broad audience of users. It allows users to have Web-based self-service access to up-to-the-moment, relevant and actionable finance-related business intelligence extracted from the UFMS system. BIRS is housed on servers at NIH.

Hyperion Planning is a centralized, Excel and Web-based planning, budgeting and forecasting solution that integrates financial and operational planning processes and improves business predictability. In FY 2010, in response to expanding requirements, OFM provided significant upgrades to the functionality of the application. The Hyperion application is hosted at FDA's Contractor Hosted Data Center in Ashburn.

These reporting systems and FDA's User Fee System, make up a single investment that supports Office of Finance activities related to fee collection and FDA budgeting.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
No PII shared or disclosed

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** For the BIRS component of this system, the Extract/Transfer/Load (ETL) process extracts financial information from HHS's Unified Financial management System (UFMS) and loads it into the BIRS database for financial and business planning and budgeting purposes. In addition to financial data, the information transmitted by HHS includes two items of PII: employee social security numbers (SSNs) and addresses. No other PII exists in the BIRS or Hyperion databases. FDA does not request or require the employee SSNs and addresses. FDA does not share this information or use it in any current or planned processes. Because this system receives the PII from UFMS the question of whether submission is voluntary or mandatory does not apply.

For additional background on the PII collected by HHS in the UFMS and its related subsystems (e.g., whether submission of the information is voluntary or mandatory), the PIA and System of Records Notice for UFMS is available through [HHS.gov](http://HHS.gov) (SORN No. 09-90-0024, Financial Transactions of HHS Accounting and Finance Offices).

The Hyperion database contains financial management, planning, and accounting information about FDA offices. It has no data on individuals.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII is limited to two items. Only SSN and address information relating to employees is included in the data received from UFMS and maintained in the BIRS database. It is neither used in BIRS nor shared with any other systems. Documentation

(SORN, PIA) for the HHS source system, UFMS, indicates that HHS provides notice and obtains consent directly from individuals electronically and in writing.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**

Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within FRS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within FRS.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 12/9/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Internet [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 12/2/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-02-01-02-1060-00

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Internet

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Josh Lehman

**10. Provide an overview of the system:** This system focuses on the information technology infrastructure to provide a platform for the display of information on FDA's public Internet web site, [www.fda.gov](http://www.fda.gov). The Office of Public Affairs, Web Site Management Staff, FDA web Content Program Manager, and center/organization content developers have responsibility for the site's specific content management. The site provides a mechanism for FDA staff to post FDA information to the public and to ensure the availability and integrity of that data so that the various FDA content managers can safely and securely provide data to the site.

FDA also provides content syndication and health awareness tools to enhance the accessibility and availability of information presented on [FDA.gov](http://FDA.gov). These tools are voluntary self-service mechanisms on [FDA.gov](http://FDA.gov) that serve as additional avenues of access to publically available web content and information. These tools are unidirectional, in that content and information flows in one direction: from FDA to public users who have control over their use of the service. These tools are not designed to collect information or make any use of the information that users voluntarily provide. FDA does not provide the user-submitted information to other entities.

As adapted from a parallel CDC program, FDA's OC Internet system will display public interface tools provided to increase access to, and distribution of, content publically available at [FDA.gov](http://FDA.gov). It will include a consolidated publishing or "content syndication" service with a self-serve element for organizations to obtain code to syndicate FDA content among organizations with an interest in FDA activities. This tool is now in the pilot stage. Use of the syndication tool will be optional. Those organizations that wish to use the content syndication service voluntarily provide a website URL and e-mail address. FDA does not validate or review this information. Use or non-use of the service does not effect access to public information through other means. Users have complete control over their use of the content syndication service, they are free to

change the website URL or e-mail address through which they receive the syndication content, and can end their use of the syndication tools at any time without any FDA involvement.

FDA makes no use of, and does not share the website or e-mail addresses users choose to employ when receiving the publically available content for syndication. Users enroll, and the automated service sends them content.

FDA.gov also provides health awareness and promotional tools such as a Break the Chain of Tobacco Addiction pledge to protect kids from tobacco (pledge widget) which FDA's Center for Tobacco Products (CTP) adapted from a similar CDC.gov flu shot pledge widget.

The pledge widget is designed for user interaction purposes only. It is an awareness tool by which participants can promote responsible tobacco retailing and protect children from tobacco products. Users voluntarily participate, or "take the pledge," by posting a first name, last initial, city and state in order to have their participation displayed on a map. No other information may be submitted. FDA does not verify or trace the information provided. Participants may effectively make data anonymous by providing information that does not identify them. The pledge widget includes a notice and disclaimer advising participants that by taking the pledge they wish FDA to display the information they provide on the pledge map.

FDA does not require, solicit, collect, use or share the information that pledge participants choose to submit. FDA.gov serves only as a pledge participation display platform.

The content syndication service is an element of the pledge tool. Participants may "spread the pledge" via email, Twitter, Facebook or copying and embedding pledge widget code.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**

No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether**

**submission of personal information is voluntary or mandatory:** This system consists of the information displayed on www.fda.gov. The content and interactive tools on the website are public facing, and do not contain PII. Each application and the associated data visible on www.fda.gov is the responsibility of the FDA Website management staff and center/organizations, which manage the content of those systems and the data being provided to the website. The system is not part of the Infrastructure project.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Sarah Kotler

**Sign-off Date:** 6/9/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Mail [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/12/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Mail

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Joe Neubauer

**10. Provide an overview of the system:** The FDA's e-mail system has evolved into a core service and is a vital component integrated into the FDA's regulatory mission and records management systems. However, significant challenges exist in supporting the agency's current FDAHSMail system. Demands for increased customer service and responsiveness, anticipated user growth, rapid changes in technologies, and increased security threats mandate the deployment and management of a new, scalable, and highly secure e-mail environment. A top priority for the FDA is to gain full control of its internal e-mail operation and transform the current messaging system to a solution based on Microsoft Exchange 2007.

The FDA has outgrown its current enterprise Exchange 2003 e-mail and archiving infrastructure and plans to migrate its users to Exchange 2007 and an archiving solution compatible with Microsoft Office 2007. By leveraging enhanced capabilities, such as high availability mailboxes and advanced clustering, the FDA's Office of Information Management (OIM) intends to reach its ultimate goal of providing a more stable and highly available enterprise e-mail capability while simultaneously reducing the amount of system management and intervention by administrators. In addition to being highly available and scalable, the system must be secure and compatible with the existing Tumbleweed e-mail encryption and IronPort anti-spam and anti-virus products. Additional capabilities, such as instant messaging (IM) and wireless access via BlackBerry devices, will also be upgraded. The implemented solution will provide system upgrades to the FDA's enterprise e-mail infrastructure; migration to the target system; Tier 3 support for the call center, desktop technicians, end users; and the operations and management of all back-office systems related to e-mail.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the**

individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system transports electronic mail. The email system is only a conduit for message traffic and is not designed to collect, store, share, or disclose PII.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 5/17/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Physical Security System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 8/11/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-10-0018, 09-90-0777

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA Physical Security System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Karl Thrash

**10. Provide an overview of the system:** The FDA Physical Security Systems (PSS) is a “major application” for Federal Information Security Management Act (FISMA) reporting and compliance purposes that currently includes two separate systems/applications implemented with commercial-off-the-shelf (COTS) software solutions.

The Building Access System (BAS) component of PSS is implemented in Monitor Dynamics, Inc. (MDI) COTS software. BAS is comprised of a card access system, intrusion alarm points, emergency contact lists, maps and a central monitoring station located at FDA’s White Oak facility, which is monitored by contract guards 24 hours per day, 7 days a week.

The LobbyGuard System (LGS) component of PSS is implemented in LobbyGuard Solutions, LLC COTS software Kiosk version 3.0. LGS consists of a visitor registration system. When an authorized FDA employee requests that a visitor be granted access to an FDA facility, that employee’s authorized administrative official will enter the visitor’s information into a web portal. This will cause an authorization e-mail to be sent the visitor. When the visitor arrives they can present a printed copy of the e-mail (with barcode) to the Lobby guard and a badge will be printed for them. The Physical Security Branch designees can process badges for contractors/visitors that do not have permanent badges.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether**

**provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The Physical Security System (PSS) contains information about employees and other individuals affiliated with FDA, as well as authorized visitors to FDA facilities. The information is used in the process of issuing an FDA Identification/Access Card permitting access to certain FDA facilities. The PII in the system includes: name, date of birth, social security number, photograph, personal identity verification (PIV) card number, height, weight, vehicle tag number, access level, building, room number and the nature of the relationship to FDA, for example, whether an individual is an employee, contractor, guest worker, or visiting scientist. Submission of this information is mandatory; it is necessary in order to verify identity and administer secure access to FDA facilities. Information is provided to HHS/FDA by the individual at the time he or she become an employee, contractor or otherwise affiliated with FDA. The information then resides in source systems from which it is provided to PSS..

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]** There are no notice and consent processes currently in place within the Physical Security branch. Notice and consent would be addressed at the time the information is initially provided to other HHS/FDA offices, such as date of hire.

Individuals may update their PII data by submitting an update form to an appropriate supervisor, the Badging Office, or the Parking Office.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within the system is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 10/28/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC Science First [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 12/6/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-10-01-2000-00-202-072

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC Science First

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Ashish Sarin

**10. Provide an overview of the system:** SCIENCE FIRST is a virtual agency-wide science center, consolidating scientific information from across the entire agency. SCIENCE FIRST contains tools and applications to support the agency's initiative of enhancing science within the agency, the continuing goal of science-based regulatory decision-making, fostering collaboration and communication between agency scientists, and increasing awareness of FDA research accomplishments. The regulation that applies to this system is the Government Paperwork Elimination Act (GPEA).

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system collects and

disseminates science-related and other pertinent regulatory information such as skills resources, research projects, scientific and regulatory publications, links to training and knowledge enrichment sources, and scientific data sources. This information will be used to support the agency's initiative to enhance science within the agency, the continuing goal of science-based regulatory decision-making, foster collaboration and communication between agency scientists, and increase awareness of FDA research accomplishments. The question of mandatory or voluntary submission of PII does not apply to Science First. There is no submission of PII. The system does not collect, maintain or transmit PII.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Eric Perakslis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 12/9/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA OC User Fees System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 7/6/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-01-01-4140-00-402-125

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** UserFee was only recently discovered to be subject to the Privacy Act. A SORN is being created, but is not completed.

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA OC User Fee System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Amy Kramer

**10. Provide an overview of the system:** The User Fee System is a component system of the Financial Enterprise Solutions (FES) Mission Critical computer security classification investment. The system application utilizes various modules of the Oracle eBusiness Suite, v.11.5.9.

The system was developed to respond to the legislative needs of:

Prescription Drug User Fee Act of 2003

Medical Device User Fee and Modernization Act of 2002

Animal Drug and User Fee Act of 2003

Mammography Quality Standards Act

Internal users access the system through the firewall-shielded secure FDA network. Thousands of external industry users access the system via the Internet through a back and front-end, firewall-shielded sub-network in a demilitarized zone. System servers are located in the FDA Network Control Center on the second floor of the Parklawn building in Rockville, Maryland.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the**

**character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**

Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
All information collected is required to exchange by the federal government to facilitate payments required by the User Fee legislation. The data collected is the minimum necessary to complete the coversheet and billing processes.

Internal users access the system through the firewall-shielded secure FDA network. Thousands of external industry users access the system via the Internet through a back and front-end, firewall-shielded sub-network in a demilitarized zone. System servers are located in the FDA Network Control Center on the second floor of the Parklawn building in Rockville, Maryland.

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The User Fee System collects data related to transactions for which external industry users must pay fees. Such transactions involve user fees associated with:

- Prescription Drug User Fee Act of 2003
- Medical Device User Fee and Modernization Act of 2002
- Animal Drug and User Fee Act of 2003
- Mammography Quality Standards Act

For internal federal users, the User Fee System collects specifically identifiable information about the names and email address. The records are of employees responsible for accessing Oracle Applications as approved by the account approval process.

For external industry, the User Fee System collects business identifiable information about name, address, telephone numbers, email addresses, DUNS, waiver information and Federal Employee Identification number.

All information collected is required to exchange by the federal government to facilitate payments required by the User Fee legislation. The data collected is the minimum necessary to complete the coversheet and billing processes.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original**

collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes in place.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**

Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within User Fees is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within User Fees.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/27/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Electronic Laboratory Exchange Network [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 4/26/2010

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-1070-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA Electronic Laboratory Exchange Network (eLEXNET)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Tim Rigg

**10. Provide an overview of the system:** The Electronic Laboratory Exchange Network (eLEXNET) was developed to facilitate secure information sharing among public health partners and collaboration among food safety experts. eLEXNET provides food safety officials with access to food test results for analytes of concern at the detail level and at the product or product industry level.

eLEXNET is a seamless, integrated, secure network that provides multiple federal, state and local government agencies engaged in food safety activities with the ability to compare, communicate, and coordinate findings in laboratory analyses. The system enables U.S. health officials to assess risks, analyze trends, and identify problem products. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**

No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** eLEXNET currently allows food safety laboratories at all levels of government (federal, state, local) to share real-time food safety sample and analysis data on selected microbiological analytes. eLEXNET receives sample status and sample analysis summary, laboratory analytical methods and results, and laboratory conclusions from other systems within FDA, as well as from participating laboratories. All data collections are necessary to meet the goals of this system. No Personally Identifiable Information is collected or stored in the eLEXNET system. Prior to obtaining access credentials, when laboratories agree with and sign the written Memorandum of Understanding (MOU), they are informed of the data collection process.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Lori Davis

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/31/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Firms Master List Services [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 5/11/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Firm Master List System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Chris Cross

**10. Provide an overview of the system:** The Firms Master List Services (FMLS) system is organizationally located within FDA's Office of Regulatory Affairs (ORA). The system provides a uniform method for accessing and maintaining firm (e.g., regulated food establishments) data across the ORA. The purpose of FMLS is to:

- (1) provide services at near real time operation due to the mission critical 24/7 nature of ORA's business and the importance of maintaining the accuracy of continuously changing firm data;
- (2) provide a set of services for validating and matching firm data that may be used throughout the FDA;
- (3) provide mechanisms for adding, updating, merging and unmerging firm data as well as functionality to change, add and update food firm data such as firm ownership, physical location and registration information; and
- (4) adhere to industry standards for Web Services in order to integrate the address validation and matching services with other FDA/ORA applications and to facilitate compliance with any future FDA Service Oriented Architecture (SOA) standards.

The FMLS system has five main components:

1. The Address Validation Web Service (AVWS v1.2) provides service consumers with the capability to validate the addresses and provide geocode information for firm records. The Address Validation Web Service uses the data quality tool, DataFlux, for address validation. The Google Geocode Service is used for the geocoding capabilities. The consumers for AVWS are the Device Registration and Listing Module (DRLM), FDA Unified Registration and Listing

System (FURLS), Food Facility Registration Module (FFRM), Firms Management System (FMS) and Automated Commercial System (ACS) Encrypted Social Security (ESS) Update external applications.

2. The Match Web Service (MWS v1.0) provides service consumers search functionality for existing firms records in the Firm Master List (FML) database. The Match WS uses the data quality tool, DataFlux, to generate match codes used for matching in FML database. The consumers for MWS are Prior Notice System Interface (PNSI), Prior Notice (PN) PNACS and FMS external applications.

3. DataFlux is the new state of the art Data Quality tool acquired by the FDA to maintain firms data quality.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The information FDA collects, maintains and disseminates via the FMLS system includes Firm Name, Physical and/or Mailing Address, Firm Contact Information, Food Facility Registration, Cross Reference to another FDA Identifier, such as data universal numbering system (DUNS) number or another FDA Establishment Identifier (FEI). The data maintained within FMLS, together with the system capabilities enable FDA to provide a set of services to FDA's internal and external system consumers for firm address validation, firm matching, adding, updating, validating, merging and unmerging firm data including food firm ownership changes and registration status changes.

The FMLS system is not intended to collect PII and does not require or solicit PII. Personally identifiable information such as the name, work mailing address, work telephone number, and

work email address for the firm employee designated as the contact person may be submitted to FMLS voluntarily as part of the contact information for the firm registration if the firm chooses to have a personal contact listed. FMLS does not collect or store any PII other than voluntarily provided firm contact information. Firms may withdraw or amend this contact information at any time. FMLS is a back-end system, and use of FMLS is not mandatory for any users (physical persons). FMLS is used by systems and provides backed interfaces to the consumer systems listed in item 10.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Agnes Kivuvani

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Sarah Kotler

**Sign-off Date:** 6/9/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Knowledge Base Tool [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:** Not Applicable

**1. Date of this Submission:** 9/16/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** n/a

**5. OMB Information Collection Approval Number:** n/a

**6. Other Identifying Number(s):** n/a

**7. System Name (Align with system Item name):** ORA Applications Knowledge Base Tool

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Al Ansorge

**10. Provide an overview of the system:** This is a consumer off-the-shelf (COTS) data repository with a search tool. System users are FDA/ORA employees and contractors. The repository contains information or 'articles' used as a guidance or 'help-desk' resource for users. Repository searches are based on subject matter of help desk issues.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
no

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The information collected in this system consists of technical instructions. The information is generated by the developers of

the various applications related to this system and by support technicians (contractors) who preserve specific problem case histories and resolutions that may be applicable to future cases. The information will improve speed and accuracy for technicians providing assistance to Office of Regulatory Affairs (ORA) system users when they contact support technicians for assistance in the use of the system. Regardless of the source of the information collected, no PII information is captured. Collection of PII is specifically prohibited in related contract agreements.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) n/a

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** none

*PIA Approval*

**PIA Reviewer Approval:**

**PIA Reviewer Name:** John Simms, CISO FDA

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/23/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Lab Systems [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 11/3/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** n/a

**5. OMB Information Collection Approval Number:** n/a

**6. Other Identifying Number(s):** n/a

**7. System Name (Align with system Item name):** ORA Lab Systems

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Cdr. Eduardo Lim

**10. Provide an overview of the system:** The Office of Regulatory Affairs (ORA) Lab Systems is comprised of two applications: the Chemical Inventory System (CISPro) and ExcelSafe.

CISPro is a reagent tracking system developed specifically for the management and tracking of laboratory chemicals. This relational database program tracks and maintains accurate, real-time chemical inventory information, for use in regulated or non-regulated environments or a combination of both.

The ExcelSafe application provides the technological tools for any MicroSoft (MS) Excel spreadsheets to be compliant with 21 CFR Part 11 (electronic records criteria) in GxP (good practice) environments. This regulation, which applies to all FDA program areas, was intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect the public health. ExcelSafe operates seamlessly with spreadsheets and once an MS Excel spreadsheet is opened, all compliance features work automatically; no changes are required to existing spreadsheets.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass**

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
n/a

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** Within ORA Lab Systems, the CISPro Chemical Inventory System is a relational database program that tracks and maintains accurate, real-time chemical inventory information, for use in regulated or non-regulated environments or a combination of both.

The ExcelSafe application provides the technological tools for any MS Excel spreadsheets to be compliant with 21 CFR Part 11 in GxP environments. This regulation applies to all FDA program areas and is intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect the public health.

No PII is contained in CISPro or ExcelSafe, or the Lab System as a whole

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) n/a

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** n/a

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Nipa Shah

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 11/15/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Compliance Management Services (CMS) [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 5/12/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-08-01-0202-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-10-0010 Bioresearch Monitoring Information System, HHS/FDA

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Mission Accomplishment and Regulatory Compliance Services - Compliance Management System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Kelemework Yimam

**10. Provide an overview of the system:** The MARCS-CMS is a web-based search and retrieval system that provides the ability for Field and Center Compliance Officers to create a Compliance Action via FACTS or independently of FACTS and electronically send Compliance Actions to the Centers or directly to OGC for review. The Centers' Compliance, other organizational and regulatory components, and its field staff use this information in the preparation of business process responses and/or actions. Some of the MARCS-CMS data for bioresearch monitoring is protected by the Privacy Act of 1974, 5 USC 552A, as Amended, 5252a. MARCS-CMS also includes data which is subject to protection under the FOIA (5 USC 552, as amended). MARCS-CMS includes predecisional & deliberative materials, drafts, etc., which are protected under Exemption (b)(5) of the FOIA, for inter- and intra-agency memoranda, and open investigatory records, subject to withholding under exemption 7 of the FOIA.

ORA and all Centers are using MARCS-CMS to increase integration of their regulatory work and reduce costs of system development and operation. It provides access to Field, Center, and other ORA regulatory components' officers and managers. An Enterprise Search component assists searching within the MARCS-CMS document repository. Through MARCS-CMS all users can obtain reference information from public sources, such as the Federal Register, and regulatory material related to a particular food safety or compliance issue. The MARCS-CMS incorporates regulatory information from other Centers including CDER, CBER, CFSAN, CVM, CTP, CDRH, and ORA.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This**

**question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** MARCS-CMS contains inspection and investigative records, sample collection reports, analytical worksheets, open investigatory files and other records supporting FDA's administrative and legal actions, including Warning Letters and Untitled Letters. Such CMS data contains PII in the form of names of clinical research investigators and their related identifying information. In some instances the business entity or firm name is the clinical research investigator's name, such as a sole proprietorship operated by the clinical research investigator. CMS files may also contain PII in the form of individual consumer names when referenced in consumer complaints or in medical records obtained during FDA inspections, investigations or other legal and administrative actions. These CMS records are used in support of FDA's efforts to track clinical research investigators, monitor complaints submitted to FDA, and in support of FDA inspections and related administrative or legal actions. Clinical research investigator names and identifiers are typically provided voluntarily or on occasion by demand of FDA. Consumer names are voluntarily provided directly to FDA or gathered as part of FDA inspections or investigations. Because this system contains individual names and personal identifiers, access to it is strictly controlled.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.])** None

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within MARCS-CMS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within MARCS-CMS.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** George Brush

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/8/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Domestic - Field Accomplishments and Compliance Tracking System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 7/5/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-08-01-1010-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-10-0010

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA MARCS Domestic - Field Accomplishments and Compliance Tracking System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Thomas Simpson

**10. Provide an overview of the system:** FDA's inspection process, managed by FACTS, is responsible for the health and safety of the American Public by providing support to the overall FDA's mission of promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use. Legislation authorizing this activity is the Food Drug and Cosmetic Act.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):** Firm data which may include Physician Names (as Firm entities) is contained within FACTS and used by many centers within the FDA for many purposes including Firm inspections.

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this**

**description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The FACTS system contains data about commercial firms and their business relationships, data, FDA decisions, manpower, procedures, establishments, commerce, compliance, enforcements, products, consumer complaints, and FDA organizations.

There are Firms that are Physician entities represented by their Physician Name. These names may be considered IIF.

The FACTS database provides information on FDA performance to Congress and the OMB, and supports the Drug industry's PDUFA initiatives. This system also presents rapid review of current and past fieldwork assignments, results, and time/cost to accomplish in the Agency mission areas of regulation, surveillance, and compliance.

The system provides support to the overall FDA's mission for promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use.

FACTS shares collected information with the following systems:

Lab data exchange between FACTS-OASIS (ORA), Data to FACTS Reports; OPAS (ORA), Assignment data to Turbo EIR (ORA),

Firm profile data to ORA/DCIQA (Intranet/Internet), Lab data to eLEXNET (ORA, CFSAN), Complaints & Adverse event data to CAERS (CFSAN),

Firm profile data feed to CDER,

Pre-approval inspection data exchange with EES (CDER),

Firm data to eDRLS (CDER),

Inspection data from MPRIS & CASS (CDRH)

The primary users of FACTS are FDA organizations (see above) that enter, update, retrieve, and otherwise manipulate the data contained in the FACTS database with the ORA Field Offices staff being the principal suppliers of FACTS data. The Centers then make extensive use of FACTS to communicate with the Field.

The secondary users of FACTS include organizations and individuals' external to the FDA that contributes industry information to the FACTS database. These include consumers, health care providers, state partners, state public health agencies, and other Federal agencies.

FACTS has built-in controls to grant or modify access to the relevant data based on the user role and District he or she belongs to with FACTS end users having only 'read only' access to data from other district offices.

For the FACTS/eSAF system there are three primary security zones. The three zones are 1) the Internet, 2) the Service Area Network, or Demilitarized Zone (DMZ), and 3) the Intranet or “inner core”. This approach separates the functions of “border control,” “identification and authentication,” and “access control.”

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes currently in place.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within RES is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within RES.

#### ***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** John R. Dyer

**Sign-off Date:** 8/22/2008

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Imports [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:**

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-08-01-1020-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA MARCS Imports (MARCS IMPORTS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Thomas Simpson

**10. Provide an overview of the system:** MARCS IMPORTS automated the re-engineered business processes which the FDA utilizes for making its admissibility determinations. These determinations are used to ensure the safety, efficacy, and quality of the foreign-origin products for which FDA has regulatory responsibility under the Federal Food, Drug and Cosmetic Act.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The information is collected

initially from the Customs and Border Protection through their ACS system. All time spent reviewing commercial entry data, both on-screen and via paper entry documentation, are recorded as Entry Review. This includes checking regulatory status by accessing Center databases or FIARS, review of FD Form 2877s, Affirmation of Compliance Codes and their qualifiers, and review for data accuracy during Entry Review.

In addition, all time spent to make and record May Proceed decisions, regulatory recommendations such as Detention Requests (DTR) or Detention w/o Exam Requests (DER) and setting up Investigations exam/collect work assignments should be recorded as Entry Review. Any changes to transmitted data found to be inaccurate are made before setting up exam/sample assignments if possible. Such errors are then provided to the district personnel responsible for conducting filer evaluations.

In summary MARCS IMPORTS is a mission critical system that supports about 3500 FDA users throughout the US users on a 24/7 basis. It provides:

- o An automated interface with US Customs Service systems
- o Automated pre-screening processes
- o Support for Entry-Reviewers and Compliance Officer review of regulated products, including computer-aided decision-making
- o Maintenance of information for reporting decision-making
- o Tracking and review of workflow

The MARCS IMPORTS information is shared with Dept. of Homeland Security, Customs and Border Protection (ACS), FACTS, ORADSS, and FDA Centers.

MARCS IMPORTS enables FDA to handle more efficiently and effectively the burgeoning volume of shipments (now over 8 million/year -- up by 50% in the last four years) of imported products, despite decreasing agency resources. It also maximizes the efficiency and accuracy of the import review process to ensure the safety of imports regulated by FDA on behalf of the American public.

MARCS IMPORTS automates a number of previously manual processes, provides more timely data and better data integrity to support decision-making. It also supports better workflow between the Entry Reviewers and Compliance Officers as well as an ability to monitor performance. No IIF information is being collected.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A**

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 8/27/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Interface [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 5/11/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-08-01-0202-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA Mission Accomplishment and Regulatory Compliance Services (MARCS) Interface (MI)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Tina Nguyen

**10. Provide an overview of the system:** The Office of Regulatory Affairs (ORA) Mission Accomplishment and Regulatory Compliance Services ( MARCS) Interface (MI) is a multi-phased effort that will use Oracle Application Development Framework (ADF) software and other Oracle Fusion Middleware technologies to create an environment where users can, with a single sign-on (SSO), access multiple FDA systems. When fully implemented, the interface will provide:

A web infrastructure that will support new applications under development at ORA, and a platform for integrating older applications as they are migrated, or reengineered, into a web environment.

A number of standard services as a part of its environment including workflow, personalization, secure role-based access to systems, Public Key Infrastructure (PKI) integration through the Agency's SSO and Active Directory (AD) Servers, content indexing and retrieval, and other standard web application features.

Process flow capability that will support import review functionality, allowing import reviewers to retrieve data from multiple databases without the manual processes and cumbersome use of legacy applications that are now required.

A comprehensive user environment for information management, allowing retrieval of data from all ORA systems, ORA Reporting, Analysis and Decision Support System (ORADSS) and Automated Laboratory Management (ALM).

An environment tailored to the ORA work community's information needs. The environment can easily be customized to each user's role, providing links to supporting systems, websites, and any FDA information needed to support each user's daily information needs.

The MARCS Interface will serve as the access control gateway for all ORA applications.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**

No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The ORA MARCS Interface will not collect or maintain data except for the minimum needed to establish a secure account ID. Data accessed through the interface may include:

Data about the facilities that manufacture, store, process, or ship FDA regulated products into the US.

Data about importers, consignees, shippers, carriers, involved in importing and/or distributing imported FDA regulated products.

Data about the size, contents, type of FDA regulated products entering the US.

Data regarding inspections, reviews, investigations or past history (including recalls) of FDA regulated products entering the US, and entities involved in their manufacture, processing, labeling, shipping or other regulated role .

FDA approved standards for FDA regulated products.

Most of this data already exists in FDA legacy systems and is currently used in processes employed to review admissibility of imported foods, drugs, medical devices, and other regulated products.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g.,**

disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** George Brush

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/2/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA On-line Program Analysis System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 2/28/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-08-01-0201-00-301-092

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA Online Program Analysis System (OPAS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Bhabani Das

**10. Provide an overview of the system:** The On-line Program Analysis System (OPAS) is a planning and analysis tool that provides the Division of Planning, Evaluation and Management (DPEM) data necessary to respond to special requests for information from Congress, Government agencies, and the public. The information collected and consolidated in OPAS includes work plan information and summary data provided by various FDA field activities.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether**

**submission of personal information is voluntary or mandatory:** OPAS contains employee accomplishment information extracted from the ORA Field Accomplishments and Compliance Tracking System (FACTS). The extracted information refers to the employee's work activities by Operation, Firm, Location, Position Class, Program Code, and Number of Hours. The only information gathered from the employee is a system-generated key called PERSON ID. The key is used to identify the number of employees who are involved in various activities. This information is then counted and aggregated for each dimension (Operation, Location, Position Class, Program Code, Fiscal Year). Values are loaded into a Microsoft Analysis Services multi-dimensional database for display to the OPAS users (Headquarters managers and analysts, and field managers).

Work plan information in OPAS is collected from the PLAN\_MODEL table in the Field Workforce Planning System (FWFPS). This table stores only the number of employees (head counts). It does not contain data related to any individual employee. OPAS does not display public information (i.e., names of Firms). Although this information is collected in FACTS, OPAS displays only counts of Firms in various categories (by Establishment Type, Industry Code, Location, and Fiscal Year). DPEM uses the information in OPAS to support data findings and decisions in its responses to requests.

OPAS does not collect, maintain or disseminate personally identifiable information (PII).

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Bhabani Das

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 3/3/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Online Reporting Analysis Decision Support System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 5/24/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-01-1040-00-111-033

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Bhabani Das

**10. Provide an overview of the system:** This is a data warehouse and reporting system developed to provide domestic and import reports to headquarters and field users.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The information available in this system can be broken down into different areas.

1. Data that is collected as a result of a product being imported into this country. Basically the type of product and how it is packaged.
2. Data that is collected as a result of sample collections. The data collected includes data such as pac, product, industry, firm name, hours, and operation date.
3. Data that is collected as a result of firm inspections. The data collected includes data such as pac, product, industry, firm name, hours, and operation date.
4. Data that is collected as a result of sample analysis. The data collected includes data such as pac, product, industry, firm name, hours, operation date, and results.
5. Data that is collected as a result of legal actions taken against a firm. The history of the legal action is recorded such as when an action was proposed, when it was sent to legal council, etc.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

#### *PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Bhabani Das

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/2/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Open Mentoring [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 10/6/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Open Mentoring

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Brooke Mullican

**10. Provide an overview of the system:** Open Mentoring is a social learning management system that facilitates the knowledge exchange process through intentional networking. It allows ORA to match, manage and measure one-to-one, group and situational mentoring relationships built around customized learning projects and objectives. Open Mentoring helps ORA preserve its intellectual capital and supports Division of Human Resource Development (DHRD) in its mission to provide high-quality learning opportunities through the delivery of timely and cost effective learning products that support the mission and strategic goals of the FDA and that meet the training and development needs of ORA personnel, state and local regulatory officials, and other stakeholders.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** The system maintains mentoring information. It will provide ORA personnel with an open forum to transfer mentoring knowledge to ORA staff. Participation in the program is voluntary. Open Mentoring will create a differentiated mentoring database system to fit the unique needs of the ORA user. The functional aspects of the system will include preparation of lesson plans, objectives, presentations, exercises and assessment tools for training ORA Mentors and Mentees. It will also include preparing, administering and recording webinars. The PII in the system is limited to name, work experience, functional expertise and educational history. The name of each participant is required in order to achieve the purpose of the system. Work experience, functional expertise and educational history are submitted on a voluntary basis; each participant controls the information they choose to provide. None of the PII is required by law or mandated by a regulation, and this program does not supersede any statute, regulation or policy.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Consent is obtained from the individuals by click-through agreement at the time they initiate participation. In the click-through process individuals are given notice that PII is being collected from them and that by proceeding they consent to use of their information. The information collection and use does not supersede any FDA regulations. Additionally, all information that users input must meet the Freedom of Information Act (FOIA) guidelines. No proprietary, confidential, or identifying information beyond name and work/educational history (e.g. social security number, home address, telephone number), regulated firm establishment identification numbers (FEI), firm names, addresses, proprietary firm information (e.g. manufacturing equipment or processes), sample numbers, legal case numbers, etc. may be placed in this database. The database is monitored by the Open Learning Network administrator(s) to assure compliance with established FOIA guidelines and other applicable legal and regulatory requirements.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Inherited controls from Rackspace Data Center in Dallas, TX.

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Nipa Shah

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 10/14/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Quality Management Services [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:**

**1. Date of this Submission:** 5/11/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** Quality Management Information System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Cathy Burns

**10. Provide an overview of the system:** The Office of Regulatory Affairs (ORA) Quality Management Information System (QMIS) supports the ORA Quality Management System including ORA laboratory accreditation in defining, tracking, understanding, and continually improving processes and methods. QMIS will support document control, corrective actions, complaints, and record control.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether**

**submission of personal information is voluntary or mandatory:** QMIS is not intended to collect, and does not require or solicit personally identifiable information (PII). QMIS does not contain PII.

QMIS is a document control and management system serving all FDA ORA Offices for core business processes:

#### QMS-1: Document Control and Management

The Document Control workflow includes recommending, processing, reviewing, approving, and automated routing of new and changed documents. The scope encompasses standard operating procedures (SOPs), policies, and other directives governing the way the agency does business. The procedure also covers storage of final documents, maintenance of active document lists and master lists, and providing search tools for documents. Forms and evidence generated during quality management activities are covered under Record Control.

#### QMS-2: Control of Records

This procedure applies to the control and management of information and collateral evidence collected or generated during quality management activities such as product reports and management reports. The information is stored and retrieved to provide evidence of system performance and effectiveness to assure that records are properly managed. Records include reports, correspondence, quality records and technical records. Quality records include the following: internal audit reports, management reviews, corrective and preventive actions. Technical records include completed forms and reports.

#### QMS-3: Management Review

Top management conducts planned reviews of the quality system events and trends to ensure the continuing suitability, adequacy, and effectiveness, of the quality system in achieving the stated quality objectives and to ensure continuous improvement. From this analysis, an action plan is developed, implemented and monitored. Action items identified in the action plan are carried out using the corrective action procedure or preventive action procedure as appropriate.

#### QMS-4: Audits

Scheduled independent audits are performed to ensure compliance of practice with documents and effectiveness of results in achieving quality system goals.

#### QMS-5: Control of Nonconforming Processes, Services, and Products

This procedure applies to responses to nonconformities (NCs) and the practices to be followed to detect, identify and trend them. Nonconformity is defined as a departure of a quality characteristic from its intended level. Both frequency of occurrence and severity level may determine if a nonconformity or pattern of repeated nonconformities merits a corrective action. On-the-spot or immediate corrections of noncritical NCs are simply logged for historical purposes and can be annotated on the worksheet, report, memo, or similar document.

## QMS-6: Continual Improvement

This procedure communicates the process that involves ORA customers and staff in the identification, design, development, and implementation of strategic and operational initiatives necessary to achieve the organization's mission: "Protecting and Promoting Public Health." This procedure defines the general methods to be followed to define goals and measure results. It will assist users to identify potential QMS improvements that may be gained through process changes, corrections or improvements. The procedure does not require a corrective action to trigger activity. It may lead to a preventive action or a workflow change that will improve staff productivity.

## QMS-7: Corrective Action

This procedure establishes the process to identify, track, trend, and complete the investigation of the non-conformance, and correct the causes of existing non-conformances including complaints in processes, services, products, and the Quality Management System. The cornerstone of corrective actions is written and retrievable documentation of actions taken and follow-up monitoring to determine that corrective actions have been performed, documented and effective.

## QMS-8: Preventive Action

Preventi

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.])** N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**

Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A

### *PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Cathy Burns

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 5/16/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA Recall Enterprise System [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 7/5/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-08-01-1011-00-110-032

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** N/A

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA Mission Accomplishment and Regulatory Compliance Services (MARCS) Recall Enterprise System (RES)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Carol Stone

**10. Provide an overview of the system:** The MARCS Recalls system provides centralized and standard safety and health alerts and regulated product recall information internally at the FDA. Alerts and recalls are an effective method of providing alert notices to the public, and for removing or correcting consumer products that are in violation of the laws administered by the FDA.

The MARCS Recalls Intranet system is FDA's first agency wide Recall IT system. MARCS Recalls supports business processes for managed application reviews, workload management, investigative, compliance, and analytical operations, quality assurance and other critical initiatives (Manage and Conduct Compliance Work; Monitor Recall; Monitor Regulatory Actions; Negotiate Compliance Action; Support Regulatory Field Action; View Firm Information).

MARCS Recalls Intranet allows FDA personnel to create recall alerts, document recall actions, and to recommend a recall strategy. The system provides capabilities to close recalls when completed and to archive/retain recall records for future use. The system also provides a capability to post a subset of the recall information to the Internet (MARCS Recalls Internet) allowing the general public to view recall information. Although the posting of the data to the Internet database is active, the website accessibility is currently not made available for public access.

The MARCS Recalls Intranet application provides automated support for the daily operations of ORA Field Offices, Center Coordinators, and Headquarters to support the compliance and enforcement activities (Office of Enforcement) of FDA's Office of Regulatory Affairs (ORA).

MARCS Recalls Intranet is an online system that also integrates with other strategic systems at the FDA to provide additional support and information for the recall. MARCS Recalls Intranet system integrates with the "FIRMS" data (holds shared information for the Field Accomplishment and Compliance Tracking System (FACTS); Operation Administrative System for Import Services (OASIS)), as read only, and allows for information to be stored with the recall record.

MARCS Recalls Intranet also allows for a precedent search for (CDRH) recalls requiring Health Hazard Evaluation (HHE) information. The MARCS Recalls Intranet supports approximately 50 to 100 concurrent users (per day). MARCS Recalls Intranet has approximately 512 FDA Intranet users that are recorded in the application users, across the U.S.

The FDA's Office of Regulatory Affairs (ORA) is focused on assuring that manufacturing firms comply with FDA regulations in order to achieve consumer safety and health protection. The FDA's Investigations Operations Manual 2003 states that "ORA's mission is to achieve effective and efficient compliance of regulated products through high quality, science-based work that results in maximizing consumer protection." Within ORA, the Recall Operations Staff (ROS) in the Office of Enforcement (OE), Division of Compliance Management and Operations (DCMO) serves as the Agency's focal point for all safety and health alerts, and product recall activities. ROS is also responsible for providing policy, procedure, and direction to the FDA field and Center recall operations as dictated by the Food, Drug and Cosmetic (FD&C) Act.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
N/A

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** Almost all of the data

captured through the RES application is non-personal and can be grouped into the following categories:

- Firm information
- Product information
- Center-specific information
- Recall Event information
- Recall Recommendation information
- Recall Classification information
- Recall Summary and Termination information

PII is not collected on this system.

The internal aspect of the system uses the business contact information (names and email addresses) of the individual FDA employees who create or work with the records in the RES application. These needed pieces of PII come from the FDA's FACTS database, which is accessed through the individual's RES login codes. The user's name and email provides access to the user's profile information record in the RES database. These records contain information regarding each user's role, and the FDA Center with responsibility for the oversight of the recall activity.

Coordinator names are also displayed or included for data collection needs of the recall event, work flow processing, and for the application to submit proper notifications. In addition, comment fields are available within the system in which the users will add necessary information, when applicable, in order to process or ensure information is provided for "recall" requirements.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - PII is not collected on this system.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A - PII is not collected on this system.

*PIA Approval*

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/2/2010

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA ShelfLife [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** Yes

**If this is an existing PIA, please provide a reason for revision:** Not Applicable

**1. Date of this Submission:** 11/9/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:**

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** n/a

**5. OMB Information Collection Approval Number:** n/a

**6. Other Identifying Number(s):** n/a

**7. System Name (Align with system Item name):** ORA Shelf Life System

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** John Ho

**10. Provide an overview of the system:** The shelf life program is a database repository employed in support of the Food and Drug Administration/Department of Defense (FDA/DOD) Shelf Life Extension Program. The FDA/DOD Shelf Life Extension Program is a key component of the Medical Readiness Strategic Plan (MRSP). The program's focus is to defer drug replacement costs for date sensitive pre-positioned stockpiled drugs by extending their useful life. The largest participants of the program are the armed services, the Department of Homeland Security's Veterans Administration Emergency Preparedness Program and the Centers for Disease Control and Prevention's Strategic National Stockpile. A range of medical products is stockpiled such as Tylenol, anti-malaria medicine, and pandemic influenza treatments. The type of products stockpiled depends on the type of inventory that is requested for shelf life testing.

**13. Indicate if the system is new or an existing one being modified:** New

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
No

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
n/a

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** In 1986, DOD asked FDA's help to see if any of the medical products would be suitable for use if they were stockpiled beyond their normal expiration dates. The pilot test conducted in 1986 by ORA's Medical Products Quality Assurance Staff (MPQAS) determined that 89 percent of the lots of medical products examined could be extended for an average of 33 months. In 1987, the Division of Information Systems (DIS) originally developed the Drug Shelf Life System using DATATRIEVE, the Virtual Address eXtension (VAX) retrieval language to capture the data and to provide necessary reports. The Shelf Life application was redesigned in 1995 using an Oracle database schema and resides on Oracle 10g databases. The Shelf Life program continues today with an estimated saving of \$25 million a year to DOD, with FDA receiving about \$450,000 in reimbursements each year. The data in the Shelf Life system is scientific in nature and includes testing lab information, sample size, test sample size, tracking dates, manufacturer's numbering scheme, and laboratory instructions for medical products being stockpiled. The system does not contain PII.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** N/A - No PII. System controls are CHDC-inherited.

#### ***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms, CISO

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 10/28/2011

**Approved for Web Publishing:** Yes

**Date Published:** February 13, 2012

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## **06.3 HHS PIA Summary for Posting (Form) / FDA ORA TurboEIR [System]**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### *PIA Summary*

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 7/5/2011

**2. OPDIV Name:** FDA

**3. Unique Project Identifier (UPI) Number:** 009-10-01-02-02-1070-00-110-246

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-10-0002 and 09-10-0010 (Bioresearch Monitoring Information System)

**5. OMB Information Collection Approval Number:** N/A

**6. Other Identifying Number(s):** N/A

**7. System Name (Align with system Item name):** FDA ORA TurboEIR

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Thomas Simpson

**10. Provide an overview of the system:** The Office of Regulatory Affairs (ORA), Turbo Establishment Inspection Reports (TurboEIR) is made up of two core applications. The first application is called "Field Agent," which resides on a Field Investigator's laptop computer. It provides a listing of inspection assignments, a database of citations, and tools for authoring FDA Form 483s and EIRs. On an as required basis, a Field Investigator connects to the FDA Network to receive assignments from the ORA, Mission Accomplishment and Regulatory Compliance Services (MARCS) Field Accomplishments and Compliance Tracking System (FACTS) or to upload the completed 483 and EIR information to a central ORA database.

The second application is Turbo-on-the-Web (TOTW) which is a web application accessible by all authorized FDA employees. Employees with a FACTS account are able to log in to TOTW and query the central ORA database for inspection results or perform searches on information designed to answer specific questions. The data and the Form 483 are uploaded to the central ORA database and district file server that the investigator is assigned. This data will then become available through the TOTW Intranet Website to authorized personnel in the FDA for analysis and trending. The standardization inherent in TurboEIR reduces inconsistency and improves uniformity in the Form 483 completion process. TurboEIR makes it possible for all investigators to become more productive more quickly.

TurboEIR is in the operational phase of the SDLC and is categorized as a moderate impact system

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether**

**provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
The information is shared with various compliance/management operational divisions (such as Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Devices and Radiological Health, Center for Veterinary Medicine) in the FDA that perform enforcement, analysis, and trending. The system shares updated telephone and address information with the MARCS Domestics application, this replaces a manual process performed by the investigator.

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** Turbo EIR collects data on FDA regulated and inspected establishments. The system collects business data in the form of professional contact information, establishment address and telephone number. Personally identifiable information collected is limited to the names of clinical research investigators (e.g., physicians) who participate in an inspection. In some instances, these names are used for Turbo EIR data searches with a linked system of records (Bioresearch Monitoring Information System, SORN number 09-10-0010). Clinical research investigator names are provided voluntarily or on occasion by demand of FDA.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]**) Assigned an inspection, the investigator travels to the establishment to perform it. If the investigator observes adverse conditions they are linked to the FDA citation database in Turbo EIR Field Agent. Within Turbo EIR Field Agent the investigator is then able to provide specific information relating to each observation. When all observations and specifics are recorded Turbo EIR Field Agent prints the FDA 483. The investigator then meets with the management of the firm and explains the adverse observations recorded. At this point the firm's management has an opportunity to have their comments added to the FDA 483. At the end of the management meeting the investigator presents the final FDA 483 (with comments) to the firm's management and the inspection is complete. Afterwards the investigator using Turbo EIR Field Agent authors the Establish Inspection Report (EIR). An EIR is created for each inspection, even if a FDA 483 is not issued. The EIR is a comprehensive report of the inspection and contains information needed to support the Violation Letter process and of interest to FDA management. The above activities directly support the FDA's responsibility to regulate food, drugs and devices.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):**  
Yes

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The information contained within Turbo EIR is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within Turbo EIR.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** John Simms

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Frederick J. Sadler

**Sign-off Date:** 9/23/2010

**Approved for Web Publishing:** Yes

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