



## **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.

Tracking systems are used to document the status of export applications and certificate processing. In certain cases, an imaging system is used for ready reference.

Records copies are maintained by the program office in each center or in FDA District offices. Pre-2002 records submitted to Center for Devices and Radiological Health (CDRH) are filed under Item A2-1 in the FDA Records Control Schedule (1989 edition).

### **1. General Export Program Files**

Includes policy development documents, instructions for completing and processing export applications, export notifications, and certificates, informational materials, working group reports, standard operating procedures, correspondence, and materials posted on the FDA web site.

Disposition: Destroy or delete when cancelled or no longer referenced.

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

Disposition: Cutoff files at end of fiscal year. Transfer to FRC 1 year after date of cutoff. Destroy 10 years after date of cutoff.

### **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 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)

Disposition: Cutoff files at end of fiscal year. Transfer to FRC 1 year after date of cutoff. Destroy 5 years after date of cutoff.

#### **4. Export Image Files**

Includes imaged files scanned in PDF from original export applications, certificate request, export certificates or comments by FDA, export notifications, and related documents. Also include image files transferred to other electronic media for off-line storage and printed copies.

- A. Electronic image files used as reference copy

Disposition: Cutoff files at end of fiscal year. Delete 5 years after cutoff.

- B. Printed copies of image files

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

#### **5. Export Tracking Systems**

Includes logs, registers and other information electronically entered into the system to document the status of export applications, certificate requests, certificates, export notifications, and FDA comments.

- A. Recordkeeping electronic version

Disposition: Cutoff files at end of fiscal year. Delete 10 years after date of cutoff.

- B. Printed copies of export tracking system information including tabulations, registers, and reports.

Disposition: Destroy when they are no longer needed for administrative, legal, audit, or other operational purposes.

#### **6. 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: 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: Destroy/delete when dissemination, revision, or updating is completed.