

REQUEST FOR RECORDS DISPOSITION AUTHORITY <i>(See Instructions on reverse)</i>		LEAVE BLANK (NARA use only)	
TO: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		JOB NUMBER <i>71-088-06-3</i>	DATE RECEIVED <i>2-28-2006</i>
1. FROM (Agency or establishment) <i>Department of Health and Human Services</i>		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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	
2. MAJOR SUBDIVISION Food and Drug Administration (FDA)			
3. MINOR SUBDIVISION Office of the Commissioner (OC) <i>Agency-Wide</i> <i>ok via email 11/8/2007</i>		DATE <i>2/28/06</i>	ARCHIVIST OF THE UNITED STATES <i>Rha Wainate</i>
4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra	5. TELEPHONE (301) 827-4274		

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,

is not required; is attached; or has been requested.

DATE FEB 23 2006	SIGNATURE OF AGENCY REPRESENTATIVE <i>Prentice Barnes, Sr.</i>	TITLE 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 GRS OR SUPERSEDED JOB CITATION	10.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)
	<p>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.</p> <p>Correspondence and other common records</p> <p><i>Seung Ja Sinatra</i> Seung Ja Sinatra - FDA Records Officer <i>4/27/05</i> Date</p> <p><i>Ann Wion</i> Ann Wion - FDA Deputy Chief Counsel <i>2/7/06</i> Date</p> <p><i>12 3/7/08 copies sent to agency, NWMB, NOME, NWMA, NWCT, & NR</i></p>		

Records Common to Offices

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1	9100	<p><u>Correspondence.</u> Records consist of incoming letters, outgoing responses, enclosures, e-mails, faxes, hand-written notes, and correspondence via other types of communication devices.</p>	
1.1	9110	<p><u>Correspondence to or from FDA Senior Officials.</u> Includes controlled and non-controlled correspondence sent to or from Offices of the Commissioner, Deputy Commissioners, Center Directors, Associate Commissioners, and Chief Counsel. Controlled correspondence is processed under special handling control procedures because of the importance of the letters or time requirements of replies and each correspondence is identified by a unique control number.</p>	
1.1.1	9111	<p><u>Significant Correspondence.</u> Consists of documents on substantive mission program activities, materials of long-range agency-wide significance, and essential backup materials. Some records contain privileged information and access is restricted according to FOIA exemptions. The format in which a record is transferred is determined for the office or center in consultation with NARA.</p>	<p>Supersedes RCS, Item 1a Correspondence— General Subject (NC 1-88-78-1/Item 1a)</p>
<p><u>Disposition:</u> PERMANENT. Media neutral. Cut off at end of calendar year in which response has been signed or correspondence received for which no response is needed and place in inactive annual file. For paper records, transfer records 2 years after cutoff to FRC. Transfer to NARA 20 years after cutoff. For electronic records, transfer to NARA with system documentation as applicable 20 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.</p>			

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1.1.2	9112	<p data-bbox="421 367 817 409"><u>Non-Significant Correspondence.</u></p> <p data-bbox="421 409 1024 514">Consists of correspondence that is routine and has limited value such as administrative documents or consumer mail.</p> <p data-bbox="421 546 1239 787"><u>Disposition:</u> TEMPORARY. Media neutral. Cut off correspondence not needing further response at end of calendar year and place in inactive file. Destroy or delete inactive correspondence 10 years after cutoff. FDA will ensure record format integrity during the retention period according to NARA regulations.</p>	<p data-bbox="1305 409 1614 577">Supersedes RCS, Item 1b Correspondence— General Subject (NC 1-88-78-1/Item 1b)</p>
1.1.3.	9113	<p data-bbox="421 829 1222 871"><u>Source Documents for Correspondence of Senior Officials.</u></p> <p data-bbox="421 871 1239 1102">Contains paper files or electronic documents used as source documents for an imaging or other electronic system maintaining the record copy correspondence. (Note: Source documents having permanent value (i.e., Significant Correspondence of Senior Officials) will not be destroyed or deleted if the electronic or imaged versions in an electronic system do not meet NARA archival standards as outlined in NARA transfer guidance and regulations.)</p> <p data-bbox="421 1144 1239 1281">Disposition: TEMPORARY. Media neutral. Destroy or delete after records are scanned or electronically transmitted into a correspondence repository upon verification of successful imaging or data entry.</p>	<p data-bbox="1305 829 1503 871">New Item</p>
1.2	9120	<p data-bbox="421 1312 817 1354"><u>Program Office Correspondence.</u></p> <p data-bbox="421 1354 1239 1444">Correspondence dealing with functional subjects, routine or administrative matters, that has not been included in other records schedules and is maintained in FDA program offices.</p>	

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1.2.1	9121	<p><u>Significant Program Office Correspondence.</u> Correspondence dealing with substantive and significant scientific/technical matters and major correspondence with long range significance dealing with specific FDA subjects that are handled and maintained by program offices. Some records contain privileged information and access is restricted in accordance with FOIA exemptions. The format in which a record is transferred is determined for the office or center in consultation with NARA.</p> <p><u>Disposition:</u> PERMANENT. Media neutral. Cut off at end of each calendar year in which a response has been signed or correspondence received for which no response is needed. Place closed correspondence in inactive annual file. For paper records, transfer records 2 years after cutoff to FRC. Transfer to NARA 20 years after cutoff. For electronic records, transfer to NARA with system documentation and index as applicable 20 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.</p>	<p>Supersedes RCS, Item 1a Correspondence— General Subject (NC 1-88-78-1/1a)</p>
1.2.2	9122	<p><u>Routine Correspondence.</u> Includes correspondence on specific subjects with limited value or chronological files containing general correspondence concerning program management.</p> <p><u>Disposition:</u> TEMPORARY. Media neutral. Cut off at end of each calendar year in which a response has been signed or correspondence received for which no response is needed. Destroy or delete 5 years after cutoff.</p>	<p>Supersedes RCS, Item 1b Correspondence— General Subject (NC 1-88-78-1/1b)</p>
1.2.3	9123	<p><u>Administrative Correspondence.</u> Includes correspondence accumulated by individual offices that relates to the internal administration or housekeeping activities of the office.</p> <p><u>Disposition:</u> TEMPORARY. Media neutral. Cut off at end of each calendar year. Destroy or delete 2 years after cutoff.</p>	<p>Supersedes RCS, Item 1b Correspondence— General Subject (NC 1-88-78-1/1b)</p>

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1.2.4.	9124	<p><u>Source Documents for Program Correspondence.</u> Contains paper files or electronic documents used as source documents for an imaging or other electronic system maintaining the record copy correspondence. (Note: Source documents having permanent value (i.e., Significant Program Office Correspondence) will not be destroyed or deleted if the electronic or imaged versions in an electronic system do not meet NARA archival standards as outlined in NARA transfer guidance and regulations.)</p> <p>Disposition: TEMPORARY. Media neutral. Destroy or delete after records are scanned or electronically transmitted into a correspondence repository upon verification of successful imaging or data entry.</p>	New Item
1.3.	9130	<p><u>Write-in Campaigns.</u> Correspondence from consumers that expresses an opinion on a particular issue, often sent on pre-printed forms or postcards, or multiple pieces of correspondence using similar language to express a view on an issue.</p> <p><u>Disposition:</u> TEMPORARY. Media neutral. Cut off at end of each calendar year. Destroy 1 year after cutoff.</p>	New Item
1.4.	9140	<p><u>Correspondence Tracking Systems and Documentation.</u> Track correspondence input information such as action dates, tracking number and status information. Also includes system documentation.</p>	
1.4.1.	9141	<p><u>Permanent Correspondence Index.</u> Generate electronic annual index for closed permanent correspondence including all data fields and applicable system documentation.</p> <p><u>Disposition:</u> PERMANENT. Cut off annually. Transfer to NARA with system documentation as applicable 20 years after cutoff with associated correspondence records. 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.</p>	Supersedes RCS, Item A2-10 (NC1-88-79-2/A2-10)
1.4.2	9142	<p><u>Correspondence Tracking Systems Data Files and Documentation.</u></p>	Supersedes

Contains system data files, system documentation, and system generated reports except for the Permanent Correspondence Index.

RCS, Item A2-10
(NC1-88-79-2/A2-10)

Disposition: **TEMPORARY.** Update as necessary. Cut off inactive files annually. Retain a minimum of 2 years after cutoff. Destroy or delete with related records or when no longer needed for administrative or reference purposes, whichever is later.

File Code: Prefix = FDA

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

2 9200 Calendars, Schedules and Logs of Daily Activities.

Files relate to calendars, schedules, logs, appointment books, diaries and other records documenting meetings, appointments, telephone calls, trips, visits and other activities of Federal employees while serving in an official capacity, excluding materials determined to be personal.

2.1 9210 Schedules of Significant Daily Activities (Senior Officials).

Records of the Commissioner, Deputy Commissioners, Associate Commissioners, Center Directors, Chief Counsel, and their staff assistants, containing unique substantive information relating to foods, drugs, other regulated materials, and long range issues of Agency-wide significance during official activities, the substance of which has not been incorporated into memoranda, reports, correspondence or other records included in the official files. It contains name, position title, time, discussion topics, decisions reached, and the outcome.

New Item

Disposition: **PERMANENT. Media neutral.** Cutoff at end of fiscal or calendar year, as office business practice dictates, in 3-year blocks and delete personal information. For paper records, transfer 2 years after cutoff to FRC. Transfer to NARA 20 years after cutoff. For electronic records, transfer to NARA with system documentation as applicable 20 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

2.2 9220 Schedules of Non-Significant Daily Activities.

Records containing routine and non-significant information relating to official activities, the substance of which has not been incorporated into official files. It covers schedules of both senior and non-senior officials.

New Item

Disposition: **TEMPORARY.** Media neutral. Destroy or delete when 2 years old.

- 2.3 9230 Schedules of Routine Daily Activities. GRS 23, Item 5b
 Records documenting routine activities containing no substantive information and records containing substantive information, the substance of which has been incorporated into organized files.

Disposition: TEMPORARY. Destroy or delete when no longer needed for convenience of reference.

File Code: Prefix = FDA

Item File No. Code	Records Description and Authorized Disposition	NARA Approved Citation
3 9300	<u>Presentations/Speeches.</u> Presentations, case studies, handouts or other materials presented by FDA employees at internal or external briefings, conferences, meetings and training programs. May include duplicate copies of travel or other related materials.	
3.1 9310	<u>Significant Presentations by Senior Officials.</u> Includes presentations by the Commissioner, Deputy Commissioners, Center Directors, Associate Commissioners, Chief Counsel, and their designees. Records containing significant and substantive information relating to major agency policies, agency position on various issues that generated high media and public attention, research breakthroughs, the substance of which has not been incorporated into memoranda, reports, correspondence or other records included in the official files. <u>Disposition:</u> PERMANENT. Media neutral. Cutoff at end of calendar year in 3-year blocks. For paper records, transfer 2 years after cutoff to FRC. Transfer to NARA 20 years after cutoff. For electronic records, transfer to NARA with system documentation as applicable 20 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 RCS, Item 1a Speeches— General Subject (NC1-88-78-1/1a)
3.2 9320	<u>Routine and Internal Administrative Presentations.</u> Includes presentations with limited value, presentations at All-Hands meetings, routine ad-hoc briefings, and administrative sessions by senior officials and ad-hoc presentations by employees. <u>Disposition:</u> TEMPORARY. Media neutral. Cutoff at end of calendar year. Destroy or delete 3 years after cutoff.	Supersedes RCS, Item 1b Speeches— General Subject (NC1-88-78-1/1b)

File Code: Prefix = FDA

Item File No. Code	Records Description and Authorized Disposition	NARA Approved Citation
4 9400	<p><u>Working Files.</u> Background materials and drafts of reports for all FDA activities, including papers, studies, grants, correspondence, presentations, audio-visual materials, documentaries, exhibit materials produced and handouts. Supporting materials used for internal/external briefings, conferences, meetings and training programs. Also, drafts of administrative materials and information used to reach conclusions. Also referred as working papers that include rough notes, preliminary worksheets and other draft documents which are not part of any official records. (Note: Significant OC Projects are permanent and contain all essential supporting background materials.)</p>	
4.1 9410	<p><u>Substantial Material.</u> Background materials relating to significant records, briefings for the Commissioner, external briefings, speeches, and other types of materials with long-term value.</p> <p><u>Disposition:</u> TEMPORARY. Media neutral. Cut off at end of calendar year in which associated project or case is completed. Maintain a minimum of 3 years then destroy 6 years after cutoff or when no longer needed for reference, whichever is sooner.</p>	<p>Supersedes RCS Item 6 and R-6 (NC-1-90-79-3/6 and NC1-88-79-1/R-6)</p>
4.2 9420	<p><u>Short Term Material.</u> Supporting documentation relating to routine and administrative briefings, reports and other types of materials with short term value.</p> <p><u>Disposition:</u> TEMPORARY. Media neutral. Destroy/delete no later than 1 year old.</p>	<p>Supersedes RCS Item 6 and R-6 (NC-1-90-79-3/6 and NC1-88-79-1/R-6)</p>
5 9500	<p><u>Reference Materials.</u> Non records materials maintained by offices and individuals including regulations, procedures, guidelines, publications, articles, catalogs, duplicate correspondence, reports/studies and other materials used as reference.</p> <p><u>Disposition:</u> TEMPORARY. Media neutral. Destroy when no longer needed for reference purposes.</p>	<p>Supersedes RCS Item 5 and R-5 Withdrawn 9/11/2007 Non-Record Material</p>

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
6		<p><u>Electronic Mail and Word Processing System Copies.</u> 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.</p>	GRS 20/Items 13 and 14
6.1		<p>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.</p> <p><u>Disposition: TEMPORARY.</u> Destroy/delete within 180 days after the recordkeeping copy has been produced.</p>	
6.2		<p>Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.</p> <p><u>Disposition: TEMPORARY.</u> Destroy/delete when dissemination, revision, or updating is completed.</p>	