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	N1-088-06-2
DATE RECEIVED	10-26-2005

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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
3/30/07	

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

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 9 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
OCT 20 2005	A Prentice Barnes, Sr.	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 GRS OR SUPERSEDED JOB CITATION	10.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 (Group 2) Seung Ja Sinatra - FDA Records Officer — Date: 9/13/05 Ann Wion - FDA Office of the Chief Counsel — Date: 10/5/05		

115-109 NSN 7540-00-634-4604 PREVIOUS EDITION NOT USABLE **STANDARD FORM 115** (REV. 3-91) (CDC Adobe Acrobat 5.0 Electronic Version, 8/2001) Prescribed by NARA 36 CFR 1228

Created by Electronic Document Services/USDHHS: (301) 443-2450

EF

SA 4/11/07 Copies Sent to Agency NWME, NWMW, NR

CDER Program Records

File Code: Prefix = CDER

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1	2900	**Application Review Support Tracking Systems.** Systems track status of various review studies and meetings between FDA and industries as part of a new drug approval process. Covers the following systems but not limited to: Pediatric Exclusivity System (KIDSEXCL) tracks information on Pediatric Exclusivity requests and determinations of Pediatric Exclusivity. Data covers information from 1998 to present; Pediatric Research Equity Act Tracking System (PREATS) tracks all pediatric waivers, deferrals, and completed studies as mandated by the Pediatric Research Equity Act of 2003; Formal Dispute Resolution System (FDR). Tracks information for the review of formal requests for dispute resolution submitted by manufacturers to CDER. As required by the Prescription Drug User Fee Act (PDUFA II), it provides statistics concerning the time required to conduct and report the results of the reviews. The formal disputes are required to be resolved within 30 days of receipt and approximately 12 disputes are handled annually. FDR covers data from February 1999. Industry Meeting Tracking System (IMTS) tracks when industry requested a meeting, meeting schedules, and when the minutes are issued. It facilitates to meet performance goals as required under PDUFA II. There are three types of meetings for consultation--critical, milestone and general matters. It covers approximately 2400 meetings per year and information dates from 1995 to present; Environmental Assessment System (EAS) tracks the status of environmental assessment of a new drug as mandated under the National Environmental Protection Act. It monitors 25 to 50 reviews annually. Information dates from 1980 to present. Final study and assessment reports, review requests, meeting minutes and other related materials are filed with related application case files and subject to records retention authorized for those files.	New
1.1	2910	Input Records.	

Data is input manually from drug application case files and electronically entered from application management/tracking systems.

Disposition: Delete/destroy duplicate copies used for input after verification of successful data entry by quality control. For original files or systems used for input, apply retention instructions authorized for those records.

2. 1.2 2920 Database Records.
Includes application number, product name, reviewers, date received and completed, company, review/meeting requests and codes, a review summary and other related data. Additional data fields: IMTS includes types of meeting, meeting participants and meeting date; FDR includes dispute category, dates resolved and decision reached at each level of the appeal, comments. Contains non-public information. FOIA exemptions apply.

Disposition: TEMPORARY.
Destroy/delete with related drug application case files, or when no longer needed for administrative or operational purposes, whichever is later.

1.3 2930 FDR Monthly Reports: Outputs.
Includes monthly statistical reports showing the number of disputes received and resolved that are used to prepare monthly management reports and an Annual Report to Congress concerning performance goals under PDUFA II.

3. 1.3.1 2931 September and December Reports.

Disposition: TEMPORARY. Cutoff at end of calendar year. Destroy/delete 5 years after cutoff.

4. 1.3.2 2932 All other reports.

Disposition: TEMPORARY.
Destroy/delete at end of calendar year.

5. 1.4 2940 IMTS Outputs: Extracted data used to produce Fiscal Year PDUFA Meeting Management Performance Report.

Disposition: TEMPORARY. Cutoff after report is produced and forwarded to OC. Destroy 5 years after cutoff.

6. 1.5 2950 All Other Outputs: Status reports and ad hoc reports.

Disposition: TEMPORARY.
Destroy when superseded or obsolete, or no longer needed for administrative or operational purposes.

7. 1.6 2960 System Documentation.
Includes systems manuals, codebooks and user instructions and other system related materials.

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

1.7 2970 ~~Backups. Electronic copy of the master file and retained in case the master file or database is damaged or inadvertently erased.~~ ~~GRS20 Item 8B~~

~~**Disposition: TEMPORARY.**~~
~~Delete when the identical records have been deleted, or when replaced by a subsequent backup file.~~

2 5300 Drug Product and Industry Reference Files. **Supersedes in part, RCS, D-30 NC 1-88-83-5**
Includes Drug Product Reference Files (DPRF) and Developers and Distributors System (DADS). DPRF provides information on drug products and DADS on names and addresses of manufacturers, re-packagers and distributors of pharmaceutical components, and individual Investigational New Drug (IND) and Drug Master File (DMF) holders. Data in these two application systems are populated to various application systems across CDER. DPRF and DADS, considered as vital systems, cover core data from 1938 to present. DPRF contains confidential information and FOIA exemptions apply.

8. 2.1 5310 Input Records:
DPRF: Data taken from drug application case files.
DADS: Data taken from Drug Registration and Listing forms.

Disposition: TEMPORARY. Apply disposition instructions authorized for appropriate records series.

9. 2.2 5320 DPRF Database Records.
DPRF: Data fields include drug application number, active and inactive ingredients, product, dosage forms, potencies, pharmacological activity and other related information.

Disposition: PERMANENT.
Cutoff when related drug application has been withdrawn from the market, disapproved or has reached an inactive state. Transfer data to NARA 5 years after cutoff, in a format complying with NARA regulations (36 CFR 1228.270), or agreed to by NARA.

10. 2.3 5330 DADS Database Records.
Includes names and addresses of drug manufacturers, sponsors, re-packagers/distributors, IND and DMF holders.

Disposition: **TEMPORARY.**
Delete upon the successful migration to the successor system and upon the deletion of the last module supported by DADS, or when no longer needed for administrative, operational purposes, whichever is later.

11. 2.4 5340 Outputs. Includes ad-hoc reports.
For extracted data directly input into various modules, apply disposition authorized for each module.

Disposition: **TEMPORARY**. Destroy when superseded or obsolete, or when no longer needed for administrative or reference purposes, whichever is later.

12. 2.5 5350 System Documentation.
Includes user manuals and codebooks. As core systems, refer to system documentation under COMIS or its successor system.

Disposition: **PERMANENT.**
Transfer to NARA with regular updates to database records.

2.6 5360 ~~Backups. Performed as part of COMIS backup procedures or its successor system. Apply disposition authorized under COMIS or its successor system.~~ ~~GRS20 Item8B~~

~~**Disposition: TEMPORARY.**~~
~~Delete when the identical records have been captured in a subsequent backup file or when the identical records have been transferred to NARA and successfully copied.~~

3 5400 **Ingredient-related Records and Databases.** **New**
The Ingredient Dictionary is a cumulative and comprehensive database of all active and inactive ingredients in drug products from both investigational and commercially marketed drugs for human use. Its nomenclature has been verified and standardized according to the requirements in Section 508, the Federal Food, Drug and Cosmetic Act. A unique identifier is assigned to each ingredient entry. Each entry includes the FDA established name or a preferred term, synonyms, company codes and trade names. As a central component of other application systems, the Ingredient Dictionary interfaces with and supports various application systems such as DPRF, DRLS, AERS, DMF, the Orange Book, the Inactive Ingredient Guide (IIG), the Substance Registration System (SRS) and their successor systems. It covers information since the 1970s. Contains confidential data. FOIA exemptions apply for public access.

13. 3.1 5410 Input Records: New Term Request Forms.
Data is input from two versions of the form: one for DMF submissions and one for NDA, ANDA, IND submissions.

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

14. 3.2 5420 Database Records.
Information includes ingredient reference identifier, established names, ingredient source, synonyms, trade names, company codes, chemical names, Chemical Abstract Service numbers (CAS). Contains confidential data. Apply FOIA exemptions for public access.
Review files every 3 years to identify ingredients that are not under clinical investigation.

Disposition: PERMANENT.
Transfer copy of data containing approved ingredients to NARA every 3 years in an approved format. Reference copy maintained in FDA until no longer needed for research or reference purposes, whichever is later.

15. 3.3 5430 Output Records. Includes ad-hoc reports and data extracted to be directly input into various applications. For extracted data input into other systems, apply disposition authorized for those systems.

Disposition: TEMPORARY.
Destroy when superseded or obsolete, or when no longer needed for administrative or operational purposes.

16. 3.4 5440 System Documentation.
Includes Oracle table definitions and Ingredient Dictionary Standard Operating Procedures.

Disposition: PERMANENT.
Transfer to NARA with related database records.

3.5 5450 ~~Backups.~~ ~~GRS 20 Item 8B~~
~~Performed as part of the Substance Registration System (SRS) or its successor system. File identical to records scheduled for transfer to NARA.~~

~~**Disposition: TEMPORARY.**~~
~~Delete when the identical records have been captured in a subsequent backup file or when the identical records have been transferred to NARA and successfully copied.~~

4. 7100 Special Products Online Tracking System (SPOTS). **New**
Provides a web-based interface for tracking certain active and inactive ingredients derived from plant, animals, microorganism and recombinant technology used in pharmaceutical products that are the subject of a drug application. It facilitates the agency

in planning and responding to public health issues and facilitates the development of science and risk based policies. Contains confidential information and FOIA exemptions apply for public access.

17. 4.1 7111 SPOTS Input Records.
Data is directly entered from the Drug Registration and Listing System (DRLS), Developers and Distributors System (DADS) and the Drug Product Reference File (DPRF). Data is also manually input from various sources.
Apply retention instructions under appropriate file series, for input taken from other systems.

Disposition: **TEMPORARY.** Delete/destroy after verification of successful data entry by quality control.

18. 4.1 7110 SPOTS Data Files.
Data fields include the country of origin, drug application type and number, drug master file number, product ingredients, source of ingredients and the beginning and ending dates of sourcing. It tracks animal tissues and plant parts used, plant name and type of organism. Contains confidential information and FOIA exemptions apply for public access.

Disposition: TEMPORARY.
Delete upon the successful migration to the successor system, or when no longer needed for administrative, operational or research purposes, whichever is later.

19. 4.2 7120 SPOTS Output Records.
Includes ad-hoc end-user reports to search for drug applications or product ingredients.

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

20. 4.3 7130 SPOTS System Documentation.
Includes codebooks, user and training manuals, functional requirements and system design documents, testing and implementation plan.

Disposition: TEMPORARY
Destroy/Delete when obsolete or superseded, or upon authorized deletion of the master file or database, whichever is later.

4.4 7140 ~~SPOTS Backups.~~ ~~GRS 20~~
~~Electronic copy of the master file and retained in case the master file or database is damaged or inadvertently erased.~~ ~~Item 8b~~

Disposition: TEMPORARY.
Delete when the identical records have been deleted, or when replaced by a subsequent backup file.

5. **Electronic Mail and Word Processing System.**
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.

5.1 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. **GRS 20 Item 13**

Disposition: TEMPORARY: Destroy within 180 days after the recordkeeping copy has been produced.

5.2 Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy. **GRS 20 Item 14**

Disposition: TEMPORARY: Destroy when dissemination, revision, or updating is completed