REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER N1-088-05-1	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-6001		Date Received 9-10-2004	
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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	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			
4. NAME OF PERSON WITH WHOM TO CONFER **Seung Ja Sinatra**	5. TELEPHONE **301-827-4274**	DATE 5/17/06	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
SEP - 7 2004	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 GRS OR SUPERSEDED JOB CITATION	10.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)

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.

See Attached Sheets

Agency-wide

Seung Ja Sinatra

Seung Ja Sinatra - FDA Records Officer

8/16/04

Date

Fred Ansell

Fred Ansell - FDA Office of the Chief Counsel

8/24/04

Date

cc: Agency, NR, NUME, NWMD, NWMW

115-109

PREVIOUS EDITION NOT USABLE

STANDARD FORM SF 115 (REV. 3-91)
Prescribed by NARA 36 CFR 1228

FDA Agency-wide Records

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1	1400	**Advisory Committee Records.** Public Advisory Committees are chartered to provide the FDA Commissioner with specific advice and recommendations on scientific and regulatory matters. Federal Advisory activities include the establishment of committees, appointment of members, and operation of chartered Federal advisory committees. Records consist of committee information, member information, committee deliberations, and other related work.	**Supersedes NC1-88-78-1, Items S-2 and K-24**
1.1	1410	Internal Working Group Records. Intra-agency working group for purpose of internal communications. Records include Council meeting agendas, which include a list of talking points. Access restricted. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year of the working group meeting. Destroy 3 years after cutoff.	**New**
~~1.2~~	~~1420~~	~~Advisory Committee Meeting Files, Reports and Minutes.~~ ~~Advisory Committee meeting files consist of Federal Register Notices, rosters of committee members, consultants and invited speakers, agenda, conflict of interest statements, signed committee charters, signed nomination packages, background documents and committee recommendations. Reports include the reports required by the Federal Advisory Committee Act (such as the Annual Report to Congress, the Annual Closed Meeting Report by Committee, and the Female Minority Report) and any other reports that are developed or required. Minutes are complete and accurate descriptions of matters discussed and conclusions reached by the Advisory Committee. Access Restricted.~~ ~~**Disposition: PERMANENT.** Cutoff annually. Transfer to FRC 5 years after cutoff. Transfer to NARA 20 years after cutoff.~~	~~**GRS 26 Item 2a**~~
~~1.3~~	~~1430~~	~~Verbatim Transcripts.~~ ~~Word-for-Word recordings of Advisory Committee meetings.~~ ~~**Disposition: PERMANENT.** Cutoff at the completion of the meeting. Transfer to FRC 5 years after cutoff. Transfer to NARA 20 years after cutoff.~~	~~**GRS 26 Item 2a**~~

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
2	1500	**Ombudsman Records.**	New
2.1	1510	Office of the Ombudsman Case Files. Files relate to responsibility of the Office of the Ombudsman of the Office of the Commissioner relating to Small Business Regulatory Enforcement Fairness Act (SBREFA), Data Quality Act, and Mammography Quality Standards Act, excluding clinical trial investigators disqualification records. Include such records documenting the initial reason that the issue was brought to the office, all supporting material that goes into the final decision (i.e., e-mails, meeting minutes, supporting precedent, summary information related to the case), and the final letter if one is issued. Access is restricted to FDA. **Disposition: TEMPORARY.** Cutoff at end of calendar year in which the final action is taken on a case, or when the appeal is completed. Transfer to FRC 5 years after cutoff. Destroy 10 years after cutoff.	
2.2	1520	Ombudsman Case Files Finding Aid. Information maintained in Microsoft Access used as a finding aid that allows the Office of the Ombudsman to locate closed case files in case a question arises or if the case is reopened. Includes the case number, a title, and one sentence description of the case. Access is restricted to FDA. **Disposition: TEMPORARY.** Cutoff at end of calendar year along with related case file. Delete with related case file, which is kept for 10 years after the final action is taken or the appeal is completed.	
2.3	1530	Ombudsman Case Files Maintained in Center. Case files regarding complaints and disputes maintained by the Center Ombudsman Office. Files consist of reasons for and information about the complaint or dispute, information collected during any investigation or Ombudsman follow-up, and the final resolution of and/or recommendation about the complaint or dispute. Any correspondence generated supporting an investigation or other Ombudsman follow-up is also included in the file. Access restricted to FDA. **Disposition: TEMPORARY**. Cutoff 3 months after the end of the calendar year in which the case is closed, or the appeal is completed. Destroy 3 years after cutoff.	

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
3	4810	**Science Forum Web Page.** Science Forum is an annual conference dealing with issues related to scientific development and associated regulatory concerns. The Science Forum Web Page presents papers showcasing FDA scientific achievements, and facilitates discussions on topics of interest to FDA and its stake holders (health professionals and the interested public). This site also provides online registration of poster presentations that occur during the event. Posters are filed in appropriate subject files.	New
3.1	4811	Abstracts. Abstracts of science posters collected during the online registration. This information is used to help populate the Science Forum booklet and provide online viewing. **Disposition: TEMPORARY.** Cutoff annually after the Forum has been completed. Destroy/delete 20 years after cutoff, or when no longer needed for reference, whichever is sooner.	
3.2	4812	Records related to the current Science Forum. Includes Forum agendas, flyers, Forum booklets, registrations and other related materials. **Disposition: TEMPORARY.** Cutoff annually after the Forum has been completed. Destroy/delete 3 years after cutoff.	
4	5200	**Orphan Products Designation Program Records.** Files include records related to Orphan Products that are used to treat "rare" diseases. To be designated as a "rare" disease under the Orphan Drug Act of 1983, there should be no more than 200,000 cases in the United States annually. Also include records documenting the Humanitarian Use Program for medical devices that are used by 4000 or fewer people.	New
4.1	5210	Program Administrative Records. Includes Policies and Procedures Handbook that is developed to orient new members of the staff within the office and provides information on organizational responsibilities and ready reference sources. Also included are informational materials on the program on the FDA web sites. **Disposition: TEMPORARY**. Destroy when superseded or obsolete.	

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Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
4.2	5220	Orphan Products Designation Records. Files include Orphan Product designation requests from manufacturers, records documenting the designation and approval of the product as an Orphan Product, correspondence, product approval or withdrawal notices from centers and other related records, since 1983. Records that document the financial assistance to the manufacturer to assist in development and human trials of the product, are maintained in the Office of Grants Management where a unique file number to each product is assigned at the time of receipt. Records dealing with withdrawn products are in microfiche (3 microfiche cases). **Disposition: PERMANENT.** Cutoff files in 5-year blocks at end of calendar year in which the product has been designated as an Orphan Product. Transfer to NARA 20 years after cutoff.	
4.3	5230	Orphan Products Designation System (OPDS). The system is used to track Orphan Product designation and financial assistance status in an Oracle database since 2000.	
4.3.1	5231	Data Files. In addition to the data taken from Orphan Product designation requests such as product name and manufacturer name, data fields include control number, grant number, approval date, and Orphan Product designation reviews, summary data, and other related information. **Disposition: PERMANENT.** Cutoff files in 5-year blocks at end of calendar year in which the product has been designated as an Orphan product. Transfer to NARA with related designation records, in a NARA acceptable format complying with 36 CFR 1228.270.	
4.3.2	5232	Output Records: Periodic lists of Orphan Products on the web and ad-hoc reports produced as needed. **Disposition: TEMPORARY.** Delete/destroy when superseded or obsolete, or when no longer needed for administrative or operational purposes, whichever is later.	
4.3.3	5233	System Documentation. Includes data dictionary, users guides, and system requirement documents.	

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		Disposition: PERMANENT. Transfer to NARA with related data files.	
4.3.4	5234	Backup tapes: Electronic copy, considered by the agency to be a Federal record, of the master copy of an electronic record or file and retained in case the master file or database is damaged or inadvertently erased. File identical to records scheduled for transfer to the National Archives. **Disposition: TEMPORARY**. Delete when the identical records have been captured in a subsequent backup file or when the identical records have been transferred to the National Archives and successfully copied.	**GRS 20, Item 8a**
5	5300	**FTC/SEC Registration Documents and Requests for Information.** Correspondence received from the Federal Trade Commission (FTC) or the Security and Exchange Commission (SEC) requesting FDA's review of the registration statements, submitted to these Commissions by FDA regulated industries, or requests for review of information regarding mergers. Files consist of the original correspondence, copies of the establishment documentation, and the FDA response.	**New**
5.1	5310	Copies of the Establishment Documentation. **Disposition: TEMPORARY**. Destroy after the review is completed.	
5.2	5320	Correspondence and FDA responses. **Disposition: TEMPORARY**. Cutoff at end of calendar year. Destroy 3 years after cutoff.	
6	8100	**Recall Files.** Supersedes RCS items A2-2 (NC-88-78-1), B-28 (NC 1-88-96-3), D-17 (NC 1-88-83-5), F-22 (NC 1-88-78-1), O-6 (NC 1-88-78-1), R-11 (NC 1-88-79-1), V-5 (NC-88-78-1).	**Supersedes Items listed in the Description**

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Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation

6.1 8110 Recall Action Files.
Materials on each action taken regarding the recalling of unsafe, impure, or mislabeled regulated products from the market for destruction or return initiated by the producer (voluntary) or FDA (involuntary). Includes notifications of action taken, summaries of the extent and effectiveness of the recall, recall inspection reports, labels, sample analysis and photographs of recalled products, distribution information, approvals or denials, summaries of establishment inspection reports, information on consumer complaints, FDA audit checks, status reports, and related correspondence and documentation.

6.1.1 8111 Records Maintained in Center Program Offices.
Recordkeeping copies of recall related records originated from the center such as health hazard reports/ risk assessment reports, documentation on recall classification, copies of the records originated from the field, tracking information and related records.

Disposition: TEMPORARY. Cutoff at end of calendar year after action is closed. Transfer to FRC 2 years after cutoff. Destroy/delete 20 years after cutoff.

6.1.2 8112 Records Maintained in Field Offices.
Recordkeeping copies of recall related materials originated in the field such as audit checks, effectiveness checks, including copies of the records originated from centers, and related records.

Disposition: TEMPORARY. Cutoff at end of calendar year after action is closed. Transfer to FRC 5 years after cutoff. Destroy/delete 10 years after cutoff.

6.1.3 8113 Records Maintained in the Office of Regulatory Affairs (ORA).
Memo on Class 1 recall actions and recommendations, duplicate copies of the recall related records maintained as working files. Records are filed by center, then recall number and year.

Disposition: TEMPORARY. Cutoff at end of calendar year after action is closed. Destroy 4 years after cutoff.

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
6.2	8120	Recall Enterprise System (RES). Includes data entered to track entire agency-wide recall activities by centers, ORA and field offices. This Oracle database includes the data fields such as field district name, recall number, product name and details, company, recall summary, alert date, recall strategy, recommendation date, audit information, FDA comments, and other data entered to collect, track, and analyze recall information. Maintained by the Office of Enforcement, ORA.	New
6.2.1	8121	Data Files. In addition to the data described above, firm information is directly entered into RES from the Field Accomplishment and Compliance Tracking System (FACTS) or its successor system without creating an input file. Also includes data directly loaded from center tracking systems. **Disposition: TEMPORARY.** Cutoff at end of calendar year in which the action is closed. Delete 75 years after cutoff.	
6.2.2	8122	Outputs: Periodic Reports and Extracted Recall Data. Regular reports generated to be part of another records such as Enforcement Report, or to be loaded onto another database. **Disposition:** File reports and extracted data files in an appropriate subject file. Apply disposition instructions for that file.	
6.2.3	8123	Outputs: Reports for Public Access. Reports generated from a subset of selected recall data created as public access copies via the RES Internet application. **Disposition**: **TEMPORARY**. Destroy/delete when superseded or obsolete, or no longer needed for reference.	
6.2.4	8124	Outputs: Ad-hoc Reports. **Disposition: TEMPORARY.** Destroy or delete when no longer needed for administrative or operational purposes.	
6.2.5	8125	Electronic Notifications. E-mail notifications to appropriate centers and offices alerting that information has been entered into the system for action. **Disposition: TEMPORARY**. Delete by recipients within	

180 days after dissemination or updating is completed.

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Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
6.2.6	8126	System Documentation. Systems specifications, file specifications, record layouts, user business rules, input/output specifications, data dictionaries and records relating to system operation. **Disposition: TEMPORARY**. Destroy/delete when superseded or obsolete, or upon authorized deletion of the related master file or database, whichever is later.	
~~6.2.7~~	~~8127~~	~~Backups of Files.~~ ~~Electronic copy, considered by the agency to be a Federal record, of the master copy of an electronic record or file and retained in case the master file or database is damaged or inadvertently erased.~~ ~~**Disposition: TEMPORARY**. Delete when the identical records have been deleted, or when replaced by a subsequent backup file.~~	~~**GRS 20, Item 8b**~~
7		**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.	
7.1		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. **Disposition: TEMPORARY:** Destroy within 180 days after the recordkeeping copy has been produced.	
7.2		Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy. **Disposition: TEMPORARY:** Destroy when dissemination, revision, or updating is completed	