REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER N1-088-04-2	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-6001		Date Received 2/27/04	
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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	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 3/6/09	ARCHIVIST OF THE UNITED STATES 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 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
FEB 24 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 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10.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 Legal, Legislative and Regulatory 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.

See Attached Sheet

Seung Ja Sinatra — 1/9/04

Seung Ja Sinatra - FDA Records Officer — **Date**

Fred Ansell — 1/21/04

Fred Ansell - Office of the Chief Counsel — **Date**

LEGAL, LEGISLATIVE AND REGULATORY RECORDS

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
1	~~Legal Opinion Precedent Files. Precedential legal opinions issued by the Chief Counsel for application to programs throughout the FDA. Included are legal opinions, directly related memoranda, copies of laws, and related documents. Since 2000, all records are electronically maintained in the Attorney Work Product System.~~ ~~Access Restricted to the Office of Chief Counsel.~~	
1 1	~~Records from 1950 through 1999~~ ~~**PERMANENT:** Series was cutoff on December 31, 1999. 30 cubic feet of paper. Transfer to NARA with related indexes 75 years after cutoff.~~	~~**Supersedes RCS OCC-01**~~ **WITHDRAWN 9/12/2005**
1 2	~~Records Post 2000.~~ ~~**PERMANENT:** Cut off in 5-year blocks at end of calendar year after paper records are scanned. Transfer to NARA with related indexes 75 years after cut off.~~	~~**Supersedes RCS OCC-01**~~ **WITHDRAWN 9/12/2005**
2	~~Attorney Work Product Documents~~ ~~Files include attorney work products such as motions, consent decrees, legal memoranda, briefs, legal opinion precedent files, position documents, and attorney versions of warning letters, which have been created or received by the FDA Office of Chief Counsel (OCC). In the course of their proceedings, OCC routinely consults these records to ensure their subsequent opinions, briefs and other issuances are not unintentionally contradictory. The records are also sent to the Department's General Counsel. Access is restricted to OCC.~~	
2 1	~~Paper records and printed recordkeeping copies of the records electronically created /received.~~ ~~**PERMANENT.** Cut off in 5 year blocks at end of fiscal year after paper records are scanned. Transfer to NARA with related indexes 75 years after cutoff.~~	~~**New Item**~~ **WITHDRAWN 9/12/2005**
2 2	~~Records created/received electronically.~~ ~~**TEMPORARY:** Delete after producing recordkeeping copies in paper and upon verification of successful data import into the Attorney Work Product System by quality~~	~~**New Item**~~ **WITHDRAWN 9/12/2005**

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
	~~control.~~	
2.3	~~Attorney Work Product System~~ ~~System stores and provides full text/keyword access to reference copies of the attorney work products described under Items 2 1 and 2.2 The system provides a quick and easy way for OCC to routinely access and consult these records in the course of their proceedings to ensure their subsequent opinions, briefs and other issuances are not unintentionally contradictory. Records are organized into three categories Office Repository, Counsel Memos, and Appellate Briefs. The system is also referred to as ISYS and access is restricted to OCC.~~	
2 3 1	~~Inputs. Paper records are scanned into the system or, if created or received electronically, directly input into the system.~~ ~~**Disposition:** Apply records disposition under Item 2 1 or 2 2 appropriately~~	~~**New Item**~~ **WITHDRAWN 9/12/2005**
2 3 2	~~Data Files. The data in the system consist of the work product documents described under the system. These records are stored either in the native format or as a scanned image Some of the pre-2000 records have been scanned into the system. Metadata elements include document title, brief description, document date, file format and other related fields~~ ~~**TEMPORARY.** Maintain records for as long as records are needed for FDA business~~	~~**New Item**~~ **WITHDRAWN 9/12/2005**
2 3.3	Outputs.	
	~~a. Reference copies. Copies of the records produced by all employees of OCC for reference use~~ ~~**TEMPORARY:** Destroy when no longer needed for reference~~	~~**New Item**~~ **WITHDRAWN 9/12/2005**
	b ~~Indexes. Printed indexes generated from the system.~~ ~~**PERMANENT.** Cut off at end of fiscal year in 5 year blocks and transfer to NARA with related records 75 years after cutoff.~~	~~**New Item**~~ **WITHDRAWN 9/12/2005**

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2 3 4	~~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.~~ ~~Delete/destroy full backup tapes when second subsequent backup is verified as successful or when no longer needed for system restoration, whichever is later.~~	**GRS 20, Item 8a and b**
3	~~Litigation Case Files. Files consist of court pleadings, correspondence, memorandums, studies, appraisals, court decisions, and similar documents related to enforcements and defensive litigation.~~ ~~**TEMPORARY:** Cut off after litigation is terminated. Transfer to FRC 2 years after cutoff. Destroy 10 years after cutoff.~~	~~**Supersedes RCS OCC-2**~~ **WITHDRAWN 9/12/2005**
4.	~~Administrative Hearing Files. Reference copies of case files to document administrative hearings and appeals within FDA. Included in these files are notices of appointments for hearing, hearing transcripts, legal briefs, affidavits, and administrative exhibits, initial decisions of the Administrative Law Judge, decision of the Commissioner, and related material. If these files exist as a separate set of records, the following disposition instructions apply. If the essential administrative hearing documents are filed in the related case file, the disposition instructions for the case file apply. The official copy of these documents is kept within Dockets.~~ ~~**TEMPORARY:** Destroy when no longer needed for reference.~~	~~**Supersedes OCC-03**~~ **WITHDRAWN 9/12/2005**
5.	Correspondence between Members of Congress and FDA. Includes incoming correspondence, replies, and supporting documents.	
5.1	Chairman and Member Letters. Include both correspondence between FDA and Committee/Subcommittee Chairman when acting in their capacity as Chairman, and correspondence between FDA	**Supersedes NC1-88-78-1, RCS Item L-2**

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
	and Members of Congress not related to constituent requests. **PERMANENT: Media neutral**. Cut off at the end of the calendar year after Congressman leaves office. For paper records, transfer records to FRC 5 years after cutoff Transfer records in all media and formats to NARA 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	
5.2	Member-Constituent Correspondence. Includes correspondence between FDA and Members of Congress relating to constituent requests or concerns. **TEMPORARY: Media neutral.** Cut off at end of calendar year in which received. For paper records, transfer records to FRC 2 years after cutoff. Destroy or delete 10 years after cutoff	**Supersedes NC1-88-78-1, RCS Item L-2 and L-3**
6.	House and Senate Hearings (Non-Legislation). Background materials prepared by FDA officials who testify in Committee hearings. Also contains copies of bills, laws, and data on DHHS appropriations. . **TEMPORARY: Media neutral.** Cut off at the end of the calendar year upon completion of hearing. For paper records, transfer records to FRC 5 years after cutoff Destroy or delete 10 years after cutoff.	**Supersedes NC1-88-78-1, RCS Item L-1**
7	Legislation and Hearing Reference Files. Documents covering current Congressional sessions, including proposed legislation, enacted legislation, and background materials **TEMPORARY: Media neutral**. Destroy or delete 1 year after legislation is enacted or withdrawn unless needed for further reference	**Supersedes NC1-88-78-1, RCS Item L-4, L-5 and L-6.**

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8	Federal Register Notices Include records that are related to the publication of notices in the Federal Register	
8 1	Published Notices. Include drafts and final notices, tear sheets from the Federal Register, newspaper clippings, press releases, citations and abstracts of articles, and correspondence. **TEMPORARY: Media neutral.** Cut off at end of fiscal year in which published. Delete/destroy 3 years after cutoff.	**NC 1-88-84-2 RCS C-7**
8.2	Notices Not Published. Includes materials related to the notices that were determined not to publish. **TEMPORARY Media neutral.** Cut off at end of the fiscal year when decision not to publish is made. Destroy or delete immediately upon cutoff.	
9	~~Federal Register Documentation Tracking System (FRDTS).~~ ~~Logs and other records to track the progress status of Federal Register documents from time of initial draft to final issuance One of the modules supported by AIMS.~~ ~~**TEMPORARY**: Destroy or delete when 2 years old, or 2 years after the date of the latest entry, whichever is applicable.~~	**GRS 23, Item 8;** **Supersedes NC-1-88-78-1, RCS C-6**
10	Evidentiary Hearing Materials. Hearing Materials for Parts 12-15 Public Hearings. Formal Evidentiary Hearings, Public Board of Inquiry Hearings, Advisory Committee Hearings, Public hearings before the Commissioner and Administrative Law Judge, and Regulatory Hearings. Also may include descriptive photographs of product examples submitted to FDA. A unique Docket control number is assigned to each record Contains trade secret and confidential commercial information that may not be publicly released; 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 (NOTE: Actual product examples are not transferred with the records to NARA)	**Supersedes N1-88-86-1; RCS C3 Item 13**

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	NOTE: Transfer any existent hardcopy indexes to these records along with the records themselves **Disposition: PERMANENT**. Media Neutral. Cut off at the end of the calendar year following the close of the hearing, including resolution of any objections and any litigation thereon Transfer paper records to FRC 3 years after cutoff Transfer records in all media or formats to the National Archives 25 years after cutoff	
11	Rule Making and Administrative Procedures Records. Include the records required in the event of litigation or for review in promulgating rulemaking. Records include final rules and related official rulemaking documentation, Federal Register notices, comments, petitions, public inquiries, responses, Administrative Hearing Files, hearing materials regarding agency policies, procedures, regulations, variances and decisions, and may include descriptive photographs of product examples A unique Docket control number is assigned to each record. Contains trade secret and confidential commercial information that may not be publicly released, 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. Records, on receipt of 90-day disposal notice from FRC, are reviewed and identified for appropriate sub-file categories which file belongs to and disposition for that sub-file series is applied.	**Supersedes N1-88-86-1; RCS C3 Items 1-12**
11 1	Substantial Rule Making and Administrative Procedures Records Includes cases that set precedents relating to legal or policy altering issues, receive intense public, media, or Congressional scrutiny, or relate to major historical events Include records submitted in paper, video, and non-electronic media, and printed copies of the records electronically submitted via Web, e-mail, fax, or on other electronic media.	

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
	NOTE: Transfer any existent hardcopy indexes to these records along with the records themselves **Disposition: PERMANENT.** Media Neutral. Cut off at the end of the calendar year after final action is taken on regulation including resolution of any objections and any litigation thereon If needed, transfer paper records to FRC 5-15 years after cutoff Transfer records in all media and formats to NARA 30 years after cutoff.	
11 2	Non-Substantial Rule Making and Administrative Procedures Records All other cases that have not met the threshold for Substantial Rule Making and Administrative Procedures Records. **Disposition: TEMPORARY.** Media neutral. Cut off at the end of the calendar year after final action is taken on regulation including resolution of any objections and any litigation thereon If needed, transfer to FRC 5-15 years after cutoff. Destroy or delete 30 years after cutoff.	**Supersedes N1-88-86-1; RCS C3 Items 1-12**
11 3	~~Duplicate Copies Produced to Use for Quality Image~~ ~~**Disposition: TEMPORARY.**~~ ~~Destroy upon verification of successful imaging by quality control.~~	**Non-record**
11 4	~~Records Submitted Electronically via Web, E-mail, or on Other Electronic Media.~~ ~~**Disposition: TEMPORARY.** Delete after producing recordkeeping copies in paper and upon verification of successful data import into the Dockets System by quality control.~~	**GRS 20, Item 2b**
11 5	~~Duplicate Copies Maintained as Part of Another FDA Files. Copies used for another FDA hearing, rulemaking or other activity, and for general reference~~ ~~**Disposition: TEMPORARY.**~~ ~~If used for reference, destroy when no longer needed.~~ ~~If copy becomes part of another FDA records, apply records disposition for that records.~~	**Non-record / Otherwise scheduled**

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
~~12~~	~~**Rule Making Documents.**~~ ~~Records includes public comments on Federal Register Notices on certain Agency topics electronically generated during rule making activities and maintained in the Federal Dockets Management System (FDMS)~~ ~~Records are closed after final action is taken on regulation including resolution of any objections and any litigation thereon. Transfer to FRC when appropriate~~	**Withdrawn** **6-12-2006**
~~12 1~~	~~3 1 Substantial Administrative Files For Dockets Management~~ ~~Include the cases that generated substantial public interest, media, or legal precedent.~~ ~~**PERMANENT.** Transfer to NARA 30 years after cutoff~~	**Withdrawn** **6-12-2006**
~~12.2~~	~~Non-Substantial Administrative Files For Dockets Management All other cases that have not met the threshold for Substantial Administrative Files For Dockets Management~~ ~~**TEMPORARY:** Destroy 30 years after cutoff~~	**Withdrawn** **6-12-2006**
13	Dockets Management and Tracking Systems. May include Dockets System, Federal Dockets Management System (FDMS), or other systems Systems that store and provide full text and keyword access to Dockets and tracks the information about the dockets files (NOTE Actual docket case files are scheduled under Items 11.1 and 11 2 as appropriate)	
13.1	Data Files Contains the data that describes the scanned images and other information within the Docket case files (metadata) Data fields may include Docket number, document title, brief description, document date, and file format, and other related information. Does not include samples or artifacts accompanying documents. NOTE: If the data is migrated into a new system, the preceding system may be deleted/destroyed after the verification of successful data migration Contains trade secret and confidential commercial	New Item

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
	information that may not be publicly released; 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.	
13 1 1	Data Files for Substantial Rule Making and Administrative Procedures Records **Disposition: PERMANENT.** Cut off at the end of the calendar year when associated Docket case file is closed after final action is taken on the regulation including resolution of any objections and any litigation thereon. Transfer to NARA 30 years after cutoff with associated Rulemaking and Substantial Administrative Proceedings Dockets.	
13 1 2	Data Files for Non-Substantial Rule Making and Administrative Procedures Records **Disposition: TEMPORARY.** Cut off at the end of the calendar year when associated Docket case file is closed after final action is taken on the regulation including resolution of any objections and any litigation thereon. Delete 30 years after cutoff.	
~~13 2~~	~~Outputs~~	
~~13 2 1~~	~~Printed Duplicate Copies - Used as reference or part of another FDA hearing, rulemaking, or other activity~~ ~~**Disposition: TEMPORARY.**~~ ~~If used for reference, destroy when no longer needed. If a copy becomes part of another FDA records series, apply records disposition for that records series.~~	**GRS 20, Item 6**
~~13.2 2~~	~~Dockets Tracking Logs. Logs, registers, chronological list of petitions, and other reports used to control or document the status of Dockets activities~~ ~~**Disposition: TEMPORARY:** Destroy or delete when 2 years old, or 2 years after the date of the latest entry, whichever is applicable.~~	**GRS 23, Item 8**
~~13 3~~	~~System Documentation. May include Administrator's~~	**GRS 20, Item 11a(1)** 2

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
	~~Manual, User Manual, data dictionaries and record layouts and other related materials~~ ~~**Disposition: TEMPORARY.**~~ Permanent ~~**Delete 3 years** after **all** records and associated metadata are migrated into the Federal Dockets Management System (FDMS) and after the verification of data migration and data entry is complete and successful~~ Please change the disposition to reflect GRS 20, Item 11a2. NPL 2/26/09 Transfer to the National Archives with the permanent electronic records to which the documentation relates.	
~~14~~	~~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, Items 13 and 14**
~~14.1~~	~~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 within 180 days after the recordkeeping copy has been produced.~~	**Non-record**
~~14.2~~	~~Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.~~ ~~**TEMPORARY:** Destroy when dissemination, revision, or updating is completed~~	**Non-record**