REQUEST FOR RECORDS DISPOSITION AUTHORITY	JOB NUMBER N1-088-04-1
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-6001	Date Received 1-29-2004
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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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)**	
4. NAME OF PERSON WITH WHOM TO CONFER: **Seung Ja Sinatra** — 5. TELEPHONE: **301-827-4274**	DATE 6/7/2005 — ARCHIVIST OF THE UNITED STATES: WITHDRAWN

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 28 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 GRS OR SUPERSEDED JOB CITATION	10.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)

WITHDRAWN

Covers Policy and Planning 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

Seung Ja Sinatra - FDA Records Officer

12/24/03

Date

Fred Ansell

Fred Ansell - Office of the Chief Counsel

12/24/03

Date

115-109

PREVIOUS EDITION NOT USABLE

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

none

POLICY & PLANNING:

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
1.	Strategic Action Plan And Development Files. Records pertaining to the annual strategic planning process for the agency. Final annual or 5 year strategic reports are either a formal document or in the form of a presentation. **TEMPORARY:** Cut off at end of the fiscal year. Transfer to FRC 5 years after cutoff. Destroy 10 years after cutoff.	**New Item**
2.	Performance Plan And Development Files. Records relating to annual performance plan for the agency.	**New Item**
2.1	Submissions to DHHS, OMB, and Congress. **TEMPORARY:** Cut off at end of the fiscal year. Destroy 10 years after cutoff.	
2.2	Materials on Incorporating Changes Suggested by DHHS and OMB. **TEMPORARY:** Cut off at end of the fiscal year. Destroy 5 years after cutoff.	
3.	Policy Documents. Program offices records establishing Food and Drug Administration (FDA) policy for good clinical practices, human subject protection, and other mission subject areas. Files contain policy statements, memoranda and developmental materials relating to regulations and guidelines, and materials of long-range significance. **PERMANENT.** Cut off at end of the calendar year. Transfer to FRC 2 years after cutoff. Transfer to NARA 20 years after file cutoff.	**New Item**
4.	Project Case Files. Planning and Policy records related to internal and external projects, undertaken by the FDA or an associated committee from start to finish.	**New Item**

WITHDRAWN

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
4.1	Significant Projects. Receiving significant awards including: prominent FDA scientists receiving recognition outside their noted area of expertise; a significant impact on public safety; vital public interest; making significant contributions to or impacting policies on a national or global scale; changing political, economic, scientific or social priorities, or resulting in significant controversy; establishing precedence for significant changes to Department of Health and Human Services (DHHS) or FDA research or administrative policies; subjected to widespread media attention or extensive Congressional, or other federal scrutiny or investigation. **PERMANENT.** Cut off at end of the calendar year in which the project is finalized. Transfer to FRC 3 years after cutoff. Transfer to NARA 20 years after cutoff.	
4.2	Non-Significant Projects. Not meeting criteria in 4.1 above. **TEMPORARY:** Cut off at end of the calendar year in which the project is finalized. Transfer to FRC 3 years after cutoff. Destroy 30 years after cutoff.	
4.3	Project Case Working Files. Raw data and background files for 4.1 and 4.2. **TEMPORARY:** Cut off at end of the calendar year in which the project is closed. Destroy 3 years after cutoff.	
5.	Public Comments Analysis Records. Includes memoranda, reports and related records written to brief agency managers on public comments submitted to FDA's Dockets on a proposed regulation and guidance. **TEMPORARY:** Cut off when ruling becomes final, or other appropriate action is taken. Destroy/delete 5 years after cutoff. For records that are included as part of other record series, apply records disposition in that record series.	**New Item**
5.1.	Public Comments Summary Databases. Databases are created on an ad hoc basis and used as a tool to help analyze public comments submitted to Dockets on proposed regulations and guidances. The systems collate abstracts and summaries of public comments directly entered into the system and generate analytical reports. Data fields vary, based on information being captured. System backups are performed as part of the regular network backup schedule.	**New Item**

Item No.	Description and Authorized Disposition of Records	NARA Approved Citation
5.1.1	Inputs. Copies made from original comments in Dockets. **TEMPORARY:** Cut off when ruling becomes final, or other appropriate action is taken. Destroy/delete 5 years after cutoff.	
5.1.2	Database Records: Abstracts and summaries of public comments. **TEMPORARY:** Cut off when ruling becomes final, or other appropriate action is taken. Destroy/delete 5 years after cutoff.	
5.1.3	System Outputs: Reports generated from the system on an ad hoc basis **TEMPORARY:** Cut off when ruling becomes final, or other appropriate action is taken. Destroy/delete 5 years after cutoff. For reports included as part of other record series, apply records disposition in that record series.	
6.	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.	**New Item**
6.1	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.	
6.2	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	

WITHDRAWN

Electronic Information Systems Inventory

1. **System Title.** Public Comment Access Databases (Titles vary; associated with specific proposed regulations or various Advance Notices of Proposed Rulemaking (ANPRMs))

2. **Agency Program Supported by System.** Good Clinical Practice Program (GCPP)

3. **Purpose/Function of System.** Collate and analyze public comments submitted to an FDA docket.

4. **System Linkages/Support.** No other systems, either inside or outside of the agency, provide data to or receive data from this system.

5. **Input Sources and Proposed Retention.** Input consists of comments posted to various public dockets.

6. **Information Content and Proposed Retention.** The databases are established for short term collation and analysis of comments submitted by the public to FDA's dockets related to proposed rules, or ANPRMs.

7. **System Outputs and Proposed Retention.** GCPP staff use the information to prepare summaries of public comments to brief agency managers and/or inclusion in other agency documents and FR notices

Data should be retained until a final rule is issued, at which time it can be destroyed.

8. **Applications Supported by System. Usage of Manipulated Data.** None.

9. **Primary Key/Unit of Analysis for Each File.** One record is created for each comment.

10. **Record Layout/Codes.** N/A

11. **Documentation.** None.

12. **Access/Use Restrictions.** Only GCPP has access to the database, which is stored on the GCPP shared drive.

13. **Public Use Version, Other Duplicate Copies, or Electronic Formats.** None.

14. **Update/Backup Process.** Backed up during routine backups of IT systems.

15. **Hardware Used.** Desktop PCs.

16. Software Used. MS Access

17. Major/Minor Subdivision(s) of the Responsible Agency. OSHC, GCPP

18. Previous Disposition Jobs. None.

Permanent Electronic Information Systems Only

19. Can you produce files from this system that meet the following specifications. N/A

Independent logical files
Hardware and software independent files
ASCII or EBCDIC character set
No internal control characters
Blocked no higher than 32,760 bytes
1/2 inch magnetic tape OR
9 track open-reel at 800, 1600 or 6250 bpi OR
18 track 3480-class cartridge at 37,871 bpi OR
CD-ROM's which include fielded data files or text files scheduled to be preserved in the National Archives that are:

(1) in conformance with the International Standards Organization (ISO) 9660 standard;
(2) in compliance with the American Standard Code for Information Interchange (ASCII) standard as defined in the Federal Information Processing Standard 1-2 (11/14/84);
(3) not dependent on control characters or codes which are not defined in the ASCII character set;
(4) not compressed unless NARA has approved the transfer of the compressed form in advance;
(5) individually addressable; and
(6) in compliance with the documentation requirements of 36 CFR 1228.188.

Agency Contact. Pat Beers Block
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Date Prepared 10/30/03

Preparer: Carolyn Hommel
7-9105