REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

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

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

2 MAJOR SUBDIVISION
Food and Drug Administration (FDA)

3 MINOR SUBDIVISION
Agency-wide

4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra	(301) 827-4274

LEAVE BLANK (NARA use only)

JOB NUMBER N1-088-09-1

DATE RECEIVED 12/19/08

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10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
10-26-09	Adrienne Thomas

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 5 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
12/16/2008		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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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 3) Seung Ja Sinatra - FDA Records Officer — Date 11/12/07 Ann Wion - FDA Office of the Chief Counsel — Date 12/9/08		

Agency-wide Program Records (Group 3)

File Code: Prefix = FDA

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1		**Establishment Inspection and Compliance Action Files.** Records copies of the domestic establishment inspection reports and related compliance files are maintained by ORA District Offices Files are also known as "Establishment Files (EF)" in the Field. Records copies of the international establishment inspection reports and related compliance files are maintained by the assigning Center	
1.1		**BIMO Domestic Inspection and Compliance Action Case Files.** Under the Bio-Research Monitoring (BIMO) Program, FDA inspects clinical investigators, sponsors, monitors, contract research organizations (CROs), Institutional Review Boards (IRBs), non-clinical (GLP) laboratory facilities, and bioequivalence facilities Inspections of establishments that conduct studies of products intended for final use in humans but which are initially being tested in animals are also covered under this program BIMO Domestic Inspection Files· Include Establishment Inspection Reports (EIR) for domestic firms including any attachments or exhibits related to the inspection; post-inspection correspondence to and from the inspected firm; memos, summaries of conference calls, e-mails, and other internal documents related to the inspection, summary database reports; referral records, and other related materials. BIMO Compliance Action Case Files. Include records on compliance actions (e.g., regulatory or legal actions) and supporting materials that are maintained by FDA Centers. May include correspondence related to the pre-approval and/or post-marketing inspections and reviews of the firms and facilities; copies of establishment inspection reports, exhibits, attachments, and investigation records, sample collection reports, complaints; copies of field laboratory test records, regulatory/enforcement letters (such as warning letters, untitled letters, cyber letters, Notices of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOEs)), warrants; precedents; reports on final actions and action items, legal interpretations; and records related to the compliance history of regulated products and	

establishments. Reference materials from public sources such as the Federal Register may be included

May include duplicate copies of litigation case files and other related records for which the records copies are maintained by the Office of Chief Counsel.

Certain records may contain personal information that cannot be publicly disclosed, 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

1.1.1	**Files with No Action Indicated (NAI).** **Disposition: TEMPORARY.** Cutoff at the end of the fiscal year when the final classification of inspection occurs. Delete/destroy 10 years after cutoff.	**Supersedes NC1-88-78-1, items A2-1a, A2-1b, A2-3, X-7, V-9, V-10; NC1-88-83-4, item X-14; NC1-88-83-5, Items 3 and 10; N1-88-03-3, Item 1**
1.1.2	**Files with Voluntary Action Indicated (VAI).** **Disposition: TEMPORARY.** Cutoff at the end of the fiscal year when the final classification of inspection occurs Delete/destroy 10 years after cutoff.	**Supersedes NC1-88-78-1, items A2-1a, A2-1b, A2-3, X-7, V-9, V-10; NC1-88-83-4, item X-14; NC1-88-83-5, Items 3 and 10; N1-88-03-3, Item 1**
1.1.3	**Files with Official Action Indicated (OAI).** **Disposition: TEMPORARY.** Cutoff at the end of the fiscal year after the case is closed Transfer paper records to the Federal Records Center (FRC) 5 years after cutoff. Delete/destroy 30 years after cutoff.	**Supersedes NC1-88-78-1, items A2-1a, A2-1b, A2-3, X-7, V-9, V-10; NC1-88-83-4, item X-14; NC1-88-83-5, Items 3 and 10; N1-88-03-3, Item 1**

1.2 **OAI Files Resulting in Investigator Disqualification.**
Files relating to clinical investigator disqualification pursuant to a Part 16 Regulatory Hearing process. Used as legal opinion precedent files for application throughout FDA Included are Presiding Officer Reports, Commissioner's Decisions, legal opinions, directly related memorandums, copies of laws, and related documents

Certain records may contain personal information that cannot be publicly disclosed, 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 after the final action
Delete/destroy 75 years after cutoff, or when no longer needed for administrative, legal, or reference purposes, whichever is the latest.

1.3 **BIMO Referral Records maintained in the Referral Office.**
Includes duplicate copies of correspondence from and responses to various organizations (e.g., the HHS Office for Human Research Protections; IRBs that have terminated or suspended research, clinical investigators or others who file complaints about the conduct of clinical research) that are referred to a responsible Center for information or follow-up

Records copies are maintained by Centers as part of the BIMO inspection files

Disposition: TEMPORARY.
Cutoff at end of the fiscal year either when the correspondence was received or when a response was sent, whichever is later.
Delete/destroy 3 years after cutoff

1.4 **GMP Domestic Inspection and Compliance Action Case Files.**
Under the Current Good Manufacturing Practices (CGMP) inspection program which includes routine surveillance, pre-approval (NDA/BLA), and for-cause inspections, FDA inspects manufacturing and testing establishments.

Includes Establishment Inspection Reports (EIR) for domestic firms including any attachments or exhibits related to the inspection and other inspection related records originated by the Field. Also includes post inspection communications such as VAI letters and approval memos for administrative/legal actions that are originated by Centers

Certain records may contain personal information that cannot be publicly disclosed; 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.

1.4.1 **Files with No Action Indicated (NAI).**

Disposition: TEMPORARY
Cutoff at end of the fiscal year when the final classification of inspection occurs. Delete/destroy 10 years after cutoff

1.4.2 **Files with Voluntary Action Indicated (VAI).**

Disposition: TEMPORARY
Cutoff at end of the fiscal year when the final classification of inspection occurs. Delete/destroy 10 years after cutoff.

1.4.3 **Files with Official Action Indicated (OAI).**

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after the case is closed Transfer paper records to the Federal Records Center (FRC) 5 years after cutoff. Delete/destroy 30 years after cutoff.

1.5 **International Establishment Inspection and Compliance Action Case Files.**

Supersedes NC1-88-78-1, item O-11; NC1-88-79-1, item R-9

Includes records of the complete files covering both GMP and BIMO foreign inspections that are maintained by the assigning center Includes signed original international inspection files, including exhibits and related correspondence such as responses from the investigated firms and corrective action plans

Certain records may contain personal information that cannot be publicly disclosed; 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

1.5.1 **Files with No Action Indicated (NAI).**

Disposition: TEMPORARY.
Cutoff at end of the fiscal year when the final classification of inspection occurs. Delete/destroy 10 years after cutoff.

1.5.2 **Files with Voluntary Action Indicated (VAI).**

Disposition: TEMPORARY.
Cutoff at end of the fiscal year when the final classification of inspection occurs. Delete/destroy 10 years after cutoff.

1.5.3 **Files with Official Action Indicated (OAI).**

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after the case is closed Transfer

paper records to the Federal Records Center (FRC) 5 years after cutoff. Delete/destroy 30 years after cutoff.

1.6 **Establishment Inspection and Compliance Management Systems.**

Provides case management and tracking functionality for domestic and international inspections, compliance and regulatory activities. Includes tracking data on inspection and compliance status, assignment, completion date, date received, date forwarded, date response sent and other related information

Includes the following systems or their successor systems maintained by lead Center offices, but not limited to:

Establishment Evaluation System (EES: CDER)· Tracks the progress and results of the inspections in support of CDER's drug approval activities;
Drug Quality Reporting System (DQRS· CDER)· Maintains the information received from a field alert reporting process, post market studies and compliance related activities to help determine if problems are a result of drug quality issues and to help resolve the problems,
Bio-Research Monitoring System (BRMS· CDRH)· Provides tracking functionality for CDRH Bio-Research Monitoring Program (BIMO) records;
Foreign Inspection Tracking Systems (FITS: Centers).
FITS tracks compliance, pre- and post-market inspections, and review of inspection documents of foreign firms. FITS captures inspection assignment and inspection summary reports and internal work processes.

For records maintained as part of the Mission Accomplishment and Regulatory Compliance Services/Compliance Management System (MARC/CMS), follow records retention instructions for that series

Certain records may contain personal information that cannot be publicly disclosed; 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

~~**1.6.1**~~ ~~**Input Records.**~~ **GRS 20 Item 2a4**

~~In addition to data electronically entered from the ORA's compliance tracking systems such as Field Accomplishments and Compliance Tracking System (FACTS) or its successor system, records are manually input from various documents from domestic and international inspection and compliance action case files~~

~~**Disposition: TEMPORARY**~~
~~Apply disposition schedule authorized for appropriate subject case files. If records are used for input or scanning only, destroy after~~

~~the information has been converted to an electronic medium and verified, when no longer needed for legal or audit purposes or to support the reconstruction of, or serve as a backup to, the electronic records, or 60 days after NARA has been provided the notification required by 36 CFR 1228.31(b)(1)(i), whichever is later.~~

1.6.2 **DQRS Database Records.**
Includes product name, lot and expiration date of drug product, nature of problem, tracking code and other related data.

Disposition: TEMPORARY.
Cutoff after last system update or reference query. Delete data 30 years after cutoff or when no longer needed for reference, whichever is later If data are migrated onto a new system, delete/destroy after the verification of successful data migration.

1.6.3 **Other Database Records.** **Supersedes NC1-88-83-5, Item 24**
Includes data fields such as action type, fiscal year, country of origin, submitting District, submitter, firm, industry code, product code, sample number, date/time received, date entered into system and other related data.

Disposition: TEMPORARY.
Cutoff records at the end of the calendar year after the case is closed. Destroy 20 years after cutoff or when no longer needed for reference, whichever is later If data are migrated onto a new system, delete/destroy after the verification of successful data migration.

~~1.6.4~~ ~~**Reports: Outputs.**~~ **GRS 20 Items 4, 5, 6, 7, 12, 16**
~~Includes routine status, statistical or ad-hoc reports generated by users.~~

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when obsolete or superseded. If reports are maintained with other records described in another records series, apply disposition authorized for that series.~~

~~1.6.5~~ ~~**Systems Documentation.**~~ **GRS 20 Item 11a1**
~~Includes systems operations manuals, user manuals, data dictionary, requirements documents, and other systems related materials.~~

~~**Disposition: TEMPORARY.**~~
~~Destroy/delete when superseded or obsolete, or upon authorized deletion of the related master file or database, or upon the destruction of the output if the output is needed to protect legal rights, whichever is latest.~~