REQUEST FOR RECORDS DISPOSITION AUTHORITY	JOB NUMBER N1-088-04-4
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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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)~~ Agency-wide Change ok by Ms. Sinatra 11-19-2007 via email.	

4. NAME OF PERSON WITH WHOM TO CONFER	5. TELEPHONE	DATE	ARCHIVIST OF THE UNITED STATES
Seung Ja Sinatra	**301-827-4274**	5/15/08	

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
JAN 16 2004	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 GRS OR SUPERSEDED JOB CITATION	10.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 Public Affairs and Information Services.

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 Sheet

Seung Ja Sinatra - FDA Records Officer — Date 12/04/03

Fred Ansell - Office of the Chief Counsel — Date 12/23/03

Rosario Cirrincione, Dir., Freedom of Info/Privacy Act — Date 1/15/04

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

LL 6/5/08 copies sent to NWMB, NWM & NWMW, NWCS, NWCT-2P, NR, & agency

Public Affairs and Information Services.

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
1.	Press Releases/Talk Papers. Information given to communications media advising of FDA's position on various subject matters and actions taken, including reports on recalls and new drug approvals. **PERMANENT.** Media Neutral. Cut off at end of the calendar year during which it was released. For paper records, transfer records 7 years after cutoff to FRC. Transfer to NARA 10 years after cutoff in 5-year blocks. For electronic records, transfer to NARA with system documentation as applicable 10 years after cutoff in 5-year blocks. 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.	**Supersedes NC-1-88-78-1, Item I-1a, b, and I-2 in Current FDA RCS.**
2.	Publications. Final copy of proofs, prints, manuscripts, and supporting materials for FDA Papers, FDA Consumer, and similar publications. **PERMANENT**. Media Neutral. Cut off at end of the calendar year when published. For paper records, transfer records 4 years after cutoff to FRC. Transfer to NARA 10 years after cutoff. For electronic records, transfer to NARA with system documentation as applicable 10 years after cutoff. 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.	**Supersedes NC-1-88-78-1, Item I-3a,b,c, in FDA RCS**
3.	FDA Public Calendar. Listing of meetings, Official Copy of the Public Calendar and/or events involving top policymakers of FDA with individuals outside the Executive Branch of the Federal Government. **TEMPORARY:** Media Neutral. Cut off at end of the calendar year. For paper records, transfer to FRC 5 years after cutoff. Destroy 10 years after cutoff. For electronic records, delete 10 years after cutoff.	**Supersedes NC-1-88-78-1, Item I-4a, b, c in FDA RCS**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
4.	FDA Today. Newsletter to all FDA employees. Final version of FDA Today that is distributed to FDA employees. **TEMPORARY**: Media Neutral. Cut off at end of the calendar year in which newsletter was distributed. For paper records, transfer to FRC 4 years after cutoff. Destroy 10 years after cutoff. For electronic records, delete 10 years after cutoff. FDA will ensure record format integrity during the retention period according to NARA regulations.	**Supersedes NC-1-88-78-1, Item I-7 a, b, c in FDA RCS**
5.	Publication Approvals. Files are the agency's copies of the justification for printing and audio/video projects within FDA, including information on the project topic, the projected cost, necessary preparation work (including research), and artwork. **TEMPORARY: Media Neutral.** Cut off at end of the fiscal year in which the work is last produced. Destroy or delete 7 years after cutoff.	**New Item**
6.0	Information Request and Response Files.	
6.1	Information Retrieval. Copies of material used to respond to public inquiries regarding topics such as public laws, regulations, speeches and testimony by FDA officials, correspondence, reports, plans, studies, publications, etc. **TEMPORARY**: Media Neutral. Destroy or delete when obsolete or superseded or 1 year after date of receipt unless needed for further reference.	**NC 1-88-78-1, Item G-1**
6.2	~~Information Request Files. Requests for information and copies of replies thereto, involving no administrative actions, no policy decisions, and no special compilations or research and requests for and transmittals of publications, photographs, and other information literature.~~ ~~**TEMPORARY**: Destroy when 3 months old.~~	**GRS 14, Item 1**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
7.	~~Audio Visual Records. Motion pictures, films, photographs, documentaries, slides, tapes, and exhibit materials produced by FDA to document problems in the industry, publicize the Agency's mission and operations, educate consumers, or other purposes. Also, related documentation providing context for the visual items, including, but not limited to finding aids, web-page printouts, publicity, subject or content files, articles, and other explanatory materials. Also include specifications, requisitions, and copies of contracts if produced under contract.~~	**Supercedes NC-1-88-78-1, FDA RCS I-8 Withdrawn 11-19-2007**
7.1	~~Photographs (including pictures and digital images) and Exhibit Materials. Original negative and a captioned print for each black and white image and the original color transparency or color original, a captioned print, and an internegative if one exists for each color image.~~ ~~**PERMANENT.** Cut off every 10 years and offer to History Office. Transfer to NARA after cutoff.~~	**Withdrawn 11-19-2007**
7.2	~~Motion Pictures and Films. Original negative or color original plus additional copies, if available. As of the year 2000, all FDA films should be sent to the FDA History Office, for cold storage preservation and proper placement. CD-ROM copies will be made available as needed.~~ ~~**PERMANENT.** Transfer 1st copy and original to NARA when no longer needed for administrative purposes or when 5 years old. Offer duplicate and 2nd prints to National Library of Medicine or alternate site.~~	**Withdrawn 11-19-2007**
7.3	~~Sound Recordings. Master tape, matrix or stamper, and one disc pressing for each conventional mass-produced multiple copy disc recording and the original tape or the earliest generation of each magnetic audio tape recording. Sound recordings should be sent to the FDA History Office.~~ ~~**PERMANENT.** Transfer 1st copy and original to NARA when no longer needed for administrative purposes or when 5 years old. Offer duplicate and 2nd prints to National Library of Medicine or alternate site.~~	**Withdrawn 11-19-2007**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
7.4	~~Video Tapes and Slides. Original or the earliest generation of the recording, or the earliest generation Beta copy of the recording. All FDA tapes no longer needed in program areas should be offered to the FDA History Office.~~ ~~**PERMANENT.** Transfer 1st copy and original to NARA when no longer needed for administrative purposes or when 5 years old. Offer duplicate and 2nd prints to National Library of Medicine or alternate site.~~	**Withdrawn 11-19-2007**
7.5	~~Finding Aids. FDA History Office maintains finding aids and indexes for all agency artifacts in its possession, including films, and other audiovisual media over 10 years old. These include background and/or archival documentation for the proper identification, retrieval, and use of the above, including but not limited to indexes, catalogs, caption lists, and production files which include contracts, scripts, and other documentation bearing on the origin, acquisition, release and ownership of the above records.~~ ~~**PERMANENT.** Offer to NARA or alternative site along with the audiovisual records to which they relate.~~	**Withdrawn 11-19-2007**
8.	~~Routine Scientific, Medical, or Engineering Footage.~~ ~~**TEMPORARY:** Destroy when 2 years old.~~	**GRS 21, Item 12**
9.	~~Rehearsal or Practice Tapes.~~ ~~**TEMPORARY:** Destroy immediately.~~	**GRS 21, Item 16**
10.	~~Recordings that Document Routine Meetings and Award Presentations.~~ ~~**TEMPORARY:** Destroy when 2 years old.~~	**GRS 21, Item 20**
11.	~~Premix Sound Elements Created During the Course of a Motion Picture, Television, or Radio Production.~~ ~~**TEMPORARY:** Destroy immediately after use.~~	**GRS 21, Item 24**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
12.	~~Daily or Spot News Recordings Available to Local Radio Stations on a Call-in Basis.~~ ~~**TEMPORARY:** Destroy when 6 months old.~~	**GRS 21, Item 26**
13.	~~Production Files or Similar Files that Document Origin, Development, Acquisition, Use, and Ownership of Temporary Audiovisual Records.~~ ~~**TEMPORARY:** Dispose of according to the instructions covering the related audiovisual records.~~	**GRS 21, Item 28**
14.	~~Finding Aids for Identification, Retrieval, or Use of Temporary Audiovisual Records.~~ ~~**TEMPORARY:** Dispose of according to the instructions covering the related audiovisual records.~~	**GRS 21, Item 29**
15.	~~FOIA Repository System. System stores and provides electronic full text and keyword access to information that has been requested and provided under FOIA. Provides an easy methodology for responding to additional FOIA requests for the same information. It is accessible via the Agency Information Management System (AIMS) and indexed by FOI control number~~.	**New Item GRS 14/11a(1) and (2)**
15.1	~~Inputs. FOIA request letter and FDA's response to requests including responsive documents that are either scanned into the system or, if created electronically, directly input into the system.~~ ~~**TEMPORARY**: Apply retention instructions specified in 21 CFR 20.31. Destroy hard copy if record is scanned or delete the source document if record is electronic upon verification of successful data entry by quality control, when electronic copies become official and maintained in accordance with 21 CFR 20.31.~~	**GRS 14/11a(1) and (2)**
15.2	~~Data Files. Records consist of FOIA requests files and FDA's responses under the Freedom of Information Act either in the native format or as a scanned image.~~ ~~**TEMPORARY**: Apply retention instructions specified in 21 CFR 20.31.~~	**GRS 14/11a(1) and (2)**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
15.3	~~Outputs. Printed records may be used as reference or become part of another FOIA response.~~ ~~**TEMPORARY**: If used for reference, destroy when no longer needed. If copy becomes part of another FDA records series, apply retention of that file.~~	**GRS 20/Item 5 and 6**
15.4	~~System Documentation. Administrator's Manual and User Manual.~~ ~~**TEMPORARY:** Destroy or delete when superseded or obsolete, or upon authorized deletion of the related master file or data base, or upon the destruction of the output of the system if the output is needed to protect legal rights, whichever is latest.~~	**GRS 20, Item 11a**
15.5	~~System Backup. Backup tapes maintained for potential system restoration in the event of a system failure or other unintentional loss of data.~~ ~~**TEMPORARY:** Delete/destroy incremental backup tapes when superseded by a full backup, or when no longer needed for system restoration, whichever is later~~	**GRS 20, Item 8a**
16.	~~FOIA Control Files. FOI tracking system captures all pertinent tracking information: address, company, person's name submitting the request, date received, date due, type of request (e.g. commercial, media, others), subject, FDA component where assigned, fees charged, comments, and other tracking related information.~~	**GRS 14, Item 13**
16.1	~~Registers or listing.~~ ~~**TEMPORARY:** Destroy 6 years after date of last entry.~~	**GRS 14, Item 13a**
16.2	~~Other FOIA Control Files.~~ ~~**TEMPORARY:** Destroy 6 years after final action by the agency or after final adjudication by courts, whichever is later.~~	**GRS 14, Item 13b**
17.	Annual FOIA Report	

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
17.1	Includes duplicate copies of the FOIA Annual Report addressed to the Department of Justice Office of Information and Privacy submitted through to the Department of Health and Human Services (HHS) where record copies are maintained. The report includes the number of requests received, the number of denials, reason for denial and appeal determinations, confidential business information determinations, disciplinary actions, FDA rules and regulations, amount of fees collected and fee schedule, administrative costs, compliance with time limitations information, and court actions. The report is made available to the public through the FDA FOIA and Department of Justice Web sites.	**New Item**
	Temporary. Media Neutral. Cut off at end of fiscal year. Destroy or delete 10 years after cut off. FDA will ensure record format integrity during the retention period according to NARA regulations.	**Disposition and description change approved by Ms. Sinatra via e-mail 4/18/2005.**
17.2	All other copies. Copies on FDA Internet.	**New Item**
	TEMPORARY: Cut off at end of fiscal year. Destroy or delete 5 years after cutoff.	**Retention and description change approved by Ms. Sinatra 4/18/2005**
18.	~~FOIA Requests Files. Files created in response to requests for information under the FOIA, consisting of the original request, a copy of the reply thereto, and all related supporting files which may include the official file copy of requested record or copy thereof. When applicable, apply retention instructions specified in 21 CFR 20.31.~~	**GRS 14, Item 11**
18.1	~~Correspondence and supporting documents (EXCLUDING the official file copy of the records requested if filed herein).~~	**GRS 14, Item 11a**
18.1.1	~~Granting access to all the requested records.~~	**GRS 14, Item 11a (1)**
	~~**TEMPORARY:** Destroy 2 years after date of reply.~~	
18.1.2	~~Responding to requests for nonexistent records; to requesters who provide inadequate descriptions; and to those who fail to pay agency reproduction fees.~~	**GRS 14, Item 11a (2)**
18.1.2.1	~~Request not appealed.~~	**GRS 14, Item 11a (2) (a)**
	~~**TEMPORARY:** Destroy 2 years after date of reply~~.	

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
18.1.2.2	~~Request appealed.~~ ~~**TEMPORARY:** Destroy as authorized under FOIA Appeals Files.~~	**GRS 14, Item 11a (2) (b)**
18.1.3	~~Denying access to all or part of the records requested.~~	**GRS 14, Item 11a (3)**
18.1.3.1	~~Request not appealed.~~ ~~**TEMPORARY:** Destroy 6 years after date of reply.~~	**GRS 14, Item 11a (3) (a)**
18.1.3.2	~~Request appealed.~~ ~~**TEMPORARY:** Destroy as authorized under FOIA appeals files.~~	**GRS 14, Item 11a (3) (b)**
18.2	~~Official file copy of requested records.~~ ~~**TEMPORARY:** Dispose of in accordance with approved agency disposition instructions for the related records or with the related FOIA request, whichever is later.~~	**GRS 14, Item 11b**
19.	~~FOIA Appeals Files. Files created in responding to administrative appeals under the FOIA for release of information denied by the agency, consisting of the appellant's letter, a copy of the reply thereto, and related supporting documents, which may include the official file copy of records under appeal or copy thereof.~~	**GRS 14, Item 12**
19.1	~~Correspondence and supporting documents (EXCLUDING the file copy of the records under appeal if filed herein).~~ ~~**TEMPORARY:** Destroy 6 years after final determination by agency, 6 years after the time at which a requester could file suit, or 3 years after final adjudication by the courts, whichever is later.~~	**GRS 14, Item 12a**
19.2	~~Official file copy of records under appeal.~~ ~~**TEMPORARY:** Dispose of in accordance with approved agency disposition instructions for the related record or with the related FOIA request, whichever is later.~~	**GRS 14, Item 12b**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
20.	~~FOIA Administrative Files. Records relating to the general agency implementation of the FOIA, including notices, memoranda, routine correspondence, and related records.~~ ~~**TEMPORARY:** Destroy when 2 years old.~~	**GRS 14, Item 15**
21.	~~Privacy Act Requests Files. Files created in response to requests from individuals to gain access to their records or to any information in the records pertaining to them, as provided for under 5 U.S.C. 552a(d)(1). Files contain original request, copy of reply thereto, and all related supporting documents, which may include the official file copy of records requested or copy thereof.~~	**GRS 14, Item 21**
21.1	~~Correspondence and supporting documents (EXCLUDING the official file copy of the records requested if filed herein).~~	**GRS 14, Item 21a**
21.1.1	~~Granting access to all the requested records.~~ ~~**TEMPORARY:** Destroy 2 years after date of reply.~~	**GRS 14, Item 21a(1)**
21.1.2	~~Responding to requests for nonexistent records; to requesters who provide inadequate descriptions; and to those who fail to pay agency reproduction fees.~~	**GRS 14, Item 21a(2)**
21.1.2.1	~~Requests not appealed.~~ ~~**TEMPORARY:** Destroy 2 years after date of reply.~~	**GRS 14, Item 21a(2)(a)**
21.1.2.2	~~Requests appealed.~~ ~~**TEMPORARY:** Destroy as authorized under Privacy Act Amendment Case Files.~~	**GRS 14, Item 21a(2)(b)**
21.1.3	~~Denying access to all or part of the records requested.~~	**GRS 14, Item 21a(3)**
21.1.3.1	~~Requests not appealed.~~ ~~**TEMPORARY:** Destroy 5 years after date of reply.~~	**GRS 14, Item 21a(3)(a)**
21.1.3.2	~~Requests appealed.~~ ~~**TEMPORARY:** Destroy as authorized under Privacy Act Amendment Case Files.~~	**GRS 14, Item 21a(3)(b)**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
21.2	~~Official file copy of requested records.~~ ~~**TEMPORARY:** Dispose of in accordance with approved agency disposition instructions for the related records or with the related Privacy Act request, whichever is later.~~	**GRS 14, Item 21b**
22.	~~Privacy Act Amendment Case Files. Files relating to an individual's request to amend a record pertaining to that individual as provided for under 5 U.S.C. 552a(d)(2); to the individual's request for a review of an agency's refusal of the individual's request to amend a record as provided for under 5 U.S.C. 552a(d)(3); and to any civil action brought by the individual against the refusing agency as provided under 5 U.S.C. 552a(g).~~	**GRS 14, Item 22**
22.1	~~Requests to amend agreed to by agency. Includes individual's requests to amend and/or review refusal to amend, copies of agency's replies thereto, and related materials.~~ ~~**TEMPORARY:** Dispose of in accordance with the approved disposition instructions for the related subject individual's record or 4 years after agency's agreement to amend, whichever is later.~~	**GRS 14, Item 22a**
22.2	~~Requests to amend refused by agency. Includes individual's requests to amend and to review refusal to amend, copies of agency's replies thereto, statement of disagreement, agency justification for refusal to amend a record, and related materials.~~ ~~**TEMPORARY:** Dispose of in accordance with the approved disposition instructions for the related subject individual's record, 4 years after final determination by agency, or 3 years after final adjudication by courts, whichever is later.~~	**GRS 14, Item 22b**
22.3	~~Appealed requests to amend. Includes all files created in responding to appeals under the Privacy Act for refusal by any agency to amend a record.~~ ~~**TEMPORARY:** Dispose of in accordance with the approved disposition instructions for related subject individual's record or 3 years after final adjudication by courts, whichever is later.~~	**GRS 14, Item 22c**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
23.	~~Privacy Act Accounting of Disclosure Files. Files maintained under the provisions of 5 U.S.C. 552a(c) for an accurate accounting of the date, nature, and purpose of each disclosure of a record to any person or to another agency, including forms for showing the subject individual's name, requester's name and address, purpose and date of disclosure, and proof of subject individual's consent when applicable.~~ ~~**TEMPORARY:** Dispose of in accordance with the approved disposition instructions for the related subject individual's records or 5 years after the disclosure for which the accountability was made, whichever is later.~~	**GRS 14, Item 23**
24.	~~Privacy Act Control Files. Files maintained for control purposes in responding to requests, including registers and similar records listing date, nature of request, and name and address of requester.~~	**GRS 14, Item 24**
24.1	~~Registers or listings.~~ ~~**TEMPORARY:** Destroy 5 years after date of last entry.~~	**GRS 14, Item 24a**
24.2	~~Other files.~~ ~~**TEMPORARY:** Destroy 5 years after final action by the agency or final adjudication by courts, whichever is later.~~	**GRS 14, Item 24b**
25.	Privacy Act Reports Files.	
25.1	~~Bi-Annual Reports to Congress~~ ~~**TEMPORARY**. Media Neutral. Cut off at end of calendar year in which report is issued and place in inactive file. For paper records, transfer 5-year block to record center when oldest record in block is 5 years old after cutoff, if needed. Destroy 20 years after cut off. For electronic records, delete 20 years after cutoff. FDA will ensure record format integrity during the retention period according to NARA regulations.~~	**New Item Withdrawn 4/18/2005**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
25.2	~~Recurring reports and one-time information requirement relating to agency implementation, including biennial reports to the Office of Management and Budget (OMB), and the Report on New Systems at all levels.~~ ~~**TEMPORARY:** Destroy when 2 years old.~~	**GRS 14, Item 25**
26.	~~Privacy Act General Administrative Files. Records relating to the general agency implementation of the Privacy Act, including notices, memoranda, routine correspondence, and related records.~~ ~~**TEMPORARY:** Destroy when 2 years old.~~	**GRS 14, Item 26**
27.	~~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.~~	
27.1	~~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.~~ ~~**TEMPORARY:** Destroy/delete within 180 days after the recordkeeping copy has been produced.~~	**GRS 20/Item 13 and 14**
27.2	~~Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.~~ ~~**TEMPORARY:** Destroy/delete when dissemination, revision, or updating is completed.~~	**GRS 20/Item 13 and 14**