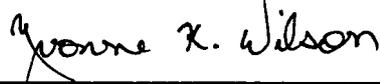
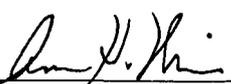


REQUEST FOR RECORDS DISPOSITION AUTHORITY <i>(See Instructions on reverse)</i>		LEAVE BLANK (NARA use only)	
TO NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		JOB NUMBER NI-088-09-8	DATE RECEIVED 8/17/09
1 FROM (Agency or establishment) <i>Department of Health and Human Services</i>		NOTIFICATION TO AGENCY	
2 MAJOR SUBDIVISION Food and Drug Administration (FDA)		In accordance with the provisions of 44 USC 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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10	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 Agency-wide		DATE 8/17/09	ARCHIVIST OF THE UNITED STATES 
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 3 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 8/12/09	SIGNATURE OF AGENCY REPRESENTATIVE 	TITLE HHS Records Officer
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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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>SEE attached sheet Agency-wide Program Records</p> <p> Seung Ja Sinatra - FDA Records Officer</p> <p><u>5/7/08</u> Date</p> <p> Ann Wion - FDA Office of the Chief Counsel</p> <p><u>8/6/09</u> Date</p>		

Agency-wide Schedules

File Code: Prefix = FDA

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
1	Planning	New
1.1	<u>Strategic Action Plan</u>	
1.1.1.	<u>Strategic Plan.</u> Plans may be developed on approximately a triennial basis or they may be developed as needed by the current Commissioner. These plans may usually change with Commissioners and with shifting priorities. <u>Disposition: PERMANENT.</u> Cut off at the end of the fiscal year in which created. Transfer to the National Archives 10 years after cutoff.	
1.1.2	<u>Other Strategic Plans</u> Plans that are developed to handle specific issues that may arise, e.g., Strategic Plan for Risk Communication. <u>Disposition: PERMANENT.</u> Cut off at the end of the fiscal year in which created. Transfer to the National Archives 20 years after cutoff.	
1.2	<u>Performance Plans.</u> Reports providing information and status on FDA performance with respect to negotiated or agreed on annual performance goals.	New
1.2.1	<u>Annual Performance Plan</u> Annual Performance Plan developed each year to address performance metrics for the Agency to comply with the Government Performance and Results Act. <u>Disposition: PERMANENT.</u> Cut off at the end of the fiscal year in which created. Transfer to the National Archives 10 years after cutoff.	
1.2.2	<u>Submissions to OMB and Congress.</u> Includes reports submitted to OMB and Congress upon request and reports that are mandated by specific acts or legislation. Records include Prescription Drug User Fee Act reports, Medical Device	

User Fee Act reports, Animal Drug User Fee Act reports, Office of Combination Products reports, and other user fee reports.

Disposition: PERMANENT.

Cut off at end of the fiscal year in which submitted. Transfer to the National Archives 10 years after cutoff.

- 1.3 **Strategic and Performance Plan Development Tracking Files.**
Records pertaining to strategic planning and performance goals for the agency. Records include reports, presentations and databases tracking progress towards strategic goals and performance.

Disposition: TEMPORARY.

Cutoff at end of the fiscal year in which created. Transfer paper records to the FRC 5 years after cutoff. Delete/destroy 10 years after cutoff.

2 **Policy**

2.1 **Policy Development Documents.**

Records establishing agency policy created by the Office of Policy. Records include policy statements, memoranda, public meeting reports and materials submitted via the formal submission process through the Regulations Editorial Staff such as policy reviews requested by external agencies and options or position papers.

**Supersedes in part
NC1-88-78-1
Item 1a**

Certain records contain trade secret and confidential commercial information, and 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.

Disposition: PERMANENT.

Cutoff at end of the calendar year in which completed. Transfer paper records to FRC 5 years after cutoff. Transfer to NARA 10 years after cutoff.

2.2 **Project Case Files.**

Records created by the Office of Policy related to internal and external projects that do not result in the establishment of agency policy. Records include informal internal reports on specific matters handled internally, correspondence on general matters to the public, industry, or other agencies, and records of public meetings including informal reports of meetings.

Certain records contain trade secret and confidential commercial

information, and 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.

Disposition: TEMPORARY.

Cutoff at the end of the calendar year in which created.

Delete/destroy 5 years after cutoff or when no longer needed for reference purposes, whichever is later. Paper records may be transferred to FRC.

2.3

Public Comments Analysis Records.

New

Records include memoranda, reports, and related materials created to brief FDA and HHS staff regarding public comments submitted on regulations and guidance documents.

Certain records contain trade secret and confidential commercial information, and 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.

Disposition: TEMPORARY.

Cutoff at the end of the calendar year when regulation or guidance document becomes final or other appropriate action (e.g. document is withdrawn or superseded) is taken. Delete/destroy 5 years after cutoff.

For records that are included as part of another record series, apply records disposition in that record series.

2.3.1

Public Comments Summary Databases.

New

Records include databases created on an ad hoc basis to analyze public comments submitted on regulations and guidance documents. Data fields vary in the databases based on the information related to the public comments being captured. This also includes abstracts and summaries of public comments created from the public comment summary databases.

Disposition: TEMPORARY.

Cutoff at the end of the calendar year when regulation or guidance document becomes final or other appropriate action (e.g. document is withdrawn or superseded) is taken. Delete/destroy 20 years after cutoff.

2.3.2

Database Records.

Includes abstracts and summaries of public comments created from

the public comments summary databases.

Disposition: TEMPORARY.

Cutoff at the end of the calendar year when regulation or guidance document becomes final, or other appropriate action (e.g. document is withdrawn or superseded) is taken. Delete/destroy 10 years after cutoff.

2.3.3

System Outputs.

~~Includes any other miscellaneous reports generated from the system on an ad hoc basis.~~

**GRS 20,
items 12 and 16**

Disposition: TEMPORARY.

~~Cutoff when regulation or guidance document becomes final, or other appropriate action (e.g. document is withdrawn or superseded) is taken. Delete/destroy 5 years after cutoff. For reports included as part of another record series, apply records disposition in that record series.~~

2.4

Miscellaneous Informational Materials.

Includes internal administrative and program support materials distributed to employees in order to share information on special issues and events; research activities; compliance and regulatory activities; agency-, center-and, office-wide news; and publications in scientific journals.

New

Certain records contain trade secret and confidential commercial information, and 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.

Disposition: TEMPORARY.

Cutoff at end of the fiscal year in which distributed. Delete/destroy 5 years after cutoff or when no longer needed for reference purposes, whichever is later.