REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

LEAVE BLANK (NARA use only)
JOB NUMBER: N1-088-05-2
DATE RECEIVED: 4-25-2005

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

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

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10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
7/8/06	[signature]

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 12 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
APR 2 1 2005	[signature]	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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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 1) [signature] 2/22/05 Seung Ja Sinatra - FDA Records Officer — Date [signature] 3/1/05 Fred Ansell - FDA Office of the Chief Counsel — Date cc: Agency, NR, NWND, NWME, NWMW		

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)
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EF

CDER Program Records

File Code: Prefix = CDER

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1	2500	**Drug Efficacy Study Implementation (DESI) Files.** Under the 1962 amendments to the Food, Drug and Cosmetic Act, drugs approved prior to1962 by FDA had to be evaluated for their efficacy as well as their safety for use The individual DESI project files for each drug reviewed (approximately 3,443 products) include the following set of the records but not limited to. reports from the Review Panels; correspondence created during the review and resolution of items; data submitted by sponsors or manufacturers of the drugs, labeling recommendations, medical reviews, and Federal Register notices and other related records These files provide the regulatory basis for drugs still being marketed and contain confidential information Access is restricted under FOIA exemptions Copies of the Panel reports, Federal Register notices, public comments and final results of the studies are also maintained by the Division of Dockets Management for public use and subject to Dockets records retention schedules **Disposition: PERMANENT.** Cutoff after completion of all DESI proceedings and any resulting litigation, or when no longer needed for review in the continued regulation of these drugs, whichever is later Transfer to NARA immediately after cutoff	**Supersedes RCS, D-3 (NC1-88-83-5)**
1.1	2510	DESI Tracking Data Tables. Information is tracked to identify the drug products and the status of the reviews under the DESI project It is accessible through the Office of Regulatory Policy tracking system within CDER. **Disposition: TEMPORARY.** Cutoff after completion of the DESI Project and any resulting litigation, or when no longer needed for review in the continued regulation of these drugs, whichever is later Delete 5 years after cutoff. If tracking data is merged into other CDER system, apply disposition authorized for that system.	**Supersedes RCS, D-37 (NC1-88-79-2)**

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Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
2	2600	**Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).** The Orange Book is a list of approved prescription drug products with related therapeutic equivalence information on their generic equivalents and on what other drugs can be used for the same medical conditions It is compiled from data tables extracted from the Drug Products Reference File (DPRF· formerly known as ASTRO-4 Drug Information System) whose input data was taken from New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDA) case files. It provides information on drug name, ingredients, manufacturer, dosages, patent numbers(s), reference to the related NDA/ANDA and other related information It does not include drugs covered by the Drug Efficacy Study Implementation (DESI) or drugs prior to 1938 It is used by CDER staff, manufacturers, and the public.	**Supersedes RCS, I-6, (NC1-88-78-1)**
2.1	2610	Orange Book Annual Edition Each subsequent edition includes new approvals and appropriate changes in the data previously published Issued since 1980 under the Federal Food, Drug and Cosmetic Act	
2 1 1	2611	Orange Book, 1980-2004 (Paper). It provides a comprehensive list of the approved drug products from 1980 to 2004 in 25 volumes. **Disposition: PERMANENT.** Cutoff at end of 2004 and after the next annual edition has been published Transfer to NARA 3 years after cutoff.	
2.1 2	2612	Electronic Orange Book, 2005- . Electronically provides a comprehensive annual list of the approved drug products on the CDER Internet site **Disposition: PERMANENT** Cutoff in 3-year block at end of calendar year and after the next annual edition has been published. Transfer to NARA in NARA approved format 2 years after cutoff	
2 2	2620	Orange Book Monthly Supplements Since 1984, it provides a monthly list of the approved drug products, as required by the 1984 Amendments of the Drug Price Competition and Patent Term Restoration Act **Disposition: TEMPORARY.** Cutoff at end of calendar year and after the next annual edition has been published Destroy/delete 50 years after cutoff	

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Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
2 3	2630	Orange Book Data Tables (Historical). Includes data tables extracted from DPRF and used for historical analysis **Disposition: PERMANENT.** Master Tables. Consult NARA for transfer instructions. Annual Tables. Cutoff in 3-year block at end of calendar year and after the next annual edition has been published Transfer to NARA in NARA approved format 2 years after cutoff	
2 4	2640	Orange Book Data Tables (Other) Includes data tables extracted from DPRF that are updated as the new information is available. **Disposition: TEMPORARY** Update data as needed and delete when superseded or obsolete.	
3	2700	**Drug Master Files (DMF).** Files consist of case files used to provide company-proprietary manufacturing or process information that can be referenced by another manufacturer (customer) as part of an NDA, ANDA, IND or another DMF (Referencing Application) A complete file includes the original records submitted by the DMF holder containing information regarding Chemistry, Manufacturing, and Control (CMC) for drugs as well as (rarely) additional non-CMC information regarding drugs, and additional submissions from the DMF holder, FDA reviews and correspondence DMFs are reviewed when· 1. the DMF holder submits a Letter of Authorization (LOA) to the DMF, 2 the DMF holder submits a copy of the LOA to a customer; 3. the customer includes that copy of the LOA in a Referencing Application. Each DMF is assigned a reference number when received. Files cover from 1947 and contain trade secrets and confidential commercial information. Access is restricted under FOIA exemptions DMF is considered "inactive" if. 1) the holder notifies FDA in an amendment to the DMF holder that they wish the DMF to be closed; 2) the holder does not respond within 90 days to an "Overdue Notice Letter (ONL). An ONL is sent when a DMF has no activity for 3 years; 3) FDA declares DMFs more than 10 years old inactive without sending an ONL Upon 90 day notice of destruction from FRC, review for any record of firm of ongoing interest or if DMF product might be referenced in an active application	**Supersedes RCS, D-7 (NC1-88-87-1)**

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3.1	2710	DMFs reviewed to support a regulatory action. Includes DMFs reviewed to support an action on a drug under an NDA or ANDA, or to support a safety decision on a drug under an IND. **Disposition: TEMPORARY.** Cutoff when the DMF is "inactive". Retire to FRC at end of calendar year 1 year after cutoff Apply disposition authorized for corresponding drug application files	
3 2	2720	DMFs with Right of Reference Granted with No Record of Review Includes DMFs with a Letter of Authorization (LOA) submitted by the holder and there is no record of a review These are either more than 10 years old, or, the DMF was referenced in an IND and there was sufficient information in the IND to assess the safety of the material DMFs were not used to support the regulatory action **Disposition: TEMPORARY.** Cutoff when the DMF is "inactive." Retire to FRC at end of calendar year 1 year after cutoff. Destroy 3 years after cutoff.	
3 3	2730	DMFs not Referenced/Reviewed. DMFs that do not have a LOA by the holder or DMFs with no records of a review **Disposition: TEMPORARY.** Cutoff when the DMF is "inactive " Retire to FRC at end of calendar year 1 year after cutoff. Destroy 3 years after cutoff.	
3 4	2740	Review Copy **Disposition: TEMPORARY** Destroy when recordkeeping copy is retired to FRC.	
3 5	2750	Drug Master File Information System (DMF) Tracks all DMF submissions and incoming/outgoing documents DMF numbers are referenced in the Drug Product Reference File (DPRF) as a supporting document for drug applications. Individual DMF volumes are tracked in the IND/NDA Volume and Accountability System (INVAS) Names and addresses of DMF holders are linked to Developers and Distributors System (DADS) Contains trade secrets and FOIA exemptions apply	**New**

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Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
3 5 1	2751	DMF Database Records. Data taken from DMF submissions includes DMF number, product type, holder and manufacturer, drug applications referenced, correspondence received, date of annual updates, amendments to file, ownership, status of file, permission to reference file, dates and status of review Data covers from 1947 to present. **Disposition: TEMPORARY.** Delete when no longer needed for FDA business If data is migrated to new system, delete after migration has been completed and after the verification of successful data migration	
3 5 2	2752	DMF Output Records Includes ad-hoc reports generated by system users **Disposition: TEMPORARY** Destroy when no longer needed for administrative or reference purposes	
3 5.3	2753	~~DMF System Documentation~~ ~~COMIS (or its successor system) database instructions are used. Refer to system documentation scheduled under COMIS or its successor system.~~	
3 5 4	2754	~~DMF System Backups.~~ ~~Performed as part of COMIS (or its successor system) backups Refer to backups scheduled under COMIS or its successor system.~~	
4	**2800**	**OTC Drug Approval Program Working Files.** Files include working files of the Over the Counter (OTC) drug monographs and related documents generated during a drug review period under the OTC drug monograph regulation (21CFR 330). Under this program, a drug is approved through a notice-and comments rulemaking process rather than through a confidential new drug application process Files cover OTC rulemaking documents related to the preparation and approval of the OTC monographs from the initial draft by an Outside Review Panel to submittal to the Federal Register for the advanced notice of proposed rulemaking, and subsequent tentative final monographs, final monographs or non-monograph documents Also included are duplicate copies of the final monograph, petitions to the monograph, Federal Register notices, public comments and other rulemaking materials whose records copies are maintained in the Division of Dockets Management and subject to Dockets records retention schedules. Contain confidential commercial and trade secret information and access may be restricted under FOIA exemptions	**New**

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		Disposition: TEMPORARY. Cutoff after completion of final monograph and/or no activity (e.g. litigation, petitions to amend) for 3 years. Destroy/delete when no longer needed for reference purposes, or 30 years after cutoff, whichever occurs first.	
4.1	2810	OTC Tracking System Information tracked includes reviewer assigned to the project, goal date, completion date, titles and types of projects, notes and other rulemaking and drug approval tracking data **Disposition: TEMPORARY.** Cutoff after completion of monograph, including litigation and petitions to amend. Delete with related OTC program working files	**Supersedes RCS, D-35 (NC1-88-83-5)**
5	**3100**	**Phonetic-Orthographic Computer Analysis (POCA).** POCA is a reference tool to analyze and review names proposed for FDA-regulated products for conflicts with another product. POCA analyzes the proposed name against previously approved product names both for similarities in spelling and for sound. The results of the analysis are used for review reports to assist in the approval of new products. The analysis is performed by an algorithm to perform the comparison and to flag any possible conflicts for manual review. Information dates from 2004 and used by the Office of Drug Safety. Review reports (consults) are filed with related application files and subject to records disposition under that series.	**New**
5 1	3110	POCA Input Records Includes batch files extracted from the Orange Book, Drug Registration and Listing System (DRLS), CBER Biologics Licensing Application system and Cerner. **Disposition. TEMPORARY.** Delete/destroy after data is successfully entered and verified	
5.2	3120	POCA Data Files Data entered from batch files described above, includes dosage form, drug application number, consult (task) number, proposed name, established name, alternate name, safety evaluation results and dates and results of reviews **Disposition: TEMPORARY.** Maintain until no longer needed for reference.	

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5 3	3130	POCA Outputs. Includes ad-hoc reports generated for reference **Disposition: TEMPORARY.** Destroy/delete when no longer needed for reference.	
5.4	3140	POCA System Documentation. Consists of user's guide, systems requirements, and technical papers describing the basis for and workings of the algorithm that is the heart of the system **Disposition: TEMPORARY.** Destroy or delete when superseded or obsolete, or upon authorized deletion of the related master file or database, whichever is later.	
5.5	3150	~~POCA Backups.~~ ~~Electronic copy of the master database and retained in case it is damaged or inadvertently erased~~ ~~**Disposition: TEMPORARY**~~ ~~Delete when the identical records have been deleted, or when replaced by a subsequent backup file~~.	~~**GRS 20, Item 8b**~~
6	**3200**	**Post-Marketing Commitments Tracking System (PMC).** PMC monitors the status of post-marketing commitment studies As mandated by Section 130 of the FDA Modernization Act, these studies are performed as part of the drug development process for new prescription drug (NDA) and biological licensing applications (BLA), which drug manufacturers have agreed to or are required to conduct for the FDA. It contains confidential information and access is restricted under FOIA exemptions. PMC was operational in 2001	**New**
6.1	3210	PMC Input records. Data is input from original and duplicate copies of selected NDA and BLA files, FDA approval and PMC letters, annual status reports from manufacturers, correspondence, protocols, final commitment study reports and other related documents **Disposition: TEMPORARY.** Delete/destroy duplicate copies used for input after the verification of successful data entry Maintain official original copies with related application case files and apply disposition authorized for that series	

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6 2	3220	PMC Database Records. Data fields include application number, drug name, sponsor name, commitment description, commitment status and explanation of status, and study schedule dates (e g protocol submission, study initiation, final study report submission) Used for historical trend analysis **Disposition: PERMANENT** Master Files. Cutoff at the close of fulfillment or release and upon successful migration into the successor system Transfer to NARA in NARA approved format 2 years after cutoff. Annual Updates. Cutoff at the close of fulfillment or release. Transfer in batches to NARA, in NARA approved format, in 3-year block at end of calendar year after cutoff	
6.3	3230	PMC Quarterly Report on the Web Outputs Includes reports generated to share the information on the remaining open commitments and recently closed commitments with the general public and sponsors of the product **Disposition: TEMPORARY.** Destroy/delete when superseded by a subsequent quarterly update	
6.4	3240	PMC Annual Report Outputs Includes an annual summary report of actions taken by CDER which is used in a Federal Register notice and a Report to Congress Status is reported for open, closed and ongoing commitments as the following· pending, ongoing, delayed, terminated, submitted, fulfilled and released **Disposition: TEMPORARY.** Cutoff after published in the Federal Register at the end of the calendar year Retire to FRC 5 years after cutoff Destroy 10 years after cutoff.	
6 5	3250	PMC Web Site Logs and Canned or Ad-hoc Reports Covers internal logs of quarterly changes in addition to the superseded data, notes on when and by whom postings were modified, and canned or ad-hoc reports . **Disposition: TEMPORARY.** Destroy/delete when no longer needed for administrative or reference purposes	
6 6	3260	PMC System Documentation Include a systems requirements document, data entry and standard operating procedures manual, and systems analysis document and online-help	

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Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
		Disposition: PERMANENT. Transfer to NARA with related database records	
6 7	3270	~~PMC Backups~~ ~~Performed as part of COMIS (or its successor system) backup~~ ~~Refer to disposition instructions under COMIS or its successor system~~	
7	**3300**	**Post-Approval Commitment Tracking System (PACT).** Post-approval commitment studies are conducted by generic drug manufacturers for FDA PACT monitors only the commitments identified during the Abbreviated New Drug Application (ANDA) review of approved or nearly approved generic drugs Each entry is linked to a corresponding ANDA file. When a commitment is pending, a flag is set that triggers an automatic entry into PACT from the ANDA file It contains commercial proprietary information and access is limited to the system administrator and project managers within the Office of Generic Drugs. PACT covers data from 2000.	**New**
7.1	3310	PACT Input Records. Data is manually input from selected ANDA, correspondence, final commitment study reports and other related documents **Disposition: TEMPORARY** Maintain official original copies with related ANDA case files and apply records disposition authorized for that series If duplicate copies are used for input, delete/destroy after the verification of successful data entry.	
7 2	3320	PACT Database Records. Data taken from the input records mentioned above, includes a brief description of the pending item, date pending and the date when the commitment is fulfilled **Disposition: TEMPORARY.** Cutoff annually after commitment is fulfilled Delete 3 year after cutoff.	
7.3	3330	Reports on Open Commitments. Outputs **Disposition: TEMPORARY.** Destroy/delete when no longer needed for administrative purposes	

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7 4	3340	~~PACT System Documentation~~ ~~Includes system and user manual~~ ~~**Disposition: TEMPORARY.**~~ ~~Destroy/delete when superseded or obsolete, or upon authorized deletion of the related master files or database, or upon the destruction of the output if the output is needed to protect legal rights, whichever is latest.~~	~~**GRS 20, Item 11a**~~
7 5	3350	~~PACT Backups.~~ ~~Performed as part of COMIS (or its successor) backup procedures.~~ ~~Refer to disposition instructions under COMIS or its successor system~~	
8	**5100**	**CDER-wide Management Information Systems.** Center-wide integrated database management systems, such as Center-wide Oracle Management Information System (COMIS) or its successor systems, provide information retrieval, tracking and reporting capability, and functions as an access entry point for various application systems they support Data tables provide a common source of data fields shared by two or more systems. It consists of the following areas, but not limited to. Menu System, Data Validation Tables, primarily drug descriptive data, and database structures and programs. Some of the systems supported are· Post-Marketing Commitments Studies Tracking System (PMC), Drug Master File Information System (DMF), Formal Dispute Resolution System (FDR) and other systems Systems supported contain confidential commercial information and FOIA exemptions apply for public access. Considered as a vital record.	**New**
8.1	5110	Inputs Data elements are taken from various records maintained in drug submissions or other case files and input into tables by authorized users. **Disposition. TEMPORARY.** If duplicate copies are used for input, delete/destroy after the verification of successful data entry. If input records are part of a separate records series, apply disposition authorized for that series	
8 2	5120	~~Database Records~~ ~~Includes data fields such as drug name, document type, decision taken, dates received/sent, status, division assigned to, therapeutic drug class, comments, etc These are shared by two or more system applications supported. Contains confidential commercial information Apply FOIA exemptions for public access.~~	

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		~~**Disposition:**~~ ~~Maintain data for the longest retention period required by the database applications supported. If the system is migrated or replaced by a successor system, cutoff after the successful migration or after the system has been replaced by the successor system. Delete copies used for migration or replacement when no longer needed for reference. If records are part of a separate series, apply the disposition authorized for that series.~~	
8 3	5130	~~Outputs. See the outputs under various applications. The system has no specific outputs itself.~~	
8.4	5140	Systems Documentation Includes systems manuals, user manuals, and code books and other materials related to system operation	
8.4 1	5141	Documentation Related to Permanent Systems **Disposition: PERMANENT**. Transfer to NARA with related database files	
8 4 2	5142	Documentation Related to Temporary Systems **Disposition: TEMPORARY** Destroy or delete when superseded or obsolete, or after all data is successfully migrated into the successor system and when no longer needed for administrative and operational purposes, whichever is later.	
8 4 3	5143	Documentation on System Security Copies of records relating to system security, including records documenting periodic audits or review and re certification of sensitive applications, disaster and continuity plans, and risk analysis, as described in OMB Circular No A-130 **Disposition: TEMPORARY.** Destroy or delete when superseded or obsolete	
8.5	5150	~~Backups.~~ ~~Electronic copy, considered by the agency to be a Federal record, of the master copy of an electronic record or file and retained in case the master file or database is damaged or inadvertently erased. Includes backup copies made for application systems supported by COMIS or its successor systems.~~	~~**GRS 20, Item 8**~~

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8 6	5151	File identical to records scheduled for transfer to the National Archives **Disposition: TEMPORARY** Delete when the identical records have been captured in a subsequent backup file or when the identical records have been transferred to the National Archives and successfully copied.	
8 7	5152	File identical to records authorized for disposal in a NARA-approved records schedule. **Disposition: TEMPORARY.** Delete when the identical records have been deleted, or when replaced by a subsequent backup file	
9	**9200**	**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.	**New**
	9211	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 **Disposition: TEMPORARY:** Destroy within 180 days after the recordkeeping copy has been produced.	
	9212	Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy **Disposition: TEMPORARY:** Destroy when dissemination, revision, or updating is completed	