Schedule Number: N1-088-04-005

Some items in this schedule are either obsolete or have been superseded by new NARA approved records schedules. This information is accurate as of: 11/14/2022

ACTIVE ITEMS

These items, unless subsequently superseded, may be used by the agency to disposition records. It is the responsibility of the user to verify the items are still active.

All other items not listed below are active.

SUPERSEDED AND OBSOLETE ITEMS

The remaining items on this schedule may no longer be used to disposition records. They are superseded, obsolete, filing instructions, non-records, or were lined off and not approved at the time of scheduling. References to more recent schedules are provided below as a courtesy. Some items listed here may have been previously annotated on the schedule itself.

Item 5 is superseded by N1-088-09-007, item 1.1.2.
Items 6.1 and 6.2 are superseded by N1-088-09-007, item 1.3.

REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER N1-088-04-5	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-6001		Date Received 3-22-2004	
1. FROM (Agency or establishment) **Department of Health and Human Services**		**NOTIFICATION TO AGENCY**	
2. MAJOR SUBDIVISION **Food and Drug Administration**		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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	
3. MINOR SUBDIVISION **Office of the Commissioner (OC)**			
4. NAME OF PERSON WITH WHOM TO CONFER **Seung Ja Sinatra**	5. TELEPHONE **301-827-4274**	DATE 7/30/07	ARCHIVIST OF THE UNITED STATES Allen Weinstein

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 of the attached ___ 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,

[X] is not required; [ ] is attached; or [ ] has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
MAR 19 2004	**A. P. Barnes** A P Barnes	**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 GRS OR SUPERSEDED JOB CITATION	10.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)

Covers OC Program Records.

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. FDA will ensure the record integrity during the retention periods according to NARA regulations (36 CFR 1228.26(b)1) and 1228.270).

See Attached Sheet

sentence addition approved by S. Sinatra via Telephone: 2/23/2007

Seung Ja Sinatra

Seung Ja Sinatra - FDA Records Officer

1/23/04

Date

Fred Ansell

Fred Ansell - Office of the Chief Counsel

1/23/04

Date

115-109 PREVIOUS EDITION NOT USABLE **STANDARD FORM SF 115** (REV. 3-91)
Prescribed by NARA 36 CFR 1228

SA 7/30/07 copies sent to Agent/NWMD/NWME/NWMW

Office of the Commissioner Mission Program Records

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
1.	Research Project Files. Records related to special research projects, undertaken by the FDA or an associated committee from start to finish.	**New Item**

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
1.1	Significant Research Projects. Research projects receiving significant recognition including: prominent FDA scientists receiving recognition outside their noted area of expertise; a significant impact on public safety; vital public interest; making significant contributions to or impacting policies on a national or global scale; changing political, economic, scientific or social priorities, or resulting in significant controversy; establishing precedence for significant changes to Department of Health and Human Services (DHHS) or FDA research or administrative policies; subjected to widespread media attention or extensive Congressional, or other federal scrutiny or investigation. May contain paper, audiovisual, electronically imaged records, databases, other electronic records, other recording materials, and all essential supporting background materials. **PERMANENT**. This disposition instruction is media neutral; it applies to all media and formats. Cut off at end of calendar year in which project is completed. Transfer paper records to FRC 3 years after cutoff. Transfer all records to NARA 10 years after cutoff with related documentation and finding aids as applicable. At time of transfer, NARA and FDA will determine the media and format in which the records will be transferred. FDA will ensure record format integrity during the retention period according to NARA regulations.	

Item No.	Records Description and Authorized Disposition	NARA Approved Citation

1.2 Non-Significant Research Projects. Research case files that do not meet criteria for Significant Research Projects.

TEMPORARY: Media neutral. Cut off at end of the calendar year in which the project is completed. Transfer paper records 3 years after cutoff to FRC. Destroy or delete records 30 years after cutoff.

1.3 Research Project Working Files. Raw data and background materials for Significant and Non-Significant Research Projects. Information content may contain lab and observation notes; reports; correspondence such as memoranda, letters, faxes, and e-mail messages; questionnaires, surveys, interview recordings and transcripts; specimen, sample, or artifact control documentation; computer printouts; documentation for interpreting electronic records; and other information. (Essential supporting background materials are filed with the project case file.)

TEMPORARY: Media neutral. Cut off files at end of the calendar year in which the project is completed. Maintain for 3 years then destroy or delete 6 years after cutoff or when no longer needed for reference, whichever is sooner.

Patient Advocate Programs

2. Patient Advocate Programs Records. **New Item**
Files related to the Patient Representatives Program and the Patient Consultant Program managed by the Office of Special Health Issues. The office staff works with patients and their advocates to encourage and support participation in FDA regulatory decision-making.

2.1 Program Management Files. Includes applications, training and lecture materials, presentations, meeting summaries, and other program related materials.

TEMPORARY: Media neutral. Cut off at end of calendar year. Destroy/delete 10 years after cut off.

2.2 Background Materials. Invitations to public meetings, meeting summaries, contact lists, working files and other related materials.

TEMPORARY: Media neutral. Cut off at end of calendar year. Destroy/delete 5 years after cut off.

Crisis Management Records

3. Crisis Exercise Related Files. Incoming and outgoing emails, correspondence, reports, guidance, and other information artifacts that are used to support offices' training exercise to respond to significant events like illness and injury reports, natural or man-made disasters and terrorism events that affect FDA-regulated products. These records contain confidential and national security sensitive information that may be access restricted by Freedom of Information Act (FOIA) exemptions such as b(1) for national security and b(7) for law enforcement. **New Item**

TEMPORARY: Media neutral. Cut off after Training Exercise has concluded. Transfer paper records to FRC 5 years after cutoff. Destroy or delete 25 years after cut off.

4. ~~Incident Files. Files capturing information on significant incidents of illness and injury, natural or man-made disasters and terrorism events that affect FDA-regulated products. These records contain confidential and national security sensitive information that may be access restricted by Freedom of Information Act (FOIA) exemptions such as b(1) for national security and b(7) for law enforcement~~ **New Item WITHDRAWN 6/18/2007**

~~**TEMPORARY:** Paper Records only. Cut off after investigation is completed. Transfer 5 years after cutoff to FRC. Destroy or delete 50 years after cutoff.~~

5. Trace Back Files. Files accumulating from investigations of food borne incidents, consisting of retained copies of reports, e-mails and related documents when the original reports are submitted for review and filing in other agencies or organizational elements, and reports and related papers concerning occurrences of such a minor nature that they are settled locally without referral to other organizational elements. These records contain confidential and national security sensitive information that may be access restricted by Freedom of Information Act (FOIA) exemptions such as b(1) for national security and b(7) for law enforcement **New Item**

TEMPORARY: Media neutral. Cut off after investigation is completed. Transfer paper records to FRC 5 years after cutoff. Destroy 50 years after cutoff.

6. Weekly and Annual Crisis Reports. Reports provide summary and status information of the incidents currently tracked. **New Item**

6.1 Weekly Reports.

TEMPORARY: Media neutral. Cut off at end of fiscal year. Destroy 3 years after cutoff.

6.2 Annual Reports.

TEMPORARY: Media neutral. Cut off at end of fiscal year. Destroy 5 years after cutoff.

International Program Records

7. Trade Agreement Documentation. **New Item**
Files relate to FDA's participation in and advisement of agreements which the United States Trade Representative (USTR) has the lead responsibility on. These agreements sometimes lead to changes in the way that FDA conducts its business. Included are comments on USTR position papers, specific instructions for negotiators, draft texts and materials developed for implementing the agreement within FDA.

7.1 Implementation Materials.

TEMPORARY: Media neutral. Cut off at end of the calendar year in which the changes to FDA were implemented. Destroy 10 years after cutoff.

7.2 Background Materials.

TEMPORARY: Media neutral. Cut off at end of the calendar year in which the agreement was finalized. Destroy 10 years after cutoff.

8. International Arrangements. Files relate to FDA-led arrangements with foreign countries or international organizations. These arrangements sometimes lead to changes in the way that FDA conducts its business. The files include the final approved agreement, background materials, such as comments and drafts, and materials developed for implementing the agreement within FDA. **New Item**

8.1 Official Arrangements.

PERMANENT. Media neutral. Cut off at end of the calendar year in which the Arrangement is completed. Transfer records to NARA 10 years after cutoff with related documentation and finding aids as applicable. At time of transfer, NARA and FDA will determine the media and format in which the records will be transferred. FDA will ensure the record integrity during the retention period according to NARA regulations.

8.2 Implementation Materials.

TEMPORARY: Media neutral. Cut off at end of the calendar year in which the changes to FDA were implemented. Destroy 10 years after cutoff.

8.3 Background Negotiations.

TEMPORARY: Media neutral. Cut off at end of the calendar year in which the changes to FDA were implemented. Destroy 10 years after cutoff.

9.	Records Related to Activities with Foreign Countries/International Organizations. These files detail various interactions that FDA experts have with international organization, foreign countries, and individual scientists from foreign countries. These activities include sending experts to meetings of international organizations, providing technical assistance, international harmonization efforts, managing visits by foreign officials, and review and preparation of documents for international organizations. **TEMPORARY:** Media neutral. Cut off at end of the calendar year in which the event took place. Destroy 10 years after cutoff.	**New Item**
10.	Country/Subject Files. Duplicate copies of information kept elsewhere within the office filed by country or subject for easy reference. **TEMPORARY:** Media neutral. Destroy or delete when no longer needed for reference purposes.	**New Item**
11.	International Travel. Forms, reports, correspondence, and other records created for travel to foreign countries for programmatic reasons. **TEMPORARY:** Media neutral. Cut off at the end of the fiscal year. Destroy 7 years after cutoff.	**Supersedes RCS Item C-2**
12.	~~Official Passports/Visas.~~	**GRS 9, Item 5**
12.1	~~Application files. Documents relating to the issuance of official passports, including requests for passports, transmittal letters, receipts, and copies of travel authorizations.~~ ~~**TEMPORARY:** Destroy when 3 years old or upon separation of the bearer, whichever is sooner.~~	**GRS 9, Item 5a**
12.2	~~Annual reports concerning official passports. Reports to the Department of State concerning the number of official passports issued and related matters.~~ ~~**TEMPORARY:** Destroy when 1 year old~~	**GRS 9, Item 5b**

12.3 ~~Passport Registers. Registers and lists of agency personnel who have official passports.~~ **GRS 9, Item 5c**

~~**TEMPORARY:** Destroy when superseded or obsolete.~~
~~NOTES: (1) Official passports should be returned to the Department of State upon expiration or upon the separation of the employee. (2) Item 5b does not pertain to copies of the annual reports held by the Department of State.~~

13. Export Program Records.
This schedule establishes the official agency-wide recordkeeping requirements for export program files on human drugs, biological products, devices, animal drugs, food, and cosmetics.
Records copies are maintained by the program office in each center or in FDA District offices. Tracking systems are used to document the status of export applications and certificate processing.

13.1 General Export Program Files. **N1-088-03-4 No change**

13.1.1 Final Policy Documents.
Final documentation resulting from or influencing policy or procedure changes to the FDA export program. Examples include decision-making memorandum, final working group reports, compliance policy guidance, action items, or strategic planning.

PERMANENT. Media neutral. Cut off files at end of fiscal year in 5 year blocks. Transfer to NARA 20 years after cutoff with related documentation and finding aids as applicable. . At time of transfer, NARA and FDA will determine the media and format in which the records will be transferred. FDA will ensure the record integrity during the retention period according to NARA regulations.

13.1.2 Instructional Manuals.
Procedure manuals for completing and processing export applications, export notifications, certificates, informational materials, working group reports, correspondence, and related materials posted on the FDA web site.

TEMPORARY: Media neutral. Destroy or delete when superceded or obsolete.

13.2 Export Applications, Export Notifications and Materials Related to the Export Firm. **N1-088-03-4 No change**

13.2.1 Official recordkeeping copies (paper or image files in PDF/TIFF) whose recordkeeping format is determined by center.

TEMPORARY: Cut off files at end of fiscal year. Transfer paper records copies to FRC 1 year after date of cutoff. Destroy paper copies 10 years after date of cutoff. Delete image files 10 years after date of cutoff.

13.2.2 Copies used for scanning or data input.

TEMPORARY: Media neutral. Destroy after all data elements are entered into the tracking database and scanned into the imaging system and after successful data entry is verified through quality control.

13.3 Export Certificate Requests and Resulting Certificate. Includes Certificates of Free Sale, European Union Export Health Certificates, Certificates to Foreign Government, Certificates of Exportability, Certificates of Pharmaceutical Product, and Non-clinical Research Use Only Certificate issued by FDA, CDER export declarations, and other export certificates, correspondence and related documents. **N1-088-03-4 No change**

Export certificates issued under the Interagency Agreements directly by the Agricultural Marketing Service (AMS) or National Marine Fisheries Service (NMFS) for FDA to the European Union, are maintained by AMS or NMFS in accordance with their records retention policy.

13.3.1 Official recordkeeping copies (paper or image files in PDF/TIFF) whose recordkeeping format is determined by center.

TEMPORARY: Media neutral. Cut off files at end of fiscal year. Transfer paper records copies to FRC 1 year after date of cutoff. Destroy paper copies 5 years after date of cutoff. Delete image files 5 years after date of cutoff.

13.3.2 Copies used for scanning or data input.

TEMPORARY: Media neutral. Destroy after all data elements are entered into the tracking database and scanned into the imaging system and after successful data entry is verified through quality control.

13.4 Export Tracking Systems. **N1-088-03-4 No change**

The databases contain data on the company, products, application receipt date, certificate sent date, FDA comments, and other related information, entered into the system to document and monitor the status of export applications, certificate requests, certificates, export notifications, and FDA comments. It is accessible by the unique certificate number that links to an imaging system.

13.4.1 Master Files.

Each record arranged by certificate or notification number contains information about the firm, the type of document requested, the certificate and general comments. The input for the tracking system is entered manually through information obtained by 13.2 and 13.3.

TEMPORARY: Cut off files at end of fiscal year. Delete with related records (Items 13.2.1, 13.2.2, 13.3.1 and 13.3.2) or when no longer needed for administrative or reference purposes.

13.4.2 Output Records.

Printed copies of ad hoc reports, including tabulations, statistics, registers, and other tracking related information. Reports are generated for billing purposes, budget planning, at special request from other agencies and by senior management at FDA or individual centers.

TEMPORARY: Media neutral. File with appropriate records series or destroy/delete when no longer needed for administrative, legal, audit, or other operational purposes.

13.4.3 Documentation.

Contains data dictionaries, standard operating procedures (SOPs) for data entry instructions and systems operations program codes and record layouts for the data fields, user manuals, glossaries for program terms and acronyms, and related materials needed to use and understand the export tracking system.

TEMPORARY: Media neutral. Destroy or delete when superseded or obsolete, or upon authorized deletion of the tracking database, whichever is sooner.

13.4.4	~~Back ups of Files.~~ ~~Daily, weekly, or monthly electronic copies of the database and retained in case that the database is damaged or inadvertently erased.~~ ~~**TEMPORARY:** Delete when the identical record has been deleted, as authorized by this schedule, or when replaced by a subsequent backup file.~~	**GRS 20/Item 8b**
14.	~~Emerging Technology Transfer Training. Covers materials developed for and during the conduct of training related to the mission of the Food and Drug Administration. This includes any agreements, such as co-sponsorship agreements, with private organizations or other government agencies, course materials, attendee lists, and other training related information.~~	**New Item** Withdrawn June 23, 2005
14.1	~~Course Materials/Handouts.~~ ~~**PERMANENT.** Cut off when course will no longer be offered. Transfer to FRC 10 years after cutoff. Transfer to NARA 20 years after cutoff.~~	Withdrawn June 23, 2005
14.2	~~Training Agreements & Financial Records.~~ ~~**TEMPORARY:** Cut off at the end of the training course. Destroy 10 years after cutoff.~~	Withdrawn June 23, 2005
14.3	~~Employee Training. Correspondence, memoranda, reports, and other records relating to the availability of training and employee participation in training programs sponsored by other government agencies or non-Government institutions.~~ ~~**TEMPORARY:** Destroy when 5 years old or when superseded or obsolete, whichever is sooner.~~	**GRS 1, item 29b**
14.4	~~Background and Working Files.~~ ~~**TEMPORARY**: Destroy when 3 years old.~~	**GRS 1, item 29a(2)**
15.	~~Electronic Mail and Word Processing System Copies. Electronic copies of records that are created on electronic mail and word processing systems and used solely to generate a recordkeeping copy of the records covered by the other items in this schedule. Also includes electronic copies of records created on electronic mail and word processing systems that are maintained for updating, revision, or dissemination.~~	**GRS 20 / Item 13 and 14**

15.1 ~~Copies that have no further administrative value after the recordkeeping copy is made. Includes copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy.~~ **GRS 20 / Item14**

~~**TEMPORARY:** Destroy within 180 days after the recordkeeping copy has been produced.~~

15.2 ~~Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.~~ **GRS 20 / Item 13**

~~**TEMPORARY:** Destroy when dissemination, revision, or updating is completed~~