REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

TO NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

LEAVE BLANK (NARA use only)	
JOB NUMBER	N1-088-07-2
DATE RECEIVED	August 13, 2007

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10

DATE	ARCHIVIST OF THE UNITED STATES
10/11/08	

1 FROM (Agency or establishment)
Department of Health and Human Services

2 MAJOR SUBDIVISION
Food and Drug Administration (FDA)

3 MINOR SUBDIVISION
~~Office of the Commissioner (OC)~~ Agency-wide

4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra	(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	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
07/25/07		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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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 Agency-wide Program Records (Group 2) Seung Ja Sinatra - FDA Records Officer — 9/29/06 Date Ann Wion - FDA Deputy Chief Counsel — 7/16/07 Date		

Agency-wide Records (Group 2)

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1		**Guidance Documents.** Published in accordance with FDA's Good Guidance Practices (GGP) (21 CFR 10 115)	
1.1		**Final Guidance Documents.** Includes guidance documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue (21 CFR 10 115(b)(1)) Includes FDA Compliance Policy Guides (CPGs) **Disposition: PERMANENT.** Cutoff at end of the fiscal year in which guidance is superseded Transfer to NARA 5 years after cutoff If electronic records are transferred, transfer in NARA approved format	**Supersedes** in part **NC1-88-78-1 Item 7a**
1.2		**Guidance Document Development Files** May include interpretations and documents supporting the development of policies reflected in guidance documents May include advisory opinions from the Office of the General Counsel, minutes and reports of meetings, conferences and hearings, and correspondence with producers, trade and professional organizations, and Federal and State agencies, clearance records, and other related materials Files are maintained by the originating office For working files maintained in other offices, see authorized disposition under a separate file series, Working Files **Disposition: TEMPORARY** Cutoff after final guidance is published, superseded, or withdrawn, or after draft guidance is withdrawn or superseded by another draft guidance Delete/destroy 10 years after cutoff.	**Supersedes NC 1-88-78-1 X-11**
2		**Internal Program Directives and Procedures Manuals.** Includes records that document FDA's major internal operational procedures originating within each Center/Office including FDA Field Offices, providing overall and specific program direction and procedures (Regulatory Procedures Manual (RPM), CDER Manual of Policies and Procedures (MaPPs), and CBER Manual of Regulatory Standard Operating Procedures and Policies (SOPPs), for example) Directives and internal procedures that are finalized and distributed	

within FDA may be considered "published" even if they are not released to the public

For duplicate reference copies used in offices, apply authorized disposition instructions under separate file series for Reference Files

2.1 **Published Copy.** — **Supersedes In part NC 1-88-78-1 Item 7a**

Records consist of official program decisions, operating procedures manuals, technical resource documents, technical and effectiveness standards, regulatory interpretation and implementation documents and essential supporting materials

Records include manuals, operating procedures, handbooks, circulars, and other FDA issuances established to announce or publish procedures Recordkeeping format is determined by each program area

Disposition: PERMANENT.
Cutoff at end of the fiscal year in which documents are superseded Transfer to NARA 5 years after cutoff If electronic records are transferred, transfer in NARA approved format

2.2 **Official Change Requests.** — **New**

Includes forms (such as the Appendix A, "RPM Change Request Form", for the RPM) requesting that changes be made to a publication Changes can be implemented immediately, or on a scheduled basis

Disposition: TEMPORARY.
Cutoff upon implementation of change Delete/destroy 5 years after cutoff or when no longer needed for business or reference purposes

3 **General Program Files.**

Includes files relating to FDA programmatic activities They may relate to Program subject files and routine program management files that are not covered elsewhere in the FDA Records Control Schedules

3.1 **Program Subject Files.**

Includes mission oriented specific subject files such as studies and reports of short-term or long range significance or with historical values

3.1.1 **Substantive Program Subject Files.** — **Supersedes in part NC 1-88-78-1 Item 1a**

Includes materials with inherent evidential and informational values vital for the primary use in developing an agency history These records furnish the researcher with the insight, planning, organizational structure, functions, and overall agency direction. They contain information on the programs, activities, decisions, FDA functions, position statements and protocols dealing with FDA's mission subject areas, opinions, correspondence, interviews, surveys, and other similar materials, including the materials dealing with subject matters that generated substantial public interest, media, legal precedent, or significant

program files

Disposition: PERMANENT.
Cutoff at end of the calendar year after the final action or when no longer needed to conduct current operations. Transfer paper records to FRC after cutoff Transfer records to NARA 20 years after cutoff

3.1.2 **Non-Substantive Program Subject Files.**
Covers files relating to FDA mission subject areas with limited value Includes correspondence, reports with short term value, unfinished reports that may be used for future studies, current issues, and other informational materials and non-substantial program records

Disposition: TEMPORARY
Destroy/delete when 30 years old, or when no longer needed for agency business after retrospective review, whichever is later

3.2 **Program Management Files.** **Supersedes NC 1-88-78-1**
Includes records generated in the course of ongoing program operations that are not covered elsewhere in the Records Control Schedules
Includes records such as staff meeting minutes, management surveys, management reports on projects undertaken on a one-time basis without initiating a formal survey and supporting material such as interview notes, analyses, recurring management reports, project plans including feasibility studies, memoranda, reports relating to general policy and program administrative matters, oversight reviews or program evaluations, proposals, interagency activity and other program related materials Also includes project control files showing assignments, progress, and completion of projects **Items A3-1, A3-2, A3-4, F-1. Item 1b**

Excluded are general administrative and routine housekeeping records for which disposition is authorized by the General Records Schedules issued by NARA

Disposition: TEMPORARY
Cutoff after the final action/report or at end of the calendar year Maintain a minimum of 3 years then destroy 7 years after cutoff or when no longer needed for reference, whichever is sooner

4 **Regulations Development Files.** **Supersedes NC 1-88-78-1 X-6**
Position and summary statements, drafts of regulations, legislative history and related material concerning FDA-regulated products Files are maintained by the originating office

Final rules and related official rulemaking documents are maintained in the Division of Dockets Management and subject to its records schedules

For working files maintained in other offices, see authorized disposition under a separate file series, Working Files

Disposition: TEMPORARY.
Cutoff after final rule is published or after proposed or final rule is

withdrawn Delete/destroy 10 years after cutoff.

5 **Adverse Event/Experience and Product Defect Reports.**
Includes materials on adverse experiences associated with the use of FDA-regulated products submitted by manufacturers, health care professionals or consumers Reports may be required by statute or FDA regulations, or may be submitted voluntarily Reports may include postmarketing problems/events or consumer complaints such as product quality issues, public health issues, medication errors, or device malfunctions, and may be submitted to the agency through the FDA Safety Information and Adverse Event Reporting Program (MedWatch), or under other adverse event reporting procedures

5.1 **Adverse Event Reports Management Files.** New
Includes materials relating to program planning and evaluation, copies of forms and forms management files, systems management, routine and statistical reports, technical and administrative reports for program support, and other related records

Disposition: **TEMPORARY.** Cutoff files at end of the fiscal year Destroy no later than 10 years after cutoff in which they were created or when obsolete, whichever is applicable.

Change approved by RO via e-mail dated 7/2/08. APL

5.2 **Adverse Event Reports or Forms.**
Mandatory adverse event reports, periodic adverse experience reports (monthly, quarterly, annual), and voluntary reports such as those submitted using FDA Form 3500, FDA Form 3500A, FDA Form 1639 and VAERS-1 from health professionals, user facilities, manufacturers, or consumers Also included are supporting documents such as lab tests, autopsy reports, product labeling, and other related records

Records may be maintained as image files, in other electronic format or in paper Recordkeeping format is determined by each Center A unique control number is assigned to each report

Duplicate copies made/printed to be filed in another subject file or to be used as reference may be destroyed/deleted when no longer needed for reference If copies are filed as part of another subject file, apply authorized disposition instructions for that file

For disposition of copies used for scanning, see AERS Input Records

Contains confidential information apply FDA's Public Information regulations (21 CFR Part 20) and Protection of Privacy regulations (21 CFR Part 21)

Supersedes NC1-88-83-3, item K-14; NC 1-88-83-5, item D28; and N1-88-96-3, Item B-16; NC 1-88-78-1, Item F-25.

Disposition: **TEMPORARY** in which recieved
Cutoff annually at end of the calendar year Destroy/delete 10 years after cutoff or when no longer needed for business

change agreed to by RO per e-mail dated 10/8/08 APL

5.3 **Adverse Event Reporting Systems.**

These systems support postmarket surveillance activities and contain the information on patients, adverse events, product problems, suspect medications, suspect medical devices, as well as reporter, manufacturer, and user facility information Some selected data in another database originating in ORA is directly entered without creating an input file The systems are used to identify increases in adverse events associated with the use of FDA-regulated products and changes in adverse events over time Commonly known as AERS, they are maintained in each FDA Center depending on the type of product.

Includes the following systems or their successor systems, but not limited to
Vaccine Adverse Event Reporting Systems (VAERS CBER),
Adverse Event Reporting System (AERS CDER),
Manufacturer and User Facility Device Experience (MAUDE CDRH),
Medical Device Surveillance Network (MedSun CDRH),
CFSAN Adverse Event Reporting System (CAERS)

Contains confidential information apply FDA's Public Information regulations (21 CFR Part 20) and Protection of Privacy regulations (21 CFR Part 21)

5.3.1 ~~**AERS Input Records**~~ **GRS 20, Items 2a and 2b**

~~Includes copies of adverse event reporting forms and consumer complaints that are manually input, medical records, if any, notations/analysis directly entered, and any additional information (See item 5-2 for disposition of recordkeeping copies of Adverse Event Reporting Forms/Reports)~~
~~May include electronic records transmitted through a gateway application~~

~~**Disposition: TEMPORARY**~~
~~Destroy/delete after all data elements have been input into AERS and verified, and if copies are used for scanning, after the verification of quality control, or when no longer needed to support the reconstruction of, or serve as the back up to, the master file, whichever is later~~

5.3.2 **AERS Database Records.** **Supersedes NC 1-88-83-5 Item D-36**

Includes data fields such as adverse event(s) or consumer complaint(s), suspected drug, name of injured person, name of complainant, reporter, report date, facility and related data
Contains confidential information apply FDA's Public Information regulations (21 CFR Part 20) and Protection of Privacy regulations (21 CFR Part 21)

Disposition: TEMPORARY.
Cutoff annually at end of the calendar year after case is closed Delete 30 years after cutoff or when no longer needed for trend analysis or reference purposes, whichever is the latest
If data are migrated into a new system or replaced by a successor system, delete/destroy after the verification of successful data migration

5.3.3 **Extracts of the Adverse Event Data for Public Access: Output Records.**

Reports from extracted adverse event data periodically generated to share information with the public or with organizations such as NTIS for public distribution

Disposition: **TEMPORARY** Cutoff annually at end of the calendar year. Delete/destroy 10 years after cutoff in which they were created

Change approved by RO via e-mail dated 6/20/08. TPL

5.3.4 ~~**Other AERS Output Reports.**~~ **GRS 20 Items 4, 5, 6, 7, 12, 16**

~~Includes Daily Reports generated for FDA internal use, such as reports generated for safety evaluators, ad-hoc reports generated on request, other database reports or extracts and form letters for FDA use~~

~~**Disposition: TEMPORARY**~~

~~Delete when the agency determines that they are no longer needed for administrative, legal, audit, or other operational purposes~~

5.3.5 ~~**AERS System Documentation**~~ **GRS 20 Item 11a(1)**

~~Includes systems operations manuals, user manuals, record layouts and other systems related materials~~

~~**Disposition: TEMPORARY**~~

~~Destroy/delete upon authorized deletion of the related electronic records or upon the destruction of the output of the system if the output is needed to protect legal rights, whichever is later~~

6 **Establishment Registration and Product Listing Program.**

Per Section 510 of the Federal Food, Drug, and Cosmetic Act, most domestic and foreign firms engaged in the manufacture, preparation, propagation, compounding, processing, or assembling of regulated products that enter interstate commerce are required to register their establishments initially and annually. In most cases, they are also required to provide listings of their products when they initially register and report any new products, certain changes to listed products, and discontinued products periodically or at the time the changes occur

6.1 **Registration and Listing Files.**

Includes FDA registration and listing forms or reports for both initial and amended registrations sent directly from an establishment for its annual registration, all applicable correspondence, annual registration reports and supporting documents

Registration and listing packages may include information on the establishment or facility, contact person, the U S agent for foreign establishments, certification statement, cancellation reports, products, product labeling, process information, packaging and other related information May be used for field inspections, shortages, recalls, import verification and control and other postmarket regulatory actions

Records may be maintained as imaged files, in other electronic format or in paper Recordkeeping format is determined by Center

Supersedes NC 1-88-83-3: Items, D-24, K-25, K-29; NC 1-88-83-5, D-23.

Disposition: TEMPORARY
Cutoff after establishment goes out of business, or product is withdrawn or no longer marketed Delete/destroy 10 years after cutoff

6.2 **Registration and Listing Systems.**
Supports premarket, postmarket and compliance activities by providing information about establishments and their regulated products Registration and Listing data is a primary part of FDA Centers' corporate management information systems, and the basis of most Centers' database applications that require establishment name, address, or product information

Includes the following systems and their successor systems, but not limited to
Drug Registration and Listing System (DRLS CDER),
Registration and Device Listing System (RDLS CDRH),
Food Facility Registration Module (FFRM CFSAN),
Low Acid/Acidified Canned Foods Registration System (LACF CFSAN),
Voluntary Cosmetic Registration Program System (VCRP CSFAN)

6.2.1 ~~**Input Records**~~ **GRS 20 Item 2a and 2b**
~~Includes FDA registration and listing forms submitted electronically or on paper by establishments to FDA Centers, U.S. agent letters, correspondence and related materials (see 6-1 for disposition of recordkeeping copy of registration and listing forms) Also includes electronic records transmitted via a gateway application referred to as FDA Unified Registration and Listing System (FURLS)~~

~~**Disposition: TEMPORARY.**~~
~~Destroy after the information has been converted to an electronic medium and verified, or when no longer needed to support the reconstruction of, or serve as the back up to, the master file, whichever is later~~

6.2.2 Database Records **Supersedes NC1-88-79-2, Item F-69**
Includes data fields such as establishment name and address, production site information, type of ownership or establishment, registration number, reason for update, date of updated annual registration report, submitter's data and other firm related information Product listings may include information such as product proprietary name, common name, firm name and address, product classification number, reason for submission, product type, establishment identifier, and other related information

Disposition: TEMPORARY
Cutoff after establishment goes out of business or product is not commercially marketed Delete/destroy 10 years after cutoff or when no longer needed for legal, research, historical or reference purposes, whichever is the latest
If data are migrated into a new system or replaced by a successor system, delete/destroy after the verification of successful data migration

6.2.3 ~~**Reports: Output Records.**~~ **GRS 20 Items 4, 5, 6, 7, 12,**
~~Includes ad-hoc reports generated for reference use and routine reports produced at an application level that are used for reports such as annual~~

~~registration reports~~

~~For extracted data automatically loaded into other systems, apply disposition authorized for appropriate corresponding systems~~

~~**Disposition: TEMPORARY.**~~
~~Delete when the agency determines that they are no longer needed for administrative, legal, audit, or other operational purposes~~

6 2 4 Monthly Registration and Listing Web Reports Output Records
Releasable registration and listing information under the Freedom of Information Act posted monthly on the web for public access

Disposition: TEMPORARY
Delete/destroy when no longer needed for public access

6 2 5 Notifications, Confirmations, Verifications Output Records
Letters of notifications, confirmations and verification regarding status and issues relating to facility registration submissions

Disposition: TEMPORARY
Delete/destroy when no longer needed for administrative or reference purposes

6 2 6 ~~Systems Documentation.~~ **GRS 20 Item 11a(1)**
~~Includes systems operations manuals, user manuals, data dictionary, requirements documents and other systems related materials~~

~~**Disposition: TEMPORARY.**~~
~~Destroy/delete upon authorized deletion of the related electronic records or upon the destruction of the output of the system if the output is needed to protect legal rights, whichever is later~~