REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

LEAVE BLANK (NARA use only)	
JOB NUMBER	N1-088-09-3
DATE RECEIVED	12/19/08

TO NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

1 FROM (Agency or establishment)
Department of Health and Human Services

2 MAJOR SUBDIVISION
Food and Drug Administration (FDA)

3 MINOR SUBDIVISION
Office of Regulatory Affairs (ORA)

4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra	(301) 827-4274

NOTIFICATION TO AGENCY

In accordance with the provisions of 44 U S C 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10

DATE	ARCHIVIST OF THE UNITED STATES
7/28/09	Adrienne Thomas

6 AGENCY CERTIFICATION

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached 7 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified, and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

Change made per Rec. Off. on 3/11/09

☒ is not required; ☐ is attached; or ☑ has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
12/16/2008		HHS Records Officer

7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)
	Unless specifically stated otherwise in the description or the retention, all items are media-neutral and apply to paper, electronic, microform, or other media in which records may exist ORA and Field Program Records (Group 2 of 2)· see attached Seung Ja Sinatra - FDA Records Officer — 1/23/07 Date Ann Wion - FDA Deputy Chief Counsel — 12/9/08 Date		

ORA and Field Program Records (Group 2)

File Code: Prefix = ORA

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
1	**Regulatory and Administrative Management Systems.** Provide automated support for field assignments, firm data, consumer complaints, inspections and investigational activities, sample collections, laboratory analytical results, import data, compliance actions and other related work within ORA Headquarters and ORA Field Offices Certain records contain trade secrets, confidential commercial information, and other information that cannot be publicly disclosed, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.	
~~1.1~~	~~**Input Records.**~~ ~~Most data are manually entered using appropriate data entry procedures at program and subprogram levels.~~ ~~Data may also be electronically loaded without creating an input file from various application systems, including but not limited to CDER's Establishment Evaluation System, CDRH's Mammography Program Reporting Information System, CFSAN's CFSAN Adverse Event Reporting System, and OC's Enterprise Administrative Support Environment. Also include import data input electronically directly from Automated Commercial System (ACS) of the Department of Homeland Security's Customs and Border Protection.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when information has been entered into the master file or database and verified, or converted to an electronic medium and verified, or when no longer needed for legal or audit purposes or to support reconstruction of, or serve as backup to, the master file or database, whichever is later.~~ ~~For inputs from FDA systems or other records scheduled elsewhere, apply the disposition authorized for those records.~~	**GRS 20, Items 2a4, 2c**
1.2	**Administrative Databases Records.** Includes data fields on fiscal year, organization, number of positions, expenditure, counts of planned and accomplished operations, hours expended on operations, counts of employees working on operations, number of firms inspected and other related data, that are maintained in administrative modules used as AMP tools	

ORA's administrative databases used as Automated Management Planning (AMP) tools include the following systems or their successors, but are not limited to:
MODEL/Field Work Force Planning System (FWFPS): Used to calculate field personnel ceilings using consistent decision rules and to project/monitor accomplishment and resource expenditures.
Online Program Analysis System (OPAS): Used for reporting, analyzing and predicting trends for compliance and regulatory activities performed by the Field.

Disposition: TEMPORARY.
Cutoff records at end of the fiscal year in which data became obsolete or superseded. Delete/destroy 10 years after cutoff, or when no longer needed for administrative, operational or reference purposes, whichever is later If data are migrated into another system, delete/destroy after the verification of successful migration.

1.3 **Program Databases Records.**
Maintains numerous data tables; over 10 system-to-system interfaces for automated data exchange between FDA systems; 4,500 data fields that support various applications/modules, and over 200 user screens for capturing and viewing information.

Supersedes NC1-88-79-1, Items R-8a, R-8b, R-16, and R-18; NC1-88-80-2, Items O-24a, O-24b, and R-36

Includes the following types of compliance and regulatory data. Inspection data, samples, investigative operations data, compliance data, compliance achievement, laboratory results and comments, consumer complaints, import-related data such as individual import refusal data and Notices of FDA action, and information on other regulatory activities.

Major systems include the following, but are not limited to:
Field Accomplishments and Compliance Tracking System (FACTS): Supports field assignments, work results, firm information, compliance actions and time reporting. It incorporates assignment management and work results for investigational activities including sample collections, firm inspections, domestic investigations and field examinations;
Operational and Administrative System for Import Support (OASIS). Supports import activities such as admissibility determinations of foreign-origin products. It incorporates assignment management and work results for import related investigational activities;
Prior Notice System Interface (PNSI). Facilitates receipt of prior notice from firms via web interface before food or animal feeds are imported or offered for import into the United States to target import inspections Data are uploaded into OASIS or its successor system for further analysis.
Mission Accomplishment and Regulatory Compliance Services

(MARCS): Is being developed to replace FACTS and OASIS and to provide additional support requirements requested by ORA

Systems functioning as subsets of FACTS/its successor or as separate databases, including but not limited to the following:
Turbo Establishment Inspection Report (Turbo EIR): Provides citations of regulations and statutes, to help inspectors and investigators prepare inspection reports, and maintains inspection reports
Firm Master List Services (FMLS). Provides official firm data by validating and standardizing the information submitted by the transmitters.
Shelf Life Extension Program Database: Tracks the status of shelf life extension projects and generates reports for testing results.
Electronic Laboratory Exchange Network (eLexnet): Used to coordinate and report results of biological, chemical and radiological analysis conducted by laboratories participating in the Food Emergency Response Network (FERN) from Federal, State and local agencies.
ORA Decision Support System (ORADSS): Provides a comprehensive repository and reporting capabilities for import data and may serve as a data warehouse for other ORA program records.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after the final action. Delete/destroy 10 years after cutoff, or when no longer need for operational, trend analysis, legal, or reference purposes, whichever is the latest. If data are migrated to a new system, delete/destroy after verification of successful data and system migration.

~~1.4~~ ~~**Output Records.**~~ **GRS 20, Items 4, 5, 6, 7, 12, 16**

~~Includes data extracted periodically from the production system and reformatted or summarized reports to support the identified reporting requirements, answer specific inquiries, and conduct trending analyses. As an automated batch feed, may include several hundred standard and/or ad hoc reports that support day-to-day operations of field activities, including inspections, collections, investigations, import operations, compliance actions, consumer complaints, registrations and laboratory analysis.~~

~~If output records are maintained as part of other subject files, apply disposition authorized for those subject files.~~

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when no longer needed for operational, trend analysis, legal or references purposes, whichever is the latest.~~

~~1.5~~ ~~**System Documentation.**~~ **GRS 20**
~~Includes systems operations manuals, user manuals, data~~ **Item 11a1**
~~dictionary, requirements documents, and other systems related~~
~~materials for all ORA Regulatory Database Management and~~
~~Support Activities.~~

~~**Disposition: TEMPORARY**~~
~~Destroy/delete when superseded or obsolete, or upon authorized~~
~~deletion of the related master file or database, or upon the~~
~~destruction of the output if the output is needed to protect legal~~
~~rights, whichever is latest.~~

2 **Import Program.**
Includes import program files on food (with the exception of most meat and poultry), drugs, biologics, cosmetics, medical devices and electronic products that emit radiation, regulated by FDA and defined by the FD&C Act and related Acts.

Individual import refusal data and Notices of FDA Actions are maintained in the import related databases supported by ORA's Regulatory and Administrative Management Systems. Apply the disposition authorized for "Program Data" under "Database Records."

2.1 **Import Entry Files.**
Includes materials related to FDA regulated products imported into the country. May include, in part, entry documents describing the articles offered for importation (e.g. copies of Customs entry documents (CF 3461s), Certificates of Analysis (COAs), Import for Export (IFE) entry documentation, forms, commercial invoices, manifests), copies of Notices of FDA Action, responses to Notices of FDA Action, sample collection records and corresponding analytical worksheets, documentation related to field exams, Detention Without Physical Examination (DWPE) recommendations, copies of Import Alerts, Import Bulletins, reconditioning proposals (Form FDA 766s) and related correspondence, authorizations to recondition, documentation regarding follow-ups to refused products, private laboratory reports, documentation of destruction and/or re-exportation of refused products, labeling, requests for redelivery, and copies of FOI requests and Congressional inquiries regarding imported product.

2.1.1 **Files of Non-violative Product Lines Released or Released with Comment.** **Supersedes NC1-88-79-1, Items R-20a, R-21a**

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year upon release of import entry

Destroy 2 years after cutoff.

2.1.2 **Files for Product Lines Detained and Subsequently Released.**

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year upon release of import entry. Destroy 2 years after cutoff.

2.1.3 **Files for Entries/Product Lines Detained and Subsequently Refused.**

Supersedes NC1-88-79-1, Items R-20b, R-21a

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year upon re-exportation. Destroy 5 years after cutoff.

2.2 **Import Alerts and Bulletins.**
Includes Import Alerts/Bulletins and ancillary supporting files.

2.2.1 **Import Alerts and Bulletins.**

Supersedes NC1-88-78-1, Items O-4a

Includes Import Alerts that are issued to commercial and public audience on the Internet; and Import Bulletins (previously known as Import Circulars) that are issued to the FDA District Offices via the Intranet to advise the importation of violative products

Certain records contain confidential commercial information and other information that cannot be publicly disclosed, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year when Import Alert/Bulletin has been terminated Delete/destroy 10 years after cutoff.

2.2.2 **Supporting Materials.**
Ancillary supporting materials maintained by FDA District Offices include exhibits, signed affidavits, photographs, copies of data extracted from OASIS/MARCS-Import or any successor system and related materials

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year when Import Alert/Bulletin has been terminated. Delete/destroy 10 years after cutoff.

2.3 **Import Refusal Report (IRR).**

Supersedes NC1-88-78-1 O-5a

IRR lists products that were refused for admission. Individual refusals are recorded in OASIS/MARCS or successor system. On a monthly basis, this information is aggregated by the system to produce the IRR The report includes information on country

of origin, product name and other related data and is published directly to the Intranet Formally known as Import Detention Lists.

Disposition: TEMPORARY.
Cutoff the date of posting on the Internet. Delete/destroy 12 months after cutoff.

3 Regulatory and Compliance

~~3.1~~ ~~**Establishment Files.**~~ **Withdrawn 7/7/09**

~~Jacketed records, containing material for firms and facilities over which FDA has jurisdiction. Includes original or printed copies of the following.~~
~~- Establishment inspection reports (EIRs) including a printed copy of the Establishment Inspection Record, attachments including copies of FDA forms issued (e.g. FDA-482, Notice of Inspection; FDA-482a, demand for records; FDA-482b, Request for Information; FDA-483 Inspectional Observations, FDA-463, Affidavit; FDA-484 Receipt for Samples);~~
~~- Assignments, exhibits including inspection checklists (BSE and Domestic Seafood HACCP, 3502 Import Seafood HACCP and Interstate Program), photographs, labeling and notices of voluntary destruction,~~
~~- Field Management Directive (FMD)-145 letters;~~
~~- Reports or memos of investigations and associated attachments/exhibits,~~
~~- State contract inspection, investigation and/or sample collection documentation,~~
~~- Consumer complaint documentation;~~
~~- Firm licenses and/or registrations;~~
~~- Regulatory letters;~~
~~- Minutes of regulatory meetings or hearings;~~
~~- Documentation regarding the execution of seizure actions including subsequent reconditioning and/or destruction of seized product;~~
~~- Correspondence between the firm and the FDA regarding FDA-483s, regulatory letters, and/or regulatory actions;~~
~~- Other establishment related records.~~

~~Records of domestic inspections are maintained by FDA District Offices.~~

~~Certain records contain trade secrets, confidential commercial information, and other information that cannot be publicly disclosed; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.~~

~~Foreign inspection files for all program areas are maintained by Centers~~

~~3.1.1~~ ~~**Firms of No Further Regulatory Interest to the Agency.**~~ ~~**Supersedes NC1-88-79-1, Items R-7a**~~

~~Includes files pertaining to the firms of no further regulatory interest to the Agency —~~

~~**Disposition: TEMPORARY.**~~ **Withdrawn 7/7/09**

~~Cutoff at the end of the fiscal year when firm is out of business and after the completion of final action. Destroy 10 years after cutoff.~~

~~3.1.2~~ ~~**Firms designated as workload obligations and of regulatory interest to the Agency**~~ ~~**Supersedes NC1-88-79-1, Items R-7b, R-7e**~~

~~Files pertaining to firms of continuing regulatory interest, including those upon which there are regulatory actions (court actions). Files are maintained in active files per "Field Management Directive #130 – Official Establishment Inventory (OEI) Development and Maintenance Procedures" (i.e., under FDA purview and inspected on a regular basis).~~ **Withdrawn 7/7/09**

~~**Disposition: TEMPORARY.**~~

~~Cutoff at the end of the fiscal year when firm is out of business and after all court actions, including appeals, have been adjudicated and case is closed (if applicable) Destroy 10 years after cutoff or when no longer needed for reference, whichever is later.~~

3.2 **Domestic Sample Analytical Documentation.**

Includes samples that did not result in regulatory actions or samples that were not analyzed.

Includes sample collection reports generated from the database and documentation on the procurement of samples of regulated products for testing and examination and the corresponding analytical worksheets, including labeling, sample seal integrity, and other such documentation

Records listed are all sample analytical documentation regardless of classification of the sample or the analysis status.

Certain records contain trade secrets, confidential commercial information, and other information that cannot be publicly disclosed; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

3.2.1 **Non-violative domestic sample documentation.** **Supersedes N1-88-79-1, Items R-14a, R-14b, R15a, R-15b, and R-17**

Disposition: TEMPORARY.

Cutoff at the end of the fiscal year after regulatory decision has been made. Destroy 2 years after cutoff.

3.2.2 **Violative domestic sample documentation.** **Supersedes N1-88-79-1,**

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year after regulatory decision has been made. Destroy 5 years after cutoff.

Items R-14a, R-14b, R15a, R-15b, and R-17

3.3 **Laboratory Records (Regulatory).**
Covers the records relating to laboratory sample analysis of FDA regulated products conducted by FDA field labs. Work status and sample accountability information (identification and processing data) are tracked and lab summary reports, comments and findings are maintained in FACTS/MARCS or its successor system.

For retention of lab records forwarded to Centers for concurrence on enforcement or legal actions, apply disposition authorized for the records series with which lab records are maintained in Centers.

3.3.1 **Laboratory Test Records related to Preapproval/Premarket Evaluations.**
Includes laboratory analytical worksheets, summary reports for lab test results, and attachments for laboratory control documents that are related to New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA) or New Animal Drug Applications (NADA)

Supersedes NC1-88-82-1, Items R-33a and R33c

Records for open cases are filed in case files known as Establishment Files (EF), follow disposition authorized for the agency-wide schedule, "Establishment Inspection and Compliance Action Files."

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year after the final action or analysis. Destroy/delete 10 years after cutoff.

3.3.2 **Laboratory Test Records Not Related to Preapproval/Premarket Evaluations.**
Includes laboratory analytical worksheets, summary reports for lab test results, attachments for laboratory control documents that are not related to NDAs, ANDAs or NADAs.
Records for open cases are filed in case files known as Establishment Files (EF); follow disposition authorized for the agency-wide schedule, "Establishment Inspection and Compliance Action Files."

Supersedes NC1-88-82-1, Items R-33a and R33c

Disposition: TEMPORARY
Cutoff at the end of the fiscal year after the final action or analysis. Destroy/delete 5 years after cutoff.

3.3.3 **Laboratory Quality Assurance Records. (Applies Agency-wide)**
Includes all lab records generated in support of lab accreditation

Supersedes R-19 (NC1-88-79-1)

and lab quality assurance. May include, but not limited to: lab notebooks on lab instrument calibration, records on collaborative studies, validation, growth media of organisms, audit reports, management reviews, corrective action reports, complaints and comments, method validation and modification, lab procedure and work instructions, quality control charts, work orders, and subcontractor qualification files.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after final action. Delete/destroy 3 years after cutoff.