

NOTICE - SOME ITEMS SUPERSEDED OR OBSOLETE

Schedule Number: NC1-088-83-02

Some items in this schedule are either obsolete or have been superseded by new NARA approved records schedules. This information is accurate as of: 11/14/2022

ACTIVE ITEMS

These items, unless subsequently superseded, may be used by the agency to disposition records. It is the responsibility of the user to verify the items are still active.

All other items not listed below are active.

SUPERSEDED AND OBSOLETE ITEMS

The remaining items on this schedule may no longer be used to disposition records. They are superseded, obsolete, filing instructions, non-records, or were lined off and not approved at the time of scheduling. References to more recent schedules are provided below as a courtesy. Some items listed here may have been previously annotated on the schedule itself.

Item B-6 is superseded by N1-088-96-003, item B-6.

Item B-7 is superseded by N1-088-96-003, item B-7.

Item B-10 is superseded by N1-088-96-003, item B-10.

Item B-11 is superseded by N1-088-96-003, item B-11.

Item B-13 is superseded by N1-088-96-003, item B-13.

Item B-16 is superseded by N1-088-96-003, item B-16.

REQUEST FOR RECORDS DISPOSITION AUTHORITY
(See Instructions on reverse)

LEAVE BLANK	
JOB NO.	NCL-88-83-2
DATE RECEIVED	6-28-83
NOTIFICATION TO AGENCY	
In accordance with the provisions of 44 U.S.C. 3303a the disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10.	
8-22-83 <i>Date</i>	<i>Robert K. Wain</i> <i>Archivist of the United States</i>

TO: GENERAL SERVICES ADMINISTRATION,
NATIONAL ARCHIVES AND RECORDS SERVICE, WASHINGTON, DC 20408

1. FROM (AGENCY OR ESTABLISHMENT) Department of Health and Human Services	
2. MAJOR SUBDIVISION Public Health Service	
3. MINOR SUBDIVISION Food and Drug Administration	
4. NAME OF PERSON WITH WHOM TO CONFER <i>Jacquelyn Tolson</i> Jacquelyn Tolson	5. TEL. EXT. 301 443-2055

6. CERTIFICATE OF AGENCY REPRESENTATIVE.

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposal of the agency's records; that the records proposed for disposal in this Request of 3 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified.

A Request for immediate disposal.

B Request for disposal after a specified period of time or request for permanent retention.

C. DATE 6/20/83	D. SIGNATURE OF AGENCY REPRESENTATIVE <i>George E. Deal</i> Dr. George E. Deal	E. TITLE DHHS Records Officer
7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO.
		10. ACTION TAKEN

This request is for changes to the FDA Records Control Schedule approved by the Archivist on 2/23/78, NC-1-88-78-1 and 10/9/79, NC-1-79-2. These changes are requested to reschedule the disposal of those records presently disposable on an indefinite basis. Certain other changes have also been made to update the Schedule. Items on the original schedules not listed below remain unchanged.

B-6 Establishment Licenses
Copies of licenses and supporting material consisting of application copies, resumes of responsible officials, changes of officials, production methods, plant layouts, production procedures, and new equipment. Also cover and follow-up letters, questions and answers, and related notes and correspondence with the manufacturer/establishment.

a. Active licenses
Retain in Agency space until license is revoked, suspended, or superseded.

b. Revoked, suspended, or superseded licenses
Transfer to FRC 2 years after revocation, suspension, or supersession. Destroy 10 years after revocation, etc.

Joseph B. Ruff
FDA Records Liaison Officer

115-107

6/9/83
date

34055
extension

copy sent to agency 8/23/83

12 items

STANDARD FORM 115
Revised April, 1975
Prescribed by General Services Administration
FPMR (41 CFR) 101-11.4

Items sent 8-29-83 to Dms **MASS DATA CHANGE SHEET ATTACHED**

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
B-7	<p><u>Product Licenses</u> Licenses and supporting material authorizing production of specific regulated products. Files consist of application copies, changes in production methods, questions and answers with procedures, cover and follow-up letters and related materials.</p> <p>a. <u>Active licenses</u> Retain in Agency space until license is revoked, suspended, or superseded.</p> <p>b. <u>Revoked, suspended, and superseded licenses</u> Transfer to FRC 2 years after revocation, suspension, or supersession. Destroy after 30 years after revocation, etc.</p>		
B-10	<p><u>Investigational New Drugs (Biologicals) (INDs)</u> Requests from producers in triplicate for approval to test new biological products on humans prior to marketing. Also supporting material consisting of supplements/amendments, form FD 1571, Notice of Claimed Investigational Exemption for a New Drug, related correspondence, and Agency evaluations and decisions.</p> <p>a. <u>Original IND (licensed and unlicensed products)</u> Transfer to FRC 2 years after inactivation or termination of the IND. Destroy 30 years after inactivation or termination.</p> <p>b. <u>Copies</u> Destroy 5 years after inactive or termination of IND.</p>		
B-11	<p><u>Efficacy Reviews</u> Documentation submitted by manufacturers regarding product efficacy, reviews and evaluations of material by Agency professionals, and reports on results of these reviews.</p> <p>a. <u>Reports</u> PERMANENT Offer to National Archives upon publication and when no longer needed for Agency reference.</p> <p>b. <u>Supporting material</u> Transfer to FRC 2 years after termination of review. Destroy 20 years after publication of report.</p>	WITHDRAWN	

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
B-13	<p><u>Inspection Reports on Firms of Regulatory Interest</u> Reports made on inspections of biological and blood producing establishments. Includes supporting material, follow-up actions, and related correspondence.</p> <p>a. <u>Licensed firms</u> Transfer to FRC 4 years after firm is out of business. Destroy 20 years after firm is out of business.</p> <p>b. <u>Unlicensed firms (intrastate)</u> Destroy all but two latest reports and all reports over 10 years old whether latest or not.</p>		
B-15	<p><u>Blood Establishment Inspection and Registration System</u> ADP file containing names, addresses, products, and other key data on blood establishments. Also inspection findings on collection and distribution data. File used to produce reports and statistics on types of products, functions, and discrepancies.</p> <p>Destroy (erase) when superseded by newer data.</p>		
B-16	<p><u>Adverse Experience Reports</u> Information consisting of product, producer, lot number, location, etc. on adverse biological experiences submitted by manufacturers and physicians. Key data transferred to ADP media.</p> <p>a. <u>Original</u> Destroy 10 years after submission of report or completion of corrective action, whichever is later.</p> <p>b. <u>ADP media</u> Destroy (erase) 30 years after submission of report.</p>		