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
Center for Drug Evaluation and Research (CDER)

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

LEAVE BLANK (NARA use only)

JOB NUMBER N1-088-08-2

DATE RECEIVED 5/29/08

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10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
2/13/09	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
MAY 22, 2008	Seung Ja Sinatra	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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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 CDER Program Records Pre-marketing and Marketing Application Files Seung Ja Sinatra - FDA Records Officer — Date 12/6/05 Seung Ja Sinatra — Date 5/6/08 Ann Wion - FDA Office of the Chief Counsel — Date 5/6/08		

CDER Program Records

File Code: Prefix = CDER

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
	2000	**Pre-Marketing and Marketing Applications**	
1	2100	**Marketing Applications.** Includes New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs) submitted by paper or electronically for approval to market drugs in interstate commerce Includes formulations, manufacturing and controls information, reports of animal studies, case reports (clinical data), test results, labeling, progress reports, adverse reactions Also includes notices of withdrawal by sponsor, notices of FDA approval or revocation, various FDA evaluations and recommendations supporting these notices, review comments, correspondence, final study evaluation reports, meeting minutes, records of telephone conversations, and other related materials. Since November 2000, electronic documents that are part of an NDA have been maintained in an electronic records repository such as Division File System (DFS) or its successor system Records date from 1938. Certain records contain trade secret and confidential commercial information and other 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. NDAs, BLAs, and ANDAs for the following types of products are considered to be historically significant (one or more criteria may apply): 1. Drugs that were the first of a new class of therapeutic agents (also known as new molecular entities). 2. Drugs involved in either an actual withdrawal from marketing or a widespread call for their	

removal from the market because of serious deleterious side effects. Recall action could have established a major legal precedent Case studies of these products would be useful to investigate flaws, for example, in clinical investigational protocols, evaluation methodology, or product development
3. Drugs that represent major changes in formulation strategies Includes but not limited to novel dosage forms, such as early controlled-release agents and implantable pharmaceuticals
4. Drugs that had a unique impact on society beyond their medicinal effect These changed the very way people conducted their lives, but not limited to so-called "lifestyle" drugs.
5. Drugs that had a much broader medical and social impact as over-the-counter medicines, as opposed to their original role as prescription drugs
6. Drugs with orphan indications.
7. NDAs, BLAs, or ANDAs not selected on the basis of historical significance but preserved as examples of existing drug evaluation methodology and drug testing during a particular year or era. These are meant to document the evolution of the drug approval process over time.

~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~

Agency Instruction Only

Estimated Current Volume: There is currently (ca. 2008) about 7900 TB of electronic records including both Marketing and Pre-Marketing Applications
The specific volume of permanent electronic records cannot be estimated until selection criteria are applied. Selection of some permanent records cannot be made until the retention period ends.
Estimated Annual Accumulation cannot be provided. Annual accumulation is dependent upon the number and size of applications received each year.

1.1 2110 Applications Approved by FDA (Record Copies).
Retire paper records copies to FRC, when appropriate (as determined by volume and space).

Cutoff files at the end of the calendar year when Withdrawn by Commissioner (WC)

		~~Every 5 years, review for applications withdrawn after approval because of safety problems or for other reasons (e.g. not commercially viable). Review records every 5 years to apply disposition to applicable records.~~	**Agency Instruction Only**
1.1.1	2111	**Records with WC status identified as historically significant.** NOTE: Transfers of permanent records to NARA will include an index or inventory of the records being transferred that includes at a minimum the application number, title (drug name), and documents associated with that application	N1-088-87-1, item D-5b
		~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~	**Agency Instruction Only**
		Disposition: PERMANENT. Transfer to NARA in 5 year blocks 20 years after the last cutoff in the block, along with related records maintained elsewhere, in a format complying with NARA regulations (36 CFR 1228.270) or agreed to by NARA. Estimated date of first accession to NARA: 2010	
1.1.2	2112	**Records with WC status identified as NOT historically significant.**	N1-088-87-1, item D-5b
		~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~	**Agency Instruction Only**
		Disposition: TEMPORARY. Destroy/delete in 5 year blocks 30 years after the last cutoff in the block.	
1.2	2120	**Applications never approved by FDA.** Retire paper records copies to FRC, when appropriate (as determined by volume and space). Cutoff at the end of the calendar year when approvable, not approvable or complete response letter issued or when withdrawn by applicant before	

an action letter issued

~~Review records every 5 years to apply disposition to applicable records.~~ **Agency Instruction Only**

1.2.1 2121 **Records without pending status identified as historically significant.** N1-088-87-1, item D-5a

NOTE. Transfers of permanent records to NARA will include an index or inventory of the records being transferred that includes at a minimum the application number, title (drug name), and documents associated with that application.

~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~ **Agency Instruction Only**

Disposition: **PERMANENT.** Transfer to NARA in 5 year blocks 20 years after the last cutoff in the block, along with related records maintained elsewhere, in a format complying with NARA regulations (36 CFR 1228.270) or agreed to by NARA.

Estimated date of first accession to NARA: 2010.

1.2.2 2122 **Records without pending status identified as NOT historically significant.** N1-088-87-1, item D-5a

~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~ **Agency Instruction Only**

Disposition: **TEMPORARY.** Destroy/delete in 5 year blocks 30 years after the last cutoff in the block.

1.3 2130 **Review copies and Source Data for FDA Audit.**
Source Data are all records collected during the course of a trial that measure a subject's clinical condition or state and that are used to make broader safety and efficacy measurements. They are used to support review of the NDA/ANDA/BLA but are not typically part of the application. They include representations of physical attributes (e.g., medical imaging studies,

photographs, ECG tracings, histopathology slides) as well as hospital or other records of clinical events. Source data submitted for FDA audit are clearly identified as such upon submission.

Disposition: TEMPORARY. Destroy/delete or return to applicant when no longer needed for review, audit or reference

1.4 2140 **Electronic transport copies.**
CDs, discs, tapes and other electronic media sent by drug application sponsors to submit their application's data as part of the electronic drug application review process. Serves solely as transport media as, upon receipt and verification, the data is copied from them onto archival media.

Disposition: TEMPORARY. Destroy electronic source documents after all data elements are copied onto archival media and loaded onto the server for review and successful transfer is verified through quality control.

1.5 2150 **Duplicate copies maintained by FDA field offices.** N1-088-87-1, item D-5c
Includes copies of the technical section of the drug application, also called the CMC section (chemistry, manufacturing & controls).

Disposition: TEMPORARY. Destroy/delete when no longer needed for operational or reference purposes.

2 2200 **Pre-Marketing Applications.**
Includes Investigational New Drug application (IND) documents, FDA notices, review comments, correspondence, final study evaluation reports, meeting minutes, records of telephone conversations, and other related materials. Once an IND is in effect, it documents progress of clinical trials and their results

INDs fall into the following broad categories: Commercial INDs; Physician-Investigator INDs, Emergency INDs, Treatment INDs; Single-Patient Investigator INDs.

Since November 2000, electronic documents that are part of an IND have been maintained in an electronic records repository such as Division File System (DFS) or its successor system.

Certain records contain trade secret and confidential commercial information, and other information that cannot 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

INDS for the following types of products are considered to be historically
significant (one or more criteria may apply):
1. Drugs that were the first of a new class of therapeutic agents.
2. Drugs involved in either an actual withdrawal from clinical trials or a widespread call for their removal from the clinical trials because of serious deleterious side effects/safety issues, (i.e., carcinogenicity, anaphylaxis, significant damage to liver, kidney, heart, etc.) Halting clinical trials could have established a major legal/procedural precedent. Case studies of these products would be useful to investigate flaws, for example, in clinical investigational protocols, evaluation methodology, or product development.
3 Drugs covered by an Emergency Use Authorization (EUA) or a Pre-EUA. EUAs are an authorization by FDA for the use of a drug (either an unapproved one or the unapproved use of an already approved drug) when an emergency or potential emergency exists, (i e , a terrorist event involving a chemical, biological, nuclear or radiological agent.) Pre-EUAs are a submission sent to FDA for review prior to an actual/potential emergency in order to reduce the time for their review and authorization for use in the event of an emergency/potential emergency.
4. Drugs developed solely for military or governmental use.

Cutoff at the end of the calendar year when IND is discontinued, withdrawn, terminated, or cancelled.

		~~Review every 5 years to apply disposition to applicable records~~	**Agency Instruction Only**
		~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~	**Agency Instruction Only**
		Estimated Current Volume: There is currently about 7900 TB of electronic records including both Marketing and Pre-Marketing Applications. The specific volume of permanent electronic records cannot be estimated until selection criteria are applied. Selection of some permanent records cannot be made until the retention period ends. Estimated Annual Accumulation cannot be provided. Annual accumulation is dependent upon the number and size of applications received each year.	
2.1	**2210**	**Historically Significant INDs with discontinued, withdrawn, terminated, or cancelled status.** Records include Form FDA 1571, animal pharmacology and toxicology studies, manufacturing data, clinical protocols and investigator qualifications, amendments, formulations, progress and other reports, FDA evaluations and recommendations, and related correspondence and material.	N1-088-87-1, Item D-6a2(aa) and D-6a2(bb)
		NOTE. Transfers of permanent records to NARA will include an index or inventory of the records being transferred that includes at a minimum the application number, title (drug name), and documents associated with that application.	
		~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~	**Agency Instruction Only**
		Disposition: PERMANENT. Transfer to NARA in 5 year blocks 20 years after the last cutoff in the block along with related records maintained elsewhere, in a format complying with NARA regulations (36 CFR 1228.270) or agreed to by NARA.	
		Estimated date of first accession to NARA: 2010.	

2.2	2220	**<u>INDs not identified as historically significant with discontinued, withdrawn, terminated, or cancelled status</u>.**	N1-088-87-1, item D-6a1
		~~NOTE: Ensure that corresponding drug master files are appropriately disposed of at the time of disposition of drug application files.~~	**Agency Instruction Only**
		<u>Disposition:</u> TEMPORARY. Destroy/delete in 5 year blocks 10 years the last cutoff in the block.	
3	~~2400~~ 2300	**<u>Applications Management Information Systems.</u>** Provide overall information on the receipt and review status of INDs/NDAs/ANDAs/BLAs Also monitor their supplements, amendments, User Fee information and other related data Include systems such as New Drug Evaluation Management Information System (NDE/MIS), Abbreviated New Drug Application Management Information System (ANDA/MIS), other related systems or their successor systems, such as Document Archiving, Reporting, and Regulatory Tracking System (DARRTS). Information maintained in these databases are considered to date from 1938. Certain records contain trade secret and confidential commercial information, and other information that cannot 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.	
3.1	2310	**<u>Database Records.</u>** Data input from or about incoming and outgoing documents submitted or created as part of the review process. Includes information about the initial application and supplements/amendments such as document types, review assignments, status of applications and reviews, dates initiated and completed, and other related information. **<u>Disposition:</u> TEMPORARY.** Cut off at the end of the calendar year following final action.	

Destroy/delete 30 years after cutoff or when no longer needed for reference or research, whichever is later

~~3.2~~ ~~2320~~ ~~**Output Records.**~~ **GRS 20, items 5, 6, & 7**

~~Includes status and ad-hoc reports generated as needed. Some output data are used as input source records for other Systems, follow disposition instructions addressing those systems.~~

~~**Disposition: TEMPORARY.** Delete/destroy when no longer needed for reference.~~

~~3.3~~ ~~2330~~ ~~**System Documentation.**~~ **GRS 20, item 11a1**

~~Include systems requirements documents, data entry and standard operating procedures manual, and systems analysis document and online help.~~

~~**Disposition: TEMPORARY.** Destroy/delete when superseded or obsolete, or upon authorized deletion of the related master file or system, whichever is later.~~

~~3.4~~ ~~2340~~ ~~**Backups.**~~ **Non-record**

~~Performed as part of COMIS (or its successor system) backup. Refer to disposition instructions addressing COMIS or its successor system.~~

4 2400 **Application Volume Tracking Systems.**
Information is tracked on a bar code assigned to each volume of the submissions. Includes current and previous locations of individual volumes, reviewers and dates checked in and out, volumes received, minor correspondence, and supplements/review status

Includes systems such as IND/NDA Volume Accountability System (INVAS), Electronic Charge and History (ECH), Global Supplement System (GSS), or their successor systems, that provide volume tracking data on INDs, NDAs, BLAs, ANDAs, and Drug Master Files (DMF).

Disposition: TEMPORARY. Delete/destroy upon the destruction of related application files, or when no longer needed for reference, whichever is later.