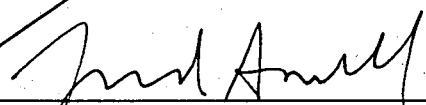
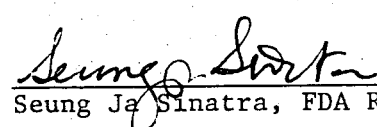


<b>REQUEST FOR RECORDS DISPOSITION AUTHORITY</b> (See Instructions on reverse)		<b>LEAVE BLANK (NARA use only)</b>	
TO: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		JOB NUMBER NI-088-02-2	DATE RECEIVED 7/15/02
1. FROM (Agency or establishment) Department of Health and Human Services		<b>NOTIFICATION TO AGENCY</b>	
2. MAJOR SUBDIVISION Food and Drug Administration		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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	
3. MINOR SUBDIVISION Office of the Commissioner		DATE	ARCHIVIST OF THE UNITED STATES
4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra	5. TELEPHONE (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 2 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 JUL 11 2002	SIGNATURE OF AGENCY REPRESENTATIVE  A. P. Barnes	TITLE HHS Records Officer
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7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
Item 1	<p>FDAMA 115 Research Project Files</p> <p>See attached schedule</p> <p> 7/5/02 Fred Ansell, FDA General Counsel</p> <p> 6/28/02 Seung Ja Sinatra, FDA Records Officer</p> <p><i>cc NWMD NWME DWMW</i></p>	<p>— withdrawn 10/29/02 —</p>	

## FDAMA 115 Research Project Files

Include research study reports and related materials on demographic, pharmaceutical and clinical trials trends related to New Drug Applications (NDAs) approved between 1995 and 1999. Also include a tracking system that contains information on gender, racial and ethnic groups' participation in clinical trials of newly approved drugs and describes to what extent sponsors presented race-related information in the labeling. The study, conducted by the Office of Special Health Issues under Section 115, the Food and Drug Modernization Act (FDAMA) of 1997, was completed in October 2001.

### 1. Project final reports

Disposition: **PERMANENT.** Cutoff after completion of the project. Offer to NARA 30 years after cutoff.

### 2. Copies of selected NDAs and related documents used in the study; project progress reports, minutes of meeting reports, correspondence, and other materials.

Disposition: **TEMPORARY.** Cutoff files after completion of the project. Destroy 3 years after cutoff.

### 3. Demographic Tracking Database

#### A. Data entered from NDAs on age, gender, race, and other information.

Disposition: **TEMPORARY.** Delete data 10 years after completion of the project.

#### B. Printed reports generated in response to ad hoc queries.

Disposition: **TEMPORARY.** Destroy when FDA determines that they are no longer needed for administrative, legal, or operational purposes.

### 4. E-mail and Word Processing System Copies

Electronic copies of records that are created on electronic mail and word processing systems and used solely to generate a record-keeping 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.

- A. Copies that have no further administrative value after the record-keeping copy is made. Includes copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories that are used only to produce the record-keeping copy.

Disposition: **TEMPORARY**. Destroy/delete within 180 days after the record keeping copy has been produced.

- B. Copies used for dissemination, revision, or updating that are maintained in addition to the record-keeping copy.

Disposition: **TEMPORARY**. Destroy/delete when dissemination, revision, or updating is completed.