REQUEST FOR RECORDS DISPOSITION AUTHORITY
(See Instructions on reverse)

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JOB NO: NC1-88-83-5
DATE RECEIVED: 7-8-83

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: Jaquelyn Tolson, PHS Records Officer
5. TEL EXT: 443-2055

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disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10

7-17-84 (Date) — Archivist of the United States

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 11 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	D. SIGNATURE OF AGENCY REPRESENTATIVE	E. TITLE
6/28/83	Dr. George E. Deal	DHHS Records Management 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 Food and Drug Administration Records Control Schedules approved by the Archivist on February 23, 1978 (NARS job No. NC 1-88-78-1) and on October 9, 1979 (NARS job No. 1-88-79-2). These changes are to reschedule the disposal of certain records presently disposable on an indefinite basis and to update the Schedule in general. The items listed include those files originated by the Offices of Drugs and New Drug Evaluation.		
1. (D-1)	Drug Study Evaluation Reports Results of statistical analyses and other evaluations made in the course of studies of various drugs to determine their safety and efficacy. May include actual analyses material in addition to final reports.		
	a. Original reports Transfer to a Federal Records Center 5 years after completion of study. Destroy 20 years after completion of study.	NC1-88-78-1/D-1	
	b. Report copies Destroy 1 year after completion of study.		
	Joseph Reiff, FDA Records Officer — 6/22/83 (date)		37 items

115-107

34055 extension

MASS DATA CHANGE SHEET ATTACHED

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

Agency sent 8-27-84 by DMW: NCW MHF MHSR Sent 8/30/84

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
D-2	Deleted.		
2. (D-3)	DESI File DESI (Drug Efficacy Study Implementation) folders containing recommendations and proposals and related source material including initial and follow-up announcements, action step charts, accession number charts, technical publications on the drugs involved, and other references. Also, log books and bioavailability card files. This program is the review for efficacy of drugs previously reviewed only for safety. a. DESI Folders Destroy on completion of review of each product and verification of microform copy. b. Card files and Log Book Destroy at same time as related folder. c. Microform Copies Destroy 5 years after completion of entire DESI project and any resulting litigation.	NC1-88-78-1/D-3	
3. (D-4)	Clinical Investigator File Documents used to evaluate the validity of research performed by clinical investigators. Transfer to FRC 1 year after completion of evaluation. Destroy 7 years after completion of evaluation unless needed for further reference.	NC1-88-78-1/D-4	
4. (D-5)	~~New Drug Applications (NDA's)~~ Applications from drug producers for approval to market new drugs (Form FD 356H). Includes clinical data, test results, other than promotional labeling, progress and other reports, adverse reactions, notices of terminations, withdrawals or approvals, FDA evaluations and recommendations, supporting material, and related correspondence.		WITHDRAWN

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	(Disposal instructions for these records will be submitted separately.)		
5.(D-6)	Investigative New Drugs (IND's) Applications from drug producers to ship drugs in inter-state commerce for testing on human subjects (Form FD 1571). Includes amendments, formulations, progress and other reports, changes, FDA evaluations and recommendations and related correspondence. (Disposal instructions for these records will be submitted separately.)		WITHDRAWN
6.(D-7)	Drug Master Files Privileged information concerning drug producers such as personnel involved, facilities, drug formulations and production methods. (Disposal instructions for these records will be submitted separately.)		WITHDRAWN
D-8	Laboratory Services Monthly Reports Work count data for Program Management System reports. Consists of documentation regarding animal housing, glassware, and media preparations. Destroy 1 year after order has been filled.	NC1-88-78-1/D-8	
D-9	Media Requests Orders from FDA professionals for culture media (Form FD 1979). Destroy 1 year after order has been filled.	NC1-88-78-1/D-9	
D-10	Glasswares Orders Orders from FDA professionals for laboratory glassware (Form FD 1903). Destroy 1 year after order has been filled.	NC1-88-78-1/D-10	
D-11	Deleted.		

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
7. (D-12)	Standards Master and working standards for defining potency of batches of antibiotics submitted by producers. Chemical and microbiological test results conducted by FDA resulting in standard approval. Related correspondence with producers. FDA certification of standards. Destroy when superseded or no longer needed for reference.	NC1-88-78-1/D-12	
D-13	Deleted.		
8. (D-14)	Certification Records Antibiotic certifications and related analytical data.	NC1-88-78-1/D-14	
	a. Insulin certifications Destroy master lot certifications after 5 years. Destroy individual dosage certifications after 3 years.		
	b. Other antibiotic certifications Destroy source listings, both paper and microforms, on 10/1/83 or 1 year after certification, whichever is later. Destroy cross references at same time.		
	c. Rejected requests for certification Destroy 5 years after date of rejection or last action, whichever is later.		
D-15	Regulatory Testing Records Laboratory data sheets used for testing USP, NF, and IND samples. Sheets are used for completion of analysts' work sheets. Destroy 5 years after preparation or when no longer needed for reference.	NC1-88-78-1/D-15	

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7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
D-16	Proposals Proposals to do research work related to drugs received from individuals, groups, and institutions. Used to review and determine missions, goals, and objectives. Destroy 5 years after final action taken.	NC1-88-78-1/D-16	
9. (D-17)	Drug Recall Files Recommendations to take recall action, approvals, notification of action taken and extent; recall inspection reports; labels, samples, and photographs of recalled products; and related correspondences and documentation. a. Original documents Transfer to FRC 5 years after recall action is effected. Destroy 15 years after action is effected. b. Copies Destroy copies 1 year after action is effected.	NC1-88-78-1/D-17	
10. (D-18)	Drug Regulatory Activities Collection records, labeling, analytical reports, certificates and affidavits, seizure reports, termination of action reports, notices and records of hearings, recomendations, criminal prosecution records, regulatory letters, injunctions and related documents pertaining to individual seizure actions. Transfer to FRC 5 years after a judgement has been entered or the seized products have been either destroyed, reconditioned, or released pursuant to a deposition of the case, whichever is later. Destroy 20 years after judgement or desposition.	NC1-88-78-1/D-18	

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
D-19	Daily Regulatory and Compliance Reports Format type reports listing each seizure, voluntary and involuntary recall, and other enforcement action taken against unsafe or ineffective drug products. Destroy 5 years after preparation of report.	NC1-88-78-1/D-19	
11. (D-20)	Drug Product Problem Reports Reports received by FDA in conjunction with USP/FDA Drug Product Defect Reporting System and Laboratory Product Problem Reporting system. This is a joint effort with the United States Pharmacopeia to ascertain what drugs and categories of drugs have above normal defects and laboratory testing difficulties. Destroy 5 years after receipt of report.	NC1-88-78-1/D-20	
12. (D-21)	Methadone Hospital Files Jackets from each hospital receiving shipments of methadone containing applications to administer it, related correspondence, and reports on use and results. Transfer to FRC 2 years after application is withdrawn or revoked. Destroy 7 years after application is withdrawn or revoked.	NC1-88-78-1/D-21	
13. (D-22)	Methadone Treatment Program Jackets containing applications requesting approval to administer methadone in the treatment of drug addiction by clinics, doctors, etc. correspondence with them, establishment inspection reports, and other reports. Transfer to FRC 2 years after application is withdrawn or revoked. Destroy ~~[illegible] transferred to FRC~~. 9 years after application is withdrawn or revoked. (telephone agreement, Linda Henry and Agnes Slavich, 7/5/84) ~~[illegible]~~	NC1-88-78-1/D-22	

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14. (D-23)	Drug Registration File Official establishment registration (Forms FD 1597 and 2656) from all drug producers and the distributors submitted annually in compliance with the Kefauver-Harris Amendment of 1962. Destroy 10 years after submission.	NC1-88-78-1/D-23	
15. (D-24)	Drug Listing Labeling File Labels and advertising material on certain drugs submitted in accordance with the Drug Listing Act of 1972 and the Survey of Marketed Drugs. Destroy 10 years after submission.	NC1-88-78-1/D-24	
D-25	Deleted		
16. (D-26)	~~Abbreviated New Drug Applications (ANDA's)~~ ~~Applications to produce drugs already approved for other manufacturers. File contents similar but less extensive than NDA's (see item D-5).~~ (Disposal instructions for these records will be submitted separately.)		WITHDRAWN
17. (D-27)	Form A File Drug container labels and evidence submitted by manufacturers to substantiate the efficacy of drugs first approved during the period 1938-1962. Material is used to evaluate the efficacy of these products in light of improved analytical methods. Destroy 5 years after completion of DESI project and any resulting litigation.	NC1-88-78-1/D-27	
18. (D-28)	Drug Experience Reports Original and duplicate (pink) copies of FD 1639, Drug Experience Report, describing effects and circumstances of adverse reactions on users of drug products. Also, microform copies of these reports made by FDA. Reports	NC1-88-78-1/D-28	

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	submitted by drug manufacturers and suppliers in conjunction with their NDA's (see item D-5) or independently by physicians, hospitals, etc., of the medical community. Used to evaluate the safety of drug products.		
	a. ~~Original forms submitted by manufacturers & producers~~ File in appropriate NDA jacket after initial processing and retire as indicated in item D-5.		WITHDRAWN
	b. Original forms submitted by the medical community Destroy after initial processing, including microfilming.		
	c. Duplicate Copies Destroy after initial processing.		
	d. Microform copies Destroy 30 years after submission of report unless needed for further study.		
19.(D-29)	Advertisements and Promotional Labeling Copies of nonviolative advertisements and promotional labels for prescription drugs, including reminders, and which may be on film or tape. Also, Form FD 2253, Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use. Destroy 2 years after completion of review.	NC1-88-78-1/D-29	
20.(D-30)	ASTRO-4 Drug Information System (ADP) This system maintains a file of data on new drug applications (NDA's) and investigational new drugs (IND's) which includes such items as drug manufacturers, drug names, drug usage information, and status of drug applications. Used to generate reports which aid in the IND/NDA review process and for compliance purposes.	NC1-88-79-2/D-30	

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	Destroy (by erasure) individual data elements 10 years after entry.		
21.(D-31)	New Drug Evaluation Management Information System (ADP) This system maintains information relative to the receipt and review of investigational new drugs (IND's), new drug applications (NDA's), and related types of submissions. Destroy (by erasure) individual data elements 10 years after entry.	NC1-88-79-2/D-31	
22(D-32)	Radioactive Drug Research Information System (ADP) This system maintains information relative to the receipt and review of submissions from radioactive drug research committees. Destroy (by erasure) individual data elements 10 years after entry.	NC1-88-79-2/D-32	
23(D-33)	Drug Product Defects (ADP) This system maintains a comprehensive file of problem data collected on drug products to determine whether the problem is peculiar to the product itself, might occur in other products made by that company, or if the problem is an industry-wide phenomenon. Destroy (by erasure) individual data elements 10 years after entry.	NC1-88-79-2/D-33	
24(D-34)	Bioresearch Monitoring Information System (ADP) This system maintains data files on clinical investigators and will maintain data on clinical and nonclinical facilities associated with an investigational new drug (IND). Data will be updated periodically and reports prepared which will facilitate the monitoring of human drug trial efforts. Destroy (by erasure) individual data elements as they are updated or 10 years after entry, whichever is sooner.	NC1-88-79-2/D-34	

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25 (D-35)	OTC Information System (ADP) This system will maintain data on regulatory actions, correspondence with drug manufacturers and review panels, comments on proposed monographs, and bibliographic citations relative to the establishment of OTC drug monographs. Destroy (by erasure) individual data elements 10 years after entry.	NC1-88-79-2/D-35	
26 (D-36)	Drug Experience Information System (ADP) This system maintains data files consisting of adverse reactions to marketed drugs as reported by manufacturers, hospitals, and physicans. Tables are generated showing adverse reaction and/or drug interactions, as well as other reports in response to specific requests. Destroy (by erasure) individual data elements 30 years after entry.	NC1-88-79-2/D-36	
D-37	Drug Efficacy Study Implementation Data System (ADP) This system maintains data related to drug products studied by the National Academy of Science/National Research Council as a result of the 1962 amendments to the Food, Drug, and Cosmetic Act. Reports are generated to assist the Agency with administration of the Drug Efficacy Study Implementaction (DESI) project. Destroy (by erasure) entire file 5 years after termination of DESI program, and any resulting litigation.	NC1-88-79-2/D-37	
27 (D-38)	Drug Abuse Treatment Monitoring Information System (ADP) This system maintains data files on the use of methadone and other treatment modalities in drug abuse treatment programs. The file includes historical data, the results of periodic Agency inspections, staffing, and annual report information.	NC1-88-79-2/D-38	

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28 (D-39)	Biopharmaceutical Review Management Information System (ADP) This system maintains a data base of information pertaining to all new drug applications (NDA's), investigational new drugs (IND's), abbreviated new drug applications (ANDA's) and Antibiotic forms 5 and 6 that have completed biopharmaceutical review. Destroy (by erasure) individual data elements 10 years after entry.	NC1-88-79-2/D-39	
29 (D-40)	Poison Control System (ADP) This system provides immediate response to selected poison control centers using cathode ray tubes on questions concerning the accidental ingestion of household products and medicines. Destroy (by erasure) individual data elements 30 years after entry.	NC1-88-79-2/D-40	
D-41	Deleted.		

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