REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

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

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

2. MAJOR SUBDIVISION
Food and Drug Administration

3. MINOR SUBDIVISION

4. NAME OF PERSON WITH WHOM TO CONFER
Seung Ja Sinatra

5. TELEPHONE
301-827-4274

LEAVE BLANK (NARA use only)

JOB NUMBER
N1-088-01-1

DATE RECEIVED
10/31/00

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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
7-6-01

ARCHIVIST OF THE UNITED STATES
[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 _____ 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,

[X] is not required; [ ] is attached; or [ ] has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
OCT 27 2000	A Prentice Barnes, Sr.	DHHS Records Management Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
D-5b	Enovid Files: New Drug Application This schedule provides permanent disposition authority for Enovid Files. SEE ATTACHED SCHEDULE Seung Ja Sinatra, FDA Records Officer 10/25/00	N1-88-87-1	

Agency, NWMP, NWCT 7/11/01

115-109 NSN 7540-00-634-4064 PREVIOUS EDITION NOT USABLE

STANDARD FORM 115 (REV. 3-91)
Prescribed by NARA
36 CFR 1228

Center for Drug Evaluation and Research. Enovid Files: New Drug Application.

These records consist of patient case files, physician's notes, investigations, and all correspondence between the G.D. Searle Company and regulators on all aspects of Enovid, the first oral contraceptive drug approved by the Food and Drug Administration (FDA). Files provide complete documentation from its initial submission as a new drug through all of the post marketing analyses made in light of concerns about its long term effects on the women taking it. An initial offer includes roughly 176 binders that occupy approximately 30 record boxes that cover files from 1959-1995. There are additional boxes of records from 1996 to 1999 that will be transferred to NARA when they become inactive.

see revised schedule per 3/13/01 email from S.S.

These records have not been vetted under the FOIA and would require limitations on access to the confidential, proprietary information. To accommodate public access, FDA will submit to NARA a redacted version along with original records under wraps. FDA requires that NARA exercise extra caution and follow FDA's policy not to disclose private information.

Disposition: PERMANENT. Transfer to NARA in April, 2001.

Justification:

These records document FDA's historical and scientific evidence in setting research standards and regulations concerning the use of a contraceptive by young women. Enovid was the first drug approved by the FDA for a "non-disease"--namely the prevention of pregnancy. In its first years on the market, it was taken by millions of healthy young women. It was a bold marketing move for the G.D. Searle Company which feared opposition and even boycotts from the Catholic church. The drug proved to be safe and many other pharmaceutical companies developed their version of what came simply to be known as "the Pill".

In late 1960, the first death from thromboembolic complications was reported to FDA. It took almost a decade to statistically link deaths with the drug. Scientists have discovered a genetic link to the thromboembolic problems caused by the Pill in some young women. This made it possible to screen for the risk factor before prescribing the Pill. Many of the statistical methods developed in evaluating Enovid became the basis of post marketing analysis of new drugs.

Enovid was approved just prior to revelations that the drug Thalidomide, when used by pregnant women, caused severe birth defects. It is important to note that Enovid and any oral contraceptives offered for approval, after revelations about Thalidomide, prompted Congress to enact new safeguards for new drug approvals in the Kefauver Harris Amendments in 1962.

Per S.S. e-mail dated 3/13/01, approved SF 115 with [illegible] edits:

1. Enovid New Drug Application File - All papers relating to the approval of the first oral contraceptive drug approved by the Food and Drug Administration (FDA). Includes records submitted by G.D. Searle, manufacture of Enovid and produced by FDA in the review process. Files provide complete documentation from the original application through post-approval changes and post-marketing safety analyses. The collection includes patient case report forms, reports of investigations, correspondence between G.D. Searle and FDA regulators, data, tests, and study methodologies from clinical trials, and review of this information. Post-approval changes and post-marketing reports include supplements for chemistry and labeling changes, annual reports, periodic safety reports, adverse event reports, and government reviews of this information. Files also include labeling, brochures, and promotional labeling.

   Files consist of materials dating from 1957-1995, during the application review, approval, and marketing period. They are arranged chronologically. Total volume is 176 binders that occupy 30 cubic feet.

   DISPOSITION: PERMANENT. Transfer to the National Archives and Records Administration upon approval of schedule. These files have access restrictions. Some information such as trade secrets and patient information will be exempt under FOIA.

2. Reports – Annual reports and Adverse Drug Experience Reports submitted by G.D. Searle, manufacturer of Enovid.

   Files consist of materials during the U.S. non-marketing periods. They are arranged chronologically and consist of a total accumulation of 1 inch per year.

   DISPOSITION: PERMANENT. Cutoff end of 1996 – 2006 files at end of FY 2006, and end of fiscal year in 10-year blocks thereafter. Transfer to the National Archives and Records Administration in 10-year blocks when latest record is 10-years old.

3. Electronic Mail and Word Processing System Copies

   a. 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. DELETE within 180 days after the recordkeeping copy has been produced.

Per S.S. e-mail dated 3/13/01, approved SF 115 with [illegible] edits:

b. Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.

DISPOSITION: TEMPORARY. DELETE when dissemination, revision, or updating is complete.