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: N1-088-03-4
DATE RECEIVED: 3/12/03

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

2. MAJOR SUBDIVISION
Food and Drug Administration

3. MINOR SUBDIVISION
Office of the Commissioner

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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
10-9-03	John W. Carlin

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,

☒ is not required; ☐ is attached; or ☐ has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
MAR – 7 2003	A. P. Barnes	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 GRS OR SUPERSEDED JOB CITATION	10.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)
1	Export Program Files SEE Attached Schedule Fred Ansell 1/21/03 Fred Ansell, FDA General Counsel — Date Seung Ja Sinatra 12/31/02 Seung Ja Sinatra, FDA Records Officer — Date cc Agency, NWMD, NWMW, NWCTC		

Export Program Files

This schedule establishes the official agency-wide recordkeeping requirements for export program files on human drugs, biological products, devices, animal drugs, food, and cosmetics.

Records copies are maintained by the program office in each center or in FDA District offices. Tracking systems are used to document the status of export applications and certificate processing.

1. **General Export Program Files**

   A. Final Policy Documents. Final documentation resulting from or influencing policy or procedure changes to the FDA export program. Examples include decision-making memorandum, final working group reports, compliance policy guidance, action items, or strategic planning.

   Disposition: **Permanent.** Cutoff files at end of fiscal year in 5 year blocks. Transfer to NARA 20 years after cutoff.

   B. Instructional Manuals. Procedure manuals for completing and processing export applications, export notifications, certificates, informational materials, working group reports, correspondence, and related materials posted on the FDA web site.

   Disposition: **Temporary**. Destroy or delete when superceded or obsolete.

2. **Export Applications, Export Notifications and Materials Related to the Export Firm**

   A. Official recordkeeping copies (paper or image files in PDF/TIFF) whose recordkeeping format is determined by center.

   Disposition: **Temporary**. Cutoff files at end of fiscal year. Transfer paper records copies to FRC 1 year after date of cutoff. Destroy paper copies 10 years after date of cutoff. Delete image files 10 years after date of cutoff.

   B. Copies used for scanning or data input.

   Disposition: **Temporary**. Destroy after all data elements are entered into the tracking database and scanned into the imaging system and after successful data entry is verified through quality control.

3. **Export Certificate Requests and Resulting Certificate**

Includes Certificates of Free Sale, European Union Export Health Certificates, Certificates to Foreign Government, Certificates of Exportability, Certificates of Pharmaceutical Product, and Non-clinical Research Use Only Certificate issued by FDA, CDER export declarations, and other export certificates, correspondence and related documents.

Export certificates issued under the Interagency Agreements directly by the Agricultural Marketing Service (AMS) or National Marine Fisheries Service (NMFS) for FDA to the European Union, are maintained by AMS or NMFS in accordance with their records retention policy.

A. Official recordkeeping copies (paper or image files in PDF/TIFF) whose recordkeeping format is determined by center.

Disposition: **Temporary**. Cutoff files at end of fiscal year. Transfer paper records copies to FRC 1 year after date of cutoff. Destroy paper copies 5 years after date of cutoff. Delete image files 5 years after date of cutoff.

B. Copies used for scanning or data input.

Disposition: **Temporary**. Destroy after all data elements are entered into the tracking database and scanned into the imaging system and after successful data entry is verified through quality control.

4. Export Tracking Systems

The databases contain data on the company, products, application receipt date, certificate sent date, FDA comments, and other related information, entered into the system to document and monitor the status of export applications, certificate requests, certificates, export notifications, and FDA comments. It is accessible by the unique certificate number that links to an imaging system.

A. Master Files. Each record arranged by certificate or notification number contains information about the firm, the type of document requested, the certificate and general comments. The input for the tracking system is entered manually through information obtained by 2B and 3B.

Disposition: **Temporary**. Cutoff files at end of fiscal year. Delete with related records (Items 2A, 2B, 3A and 3B) or when no longer needed for administrative or reference purposes.

B. Output Records: Printed copies of ad hoc reports, including tabulations, statistics, registers, and other tracking related information. Reports are generated for billing purposes, budget planning, at special request from other agencies and by senior management at FDA or individual centers.

Disposition: **Temporary.** File with appropriate record series or destroy/delete when no longer needed for administrative, legal, audit, or other operational purposes.

C. Documentation: Contains data dictionaries, standard operating procedures (SOPs) for data entry instructions and systems operations program codes and record layouts for the data fields, user manuals, glossaries for program terms and acronyms, and related materials needed to use and understand the export tracking system.

Disposition: **Temporary.** Destroy or delete when superseded or obsolete, or upon authorized deletion of the tracking database, whichever is sooner.

D. Back ups of Files: Daily, weekly, or monthly electronic copies of the database and retained in case that the database is damaged or inadvertently erased.

Disposition: **Temporary**. Delete when the identical record has been deleted, as authorized by this schedule, or when replaced by a subsequent backup file.

5. E-mail and Word Processing System Copies

Includes 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.

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 that are used only to produce the record-keeping copy.

Disposition: **Temporary**. Destroy/delete within 180 days after the recordkeeping copy has been produced or when it has no further archival value.

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

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