Schedule Number: N1-088-87-01

Some items in this schedule are either obsolete or have been superseded by new NARA approved records schedules.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These items, unless subsequently superseded, may be used by the agency to disposition records.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SUPERSEDED AND OBSOLETE ITEMS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 They are superseded, obsolete, filing instructions, non-records, or were lined off and not approved at the time of scheduling.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Item D-5a is superseded by N1-088-08-002, item 1.2.1.
Item D-5b is superseded by N1-088-08-002, items 1.1.1 and 1.1.2.
Item D-5c is superseded by N1-088-08-002, item 1.5.
Item D-6a1 is superseded by N1-088-08-002, item 2.2.
Items D-6a2(aa) and D-6a2(bb) are superseded by N1-088-08-002, item 2.1.
Item D-7 is superseded by N1-088-05-002, item 3.

REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

LEAVE BLANK

JOB NO. N1-88-87-1

DATE RECEIVED 3-3-87

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disposal request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10. If no records are proposed for disposal, the signature of the Archivist is not required.

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	5. TELEPHONE EXT.	DATE	ARCHIVIST OF THE UNITED STATES
Linda Querec	(301)443-2055	8-26-87	

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 7 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, if required under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies, is attached.

A. GAO concurrence: ☐ is attached; or ☒ is unnecessary.

B. DATE	C. SIGNATURE OF AGENCY REPRESENTATIVE	D. TITLE
2/17/87	Dr. George Deal	DHHS Records Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM *(With Inclusive Dates or Retention Periods)*	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN *(NARS USE ONLY)*
	This request is for a change to former Bureau of Drugs records disposal instructions items D-5, D-6, D-7, and D-26 that were approved on 2/23/78 (NARS Job No. NC-1-88-78-1). The records included in these items are presently disposable on an indefinite basis. The requested change will authorize their destruction at specified times. The records included in these items are identified by sequentially assigned numbers. This Agency transfers an average of 678 cubic feet of NDAs (item D-5), 302 feet of INDs (item D-6), and 123 feet of ANDAs (item D-26) to the Washington National Records Center each year. No Drug Master Files have been transferred since 1979. There are over 20,000 cubic feet of records in these four files presently stored at the Center. Delores D. Willis FDA Records Management Officer 2-12-87 date 443-4055 extension Copy to agency 9-8-87 Copy to NCF 9-9-87 TRT		20 items

115-108

NSN 7540-00-634-4064

STANDARD FORM 115 (REV. 8-83)
Prescribed by GSA
FPMR (41 CFR) 101-11.4

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARS USE ONLY)
1.	D-5 New Drug Applications (NDA's) Files including Abbreviated New Drug Applications (ANDA's) and Antibiotic Forms 5 and 6. Applications (Form FDA 356H), in triplicate, from drug producers for approval to market new drugs in interstate commerce. Includes case reports (clinical data), test results, labeling, progress and other reports, and adverse reactions. Also notices of termination/withdrawal/approval, FDA evaluations and recommendations supporting these notices, with related correspondence and other material. a. Original applications disapproved by FDA or withdrawn by applicant before approval, and related material. (1) Case reports. Cutoff when disapproved or withdrawn. Transfer to WNRC monthly, after cutoff. Destroy 7 years after cutoff. (2) Other application material. Cutoff when disapproved or withdrawn. Transfer to WNRC monthly, after cutoff. Destroy when 7 years old, EXCEPT: (a) applications on which the sponsor resubmits a disapproved/withdrawn application with revised or additional documentation. (On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted and the date of final action.) Destroy 7 years after final action taken on revised application if it is again disapproved or withdrawn.	NC1-88-78-1/ D-5 and D-26.	

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARS USE ONLY)

(b) applications involving new chemical entities that were disapproved or withdrawn because of safety problems.

(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted. After the application is reconsidered for approval, disapproval, or withdrawal, FDA will notify WNRC of the action taken and the records destroyed as prescribed under D-5a above or D-5b below. FDA will review the excepted records at least every 5 years to determine if any files are no longer excepted and may be destroyed.)

(c) applications having unusual historical/scientific interest to FDA.

(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted.)

(i) applications withdrawn from WNRC.

Destroy in agency when no longer needed for research purposes.

(ii) applications not withdrawn from WNRC.

Destroy 8 years after cutoff.

b. Original applications approved by FDA, with related material.

(1) Case reports.

Cutoff when approved by FDA.

Transfer to WNRC monthly, after cutoff.

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARS USE ONLY)

Destroy 10 years after cutoff EXCEPT:

(a) case reports supporting applications for which safety issues are currently being considered.

(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted. FDA will review the excepted records at least every 5 years to determine which files are no longer excepted and may be destroyed.

(b) case reports supporting applications having unusual historical/scientific interest to FDA.

(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted.)

(i) applications withdrawn from WNRC.

Destroy in agency when no longer needed for research purposes.

(ii) applications not withdrawn from WNRC.

Destroy 11 years after cutoff.

(2) Other application material.

Cutoff when approved by FDA.

Transfer to WNRC monthly, after cutoff.

(a) applications for which approval has been revoked or withdrawn after approval.

(FDA will notify WNRC when this

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARS USE ONLY)

action occurs. The agency will review the file at least every 5 years to determine if this action occurred.)

Destroy 10 years after revoked or withdrawn after approval EXCEPT:

(i) those applications for which approval was revoked or withdrawn because of safety problems or used for orphan drug indications.

(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted. FDA will review the excepted records at least every 5 years to determine which files are no longer excepted and may be destroyed.

(ii) those aplications having unusual historical/ scientific interest to FDA.

(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted.)

(aa) applications withdrawn from WNRC.

Destroy in agency when no longer needed for research purposes.

(bb) applications not withdrawn from WNRC.

Destroy 11 years after revoked or withdrawn after approval.

(b) other approved applications.

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARS USE ONLY)
	Retain until approval has been revoked or withdrawn after approval.		
	c. Duplicate and triplicate copies of all applications.		
	Destroy when original is transferred to WNRC.		
2.	D-6 Notice of Claimed Investigational Exemption a.k.a. Investigational New Drug's (IND's) Files	NC1-88-78-1/ D-6	
	Applications (Form FDA 1571), in triplicate, from drug producers to ship in interstate commerce and test new drugs on human subjects. Including amendments, formulations, progress and other reports, changes, FDA evaluations and recommendations, and related correspondence and material.		
	a. Original.		
	Cutoff when investigation has been discontinued or terminated or when no communication has been received from the sponsor for 3 years and the investigation is presumed to have been abandoned.		
	Transfer to WNRC monthly after cutoff.		
	Destroy 7 years after cutoff EXCEPT:		
	(1) those IND's that FDA determines were discontinued, terminated, or abandoned because of safety problems, or were used for orphan drug indications; or IND's sponsored other than by an individual investigator and FDA determines that they contain a new chemical entity or there is another IND pending from the sponsor for the drug that contains revised or additional documentation.		
	(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted. FDA will review the excepted records at least every 5years to determine which files are no longer excepted and may be destroyed.		

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARS USE ONLY)

(2) those applications having unusual historical/scientific interest to FDA.

(On receipt of 90 day disposal notice from WNRC, the FDA will notify WNRC which accessions and box numbers are excepted.)

(aa) applications withdrawn from WNRC.

Destroy in agency when no longer needed for research purposes.

(bb) applications not withdrawn from WNRC.

Destroy 8 years after cutoff.

b. Duplicate and triplicate copies.

Destroy when original is transferred to WNRC.

3. D-7 Drug Master Files.

NC1-88-78-1/D-7

Privileged information, in triplicate, concerning and provided by drug producers such as personnel involved, facilities, production methods, and drug formulations.

a. Original.

Cutoff when initial review is completed and file is no longer active.

Transfer to WNRC 1 year after cutoff.

Destroy 15 years after cutoff.

(On receipt of 90 day disposal notice from WNRC, FDA will review the records to ensure that no submissions and/or authorizations (permission to an applicant from the producer who originally provided the information to use this information in support of the applicant's NDA) to refer to the file have been received since transfer to WNRC. FDA will notify WNRC if such files are noted and indicate the updated disposal date for the affected records.)

I concur w t t e revisions to this schedule.

Deborah Tickle — 6-16-87

Agency Representative — Date

FDA Records Management Officer

Ronald Pilgrim — 17 Jun 87

NARA Appraiser — Date