

REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER NI-88-04-03	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-600		Date Received 03/09/2004	
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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	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			
4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra	5. TELEPHONE 301-827-4274	DATE 1/16/04	ARCHIVIST OF THE UNITED STATES Allen Wainstein
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, <input checked="" type="checkbox"/> is not required; <input type="checkbox"/> is attached; or <input type="checkbox"/> has been requested.			
DATE MAR 12 2004	SIGNATURE OF AGENCY REPRESENTATIVE A. P. Barnes		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 GRS OR SUPERSEDED JOB CITATION	10.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)

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

FDA Administrative Records

Seung Ja Sinatra
Seung Ja Sinatra - FDA Records Officer

1/30/04
Date

Fred Ansell
Fred Ansell - FDA Office of the Chief Counsel

2/3/04
Date

cc Agency, NR, NWMD, NWMW, NWETC

Administrative Program Records

Item No.	Records Description and Authorized Disposition	NARA Approved Citation	
1.	<u>Administrative Directives (Staff Manual Guides (SMGs)).</u>		
1.1	<u>Organizations (Staff Manual Guides, Volume 1).</u> Functional statements, organization charts, clearances and essential supporting documents relating to FDA organization.	Supersedes RCS Item 7 and A3-5	
1.1.1	<u>Approved Organizations.</u> PERMANENT: Cut off at end of calendar year in 5 year blocks when superseded. Transfer to FRC 10 years after cutoff. Transfer to NARA 20 years after cutoff.		
1.1.2	<u>Unapproved or Withdrawn Organizations:</u> TEMPORARY: Cut off at end of calendar year in which it is disapproved or withdrawn. Destroy 10 years after cutoff.		
1.2	<u>Delegations of Authority (Staff Manual Guides, Volume 2).</u>		
1.2.1	<u>Delegations of Authority (Programs).</u> Delegations issued by the FDA Commissioner, Center Directors and other senior management that assign to others responsibility for mission-related programs and authorize them to take actions on their behalf. PERMANENT: Cut off in 5 year blocks at end of calendar year in which it is superseded. When volume permits, retire to FRC. Transfer to NARA 20 years after cutoff.	Supersedes RCS Item 7 and A3-6	
1.2.2	<u>Administrative Delegations of Authority.</u> Delegations issued by the FDA Commissioner, Center Directors and other senior management that assign to others responsibility for administrative programs and authorize them to take actions on their behalf. TEMPORARY: Cut off when superseded. When volume permits retire to FRC. Destroy 20 years after cut off.		
1.2.3	<u>Interim Delegations of Authority.</u> Delegations issued to authorize the individuals to act on their supervisor's behalf during their absence or for a specific activity. These records are effective for a short period of time. TEMPORARY: Destroy when no longer needed.		

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1.3	<p><u>Administrative Responsibilities and Procedures Manuals (Staff Manual Guides, Volume 3).</u> Records cover administrative operational procedures and instructions relating to the implementation of administrative functions and policies issued by FDA administrative program offices.</p> <p>TEMPORARY: Cut off when superseded or obsolete. Destroy 20 years after cutoff.</p>	Supersedes RCS Item 7
2.	<p><u>Administrative Issuances.</u></p>	GRS 16, Item 1
2.1	<p><u>Notices and other types of issuances related to routine administrative functions (e.g., payroll, procurement, personnel).</u></p> <p>TEMPORARY: Destroy when superseded or obsolete.</p>	
2.2	<p><u>Case files related to 2.1 above that document aspects of the development of the issuance.</u></p> <p>TEMPORARY: Destroy when issuance is destroyed.</p>	
3.1	<p><u>Office of Inspector General (OIG) Reports.</u> Records consisting of FDA responses to reports conducted by the Office of the Inspector General and material regarding the implementation of OIG's recommendations. These files consist of working drafts, draft reports, public comments, and the final report from OIG, agency comments to OIG on the draft, and an implementation plan for the final report.</p> <p>TEMPORARY: Cut off when all the recommendations of the report have been implemented within the agency. Destroy 10 years after cutoff.</p>	New Item
3.2	<p><u>OIG Administrative Reviews.</u> Documents the reviews conducted by FDA for the centers and district offices regarding their administrative procedures (procurement, budget, property management, etc). These records may include copies of reviewers' annotated checklists, copies of comments, a final summary document/report, and background materials.</p>	

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3.2.1	<p><i>And Inspection</i> <i>the by you for 6/6/06 sent to SI on April 2006 meeting</i></p> <p><u>Audit Case Files.</u> Reviews of the district offices' administrative policies conducted by a team of FDA auditors. Records include a final report that includes copies of the annotated checklists, comments, and required tasks to be completed.</p> <p>TEMPORARY: Cut off when the final required task is completed. Destroy 8 years after cutoff.</p>	
3.2.2	<p><u>Self Assessments.</u> Records documenting each center's reviews of their administrative policies and procedures to provide a consistent basis for determining areas of improvement and where training needs to be focused. These files consist of annually submitted checklists and summaries of required tasks.</p> <p>TEMPORARY: Cut off when the final required task is completed. Destroy 8 years after cutoff.</p>	
4.	<p><u>Interagency Agreements/Memoranda of Understanding.</u> Agreement and understandings with other agencies, both technical and administrative for work to be done, time frames, costs or other remuneration, and details of the personnel and equipment involved. Also includes subsequent amendments, comments, approvals and related correspondence.</p>	<p>No change NC1-88-78-1, Item A5-1</p>
4.1	<p><u>Final Agreement/ Understanding Documents.</u></p> <p>TEMPORARY: Destroy 2 years after termination of entire agreement/ understanding.</p>	
4.2	<p><u>Background/Working Files.</u></p> <p>TEMPORARY: Destroy 2 years after termination of entire agreement/ understanding.</p>	
5	<p><u>Grants.</u></p> <p>Notice of grant awards, opinions, comments, approvals or declinations funding documents, progress and expenditure reports, published materials, and correspondence concerning grants awarded by FDA.</p>	<p>Supersedes NC1-88-78-1, Item A5-2</p>
5.1	<p><u>Grants Awarded by FDA.</u></p> <p>TEMPORARY: Cut off after termination of grant or date of final payment, whichever is later. Destroy 7 years after cut off.</p>	

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5.2	<p><u>Grants Approved (but not funded) or Disapproved Applications.</u></p> <p>TEMPORARY: Destroy ³ year after cancel date or after competitive review date, whichever is applicable. <i>OK by Seung JA SINAYNA on May 19, 2005 via E-mail</i></p>	
6.	<p><u>Acquisition Library Database.</u> System tracks the information on closed grants and contracts such as work description, property, and personnel involved, period of performance, billing and payment information. The system functions as a finding aid for the office.</p> <p>TEMPORARY: Destroy or delete with related procurement records.</p>	New Item
7.	<p><u>Agency Information Management System (AIMS).</u></p> <p>AIMS, a database management system, provides application tracking, document management, and reporting capability for various modules, and functions as an access entry point. AIMS tables provide a common source of core data elements shared by two or more modules. Some of the modules supported by AIMS are Dockets System, Federal Register Documents Tracking System, Ethics, Freedom of Information Tracking System, Awards Program and others. Access is restricted at the module level. Some modules are protected under the Privacy act.</p>	New Item
7.1	<p><u>Inputs.</u> Data elements are input into a table upon its creation and entered by authorized users designated for each module.</p> <p>TEMPORARY: Destroy when no longer needed for input or verification purposes. If input data is part of a records series under a particular module, apply retention for that series.</p> <p>Note: Personnel and organizational data directly fed into AIMS from EASE (Enterprise Administrative Support Environment) do not create input files.</p>	
7.2	<p><u>Data Files.</u> Includes the information updated by authorized users assigned to each module. Also includes personnel and organization data fed from EASE periodically. Data Files are linked to the records in the various modules.</p> <p>TEMPORARY: Maintain data for the longest retention period required by the modules.</p>	
7.3	<p><u>Outputs.</u> See the outputs under the various modules. The system has no specific outputs itself.</p>	

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7.4	<p><u>System Documentation.</u> See the documentations for the various modules. The emphasis has been on documentation for the modules rather than the core elements.</p>	
7.5	<p><u>System Backup.</u> Backup tapes maintained for potential system restoration in the event of a system failure or other unintentional loss of data.</p> <p>TEMPORARY: Delete/destroy incremental backup tapes when superseded by a full backup, or when no longer needed for system restoration, whichever is later.</p> <p>Destroy/delete full backup tapes when second subsequent backup is verified as successful or when no longer needed for system restoration, whichever is later.</p>	GRS 24, Item 4
8.	<p><u>Enterprise Administrative Support Environment (EASE).</u></p> <p>EASE Core was designed to function as an FDA-wide corporate repository that provides essential personnel, organization and locator data from 1985. EASE RAM was designed to provide current and historical reporting capability for administrative data such as trend analysis, statistical and ad-hoc reporting. It is used by employees to review their official personnel, location and timekeeping information. It also provides information on facilities and some training. Its data is fed to various FDA systems and linked to systems such as AIMS, Badge System, OFM Travel Manager, FACTS/OASIS and other modules. It superseded Administrative Resource Information Exchange System (ARIES). Data is protected under the Privacy Act and treated as a vital system.</p>	New Item
8.1	<p><u>Inputs.</u></p>	
8.1.1	<p><u>Core and Other Data:</u> Data prior to 1999 was migrated from ARIES. Personnel data created as temporary records for new employees within EASE is directly overwritten by the official information from Enterprise Human Resources and Payroll Project (EHRP) system operated by the Department. No input file is created for these. Also includes data on organization, locator, facilities and other areas entered by authorized users.</p> <p>TEMPORARY: Destroy when no longer needed for verification of information. If input data is part of another records series, apply retention for that series.</p>	

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8.1.2	<u>Employee Time and Attendance (ETA) Source Records</u>	GRS 2, Item 7
	TEMPORARY: Destroy after GAO audit or when 6 years old whichever is sooner.	
8.2	<u>Data Files.</u>	
8.2.1	<u>Core and other data: Employee personnel, organization, location, facilities and other administrative data.</u>	
	TEMPORARY: When the official system has accepted the changes to the data files, the data is superseded and deleted.	
8.2.2	<u>Employee Time and Attendance (ETA) Input Records.</u> (Note: this is also an input file as FDA sends this information to the Department's payroll system.)	GRS 2, Item 8
	TEMPORARY: Destroy after GAO audit or when 6 years old whichever is sooner.	
8.3	<u>Outputs.</u>	
8.3.1	<u>Reports generated by employees and offices.</u>	
	TEMPORARY: All outputs are reference copies and can be destroyed when no longer needed. If a copy becomes part of another records series, apply retention for that series.	
8.3.2	<u>ETA:</u> Reports generated by supervisors to document time and attendance for their offices and by individual employees for reference.	
	TEMPORARY: Delete when no longer needed for administrative or reference purposes.	
8.4	<u>System Documentation.</u> Consists of database administration standard operating procedures (DBA SOP), System Manuals, User Manuals, File Format and Layouts, and Security Plans.	
	TEMPORARY: Destroy when superseded or obsolete, or when no longer needed for system operation.	

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GRS 24, Item 4

8.5 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. Destroy/delete full backup tapes when second subsequent backup is verified as successful or when no longer needed for system restoration, whichever is later.

9. Administrative Resource Information Exchange System (ARIES). ARIES provided essential personnel, organization and locator information in the form of reports. Since 1999, the system has not been used except to extract historical data and access was limited to those in development and managerial roles in IT. All data has been migrated from ARIES to EASE in January 2004. It is protected under the Privacy Act.

New Item

*Withdrawn
April 12, 2005
ok by Seung Ja Simtra
at meeting.*

TEMPORARY: Delete 2 years after final migration and verification of migration of information to EASE.

9.1 Inputs. There have been no inputs into this system since 1999.

TEMPORARY: Destroy when no longer needed for verification of information contained in the system.

9.2 Data Files. Data imported from various personnel, organization and locator systems.

TEMPORARY: Delete 2 years after final migration to EASE and verification of successful migration by quality control.

9.3 Outputs. Reports generated on an ad hoc basis for administrative and reference purposes.

TEMPORARY: Destroy when no longer needed.

9.4 System Documentation.

TEMPORARY: Destroy when superseded or obsolete, or after all data is successfully migrated into EASE and when no longer needed for administrative purposes, whichever is later.

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9.5 ~~System Backup. Backups were made upon the receipt of each FDA portion of the HHS personnel files. Operational data such as location data was updated as required. Production data was backed up daily by the National Institute of Health (NIH) computer center.~~
~~**TEMPORARY:** Follow back up procedures documented by NIH. Destroy/delete when data in the system is completely migrated to EASE and no longer needed for administrative purposes.~~

*Withdrawn
April 12, 2005
by Seung JA Simatra
at meeting.*

10. 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

10.1 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.

10.2 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.