NOTICE - SOME ITEMS SUPERSEDED OR OBSOLETE

Schedule Number: NC1-088-83-05

Some items in this schedule are either obsolete or have been superseded by new NARA approved records schedules.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These items, unless subsequently superseded, may be used by the agency to disposition records.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SUPERSEDED AND OBSOLETE ITEMS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 They are superseded, obsolete, filing instructions, non-records, or were lined off and not approved at the time of scheduling.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Item 2 is superseded by N1-088-05-002, item 1. Items 3 and 10 are superseded by N1-088-09-001, items 1.1.1, 1.1.2, and 1.1.3.. Item 9 superseded by N1-088-05-001, item 6. Item 14 is superseded by N1-088-07-002, items 5.2 and 6.1. Item 20 is superseded by N1-088-06-002, item 2. Item 24 is superseded by N1-088-09-001, item 1.6.3. Item 25 is superseded by N1-088-05-002, item 4.1. Item 26 is superseded by N1-088-07-002, item 5.3.2.

(See Instructions on reverse) JOB NO. NOTIFICATION TO AGENCY PUBLIC Health Service NOTIFICATION TO AGENCY PUBLIC Health Service AMJOB SUBDIVISION PO. PUBLIC Health Service Jacuelyn Tolson PTISE Records Officer Answer Prepresentative 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	•	EQUEST FOR RECORDS DISPOSITION AU	THORITY	· · ·	LEAVE BLANK	
TO: GENERAL SERVICES ADMINISTRATION, MITMAL ARCHIVES AND RECORDS SERVICE. WASHINGTON, DC 20408 DATE RECEIVED FROM (AGENCY OR ESTABLISHENT) Department of Health and Human Services Date RECEIVED A MORE SUBJECTIVE OR ESTABLISHENT) Department of Health and Human Services Date RECEIVED HUDDIC Health Service Date Service and the personal of the service of t		(See Instructions on reverse)				<u> </u>
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Jacuelyn Tolson Query 443-2055 7-17-54 1/2-91				be stamped "disposa! no	t approved" or "withdr	awn" in column
PHS Records Officed Import of Account of the United States 6. CREMICATE OF ACENCY REPRESENTATIVE Ihereby 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 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 disposal after a specified period of time or request for permanen retention. B Request for disposal after a specified period of time or request for permanen retention. C. DATE D StoMyDue or AGENCY PEPRESENTATIVE E TILE Management DHHS Records/Officer C. DATE D StoMyDue or AGENCY PEPRESENTATIVE E TILE Management DY: D StoMyDue or AGENCY PEPRESENTATIVE E TILE Management DY: D StoMyDue or AGENCY PEPRESENTATIVE E TILE Management DY: D StoMyDue or AGENCY PEPRESENTATIVE E TILE Management DY: D StoMyDue or AGENCY PEPRESENTATIVE E TILE Management DY: D StoMyDue or AGENCY PEPRESENTATIVE E TILE Management	4. NAME OF	PERSON WITH WHOM TO CONFER			KIDA	V.
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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-2	Deleted.		
Д. (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.	NC1-88-7	3 - 1/D-3
	a. <u>DESI Folders</u>		
	Destroy on completion of review of each product and verification of microform copy.		×
	b. <u>Card files and Log Book</u>		
	Destroy at same time as related folder.		
	c. <u>Microform Copies</u>		,
	Destroy 5 years after completion of entire DESI project and any resulting litigation.		
3. (D-4)	Clinical Investigator File		
	Documents used to evaluate the validity of research performed by clinical investigators.	NC1-88-78	-1/D-4
	Transfer to FRC 1 year after completion of evaluation. Destroy 7 years after completion of evaluation unless needed for further reference.		
4.(D-5)	New Drug Applications (NDA's)		
	Applications from drug producers for approval to market new drugs (Form ED 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
115-203	Four copies, including original, to be submitted to the National Archives	Revised Ju	D FORM 115-A ily 1974 I by General Serv

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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.	•	WITHDRAWN
	(Disposal instructions for these records will be submitted separately.)		
6.(D-7)	Drug Master Files		
	Privileged information concerning drug producers such as personnel involved, facilities, drug formulations and production methods.		WITHDRAWN
	(Disposal instructions for these records will be submitted separately.)		
D-8	Laboratory Services Monthly Reports		
	Work count data for Program Management System reports. Consists of documentation regarding animal housing, glassware, and media preparations.	NC1-88-78	3-1/D-8
	Destroy 1 year after order has been filled.	•	
D-9	Media Requests		
	Orders from FDA professionals for culture media (Form FD 1979).	NC1-88-78	3-1/D-9
	Destroy I year after order has been filled.		
D-10	<u>Glasswares Orders</u>		
	Orders from FDA professionals for laboratory glassware (Form FD 1903).	NC1-88-78	-1/D-10
	Destroy 1 year after order has been filled.		
D-11	Deleted.		
115-203	Four copies, including original, to be submitted to the National Archives	STANDARI Revised Ju	D FORM 115-A ly 1974
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Request	or Records Disposition JOB N	0.	PAGE OF	- 11
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 Л. (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.	NC1-88-78	3 - 1/D-12	
	Destroy when superseded or no longer needed for reference.			
D-13	Deleted.			
8.(D-14)	Certification Records			
	Antibiotic certifications and related analytical data.	NC1-88-78	3-1/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.	NC1-88-78	3-1/D-15	
	Destroy 5 years after preparation or when no longer needed for reference.			
115-203	Four copies, including original, to be submitted to the National Archives	STANDARI Revised Ju	D FORM 115-A	
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7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)		9. Sample or JCB NO	10. Action take
D-16	<u>Proposals</u> Proposals to do research work related to drugs re from individuals, groups, and institutions. Used review and determine missions, goals, and object	d to	NC1-88-78	-1/D-16
. (D-17)	Destroy 5 years after final action taken. Drug Recall Files Recommendations to take recall action, approvals, notification of action taken and extent; recall inspection reports; labels, samples, and photogra recalled products; and related correspondences ar documentation.	aphs of	NC1-88-7	3–1/D–17
	 a. <u>Original documents</u> Transfer to FRC 5 years after recall action in effected. Destroy 15 years after action is effected. b. <u>Copies</u> Destroy copies 1 year after action is effected 			
0. (D-18)	Drug Regulatory Activities Collection records, labeling, analytical reports, certificates and affidavits, seizure reports, termination of action reports, notices and record hearings, recomendations, criminal prosecution re regulatory letters, injunctions and related docum pertaining to individual seizure actions.	s of cords,	NC1-88-7	8–1/D–18
	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.			
115-203	Four copies, including original, to be submitted to the National .	Archives	Revised Ju	D FORM 115-A Jy 1974 5 by General Sei

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D-19	Daily Regulatory and Compliance Reports	•		
	Format type reports listing each seizure, voluntar involuntary recall, and other enforcement action t against unsafe or ineffective drug products.	y and aken	NC1-88-78	-1/D-19
	Destroy 5 years after preparation of report.			
(D-20)	Drug Product Problem Reports			
	Reports received by FDA in conjunction with USP/FD Drug Product Defect Reporting System and Laborator Product Problem Reporting system. This is a joint effort with the United States Pharmacopeia to ascertain what drugs and categories of drugs have normal defects and laboratory testing difficulties	y above	NC1-88-	′8–1/D–20
	Destroy 5 years after receipt of report.			
(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 res	, ults.	NC1-88-7	-1/D-21
	Transfer to FRC 2 years after application is withdn or revoked. Destroy 7 years after application is withdrawn or revoked.	rawn		
(D-22)	Methadone Treatment Program		NC1-88-	8-1/D-22
	Jackets containing applications requesting approval administer methadone in the treatment of drug addic by clinics, doctors, etc. correspondence with them, establishment inspection reports, and other reports	tion		
	Transfer to FRC 2 years after application is withdr or revoked. Destroy	awn		
	(telephone agreement, Linda Henry and Agnes Slavich, 7/5/84)			
115-203	Four copies, including original, to be submitted to the National A	rchives	Revised Ju	by General Sei

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7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	I	9. SAMPLE OR JOB NO	10. ACTION TAKEN
14. (D-23)	Drug Registration File		NC1-88-7	9_1/p_22
-	Official establishment registration (Forms FD 159 2656) from all drug producers and the distributor submitted annually in compliance with the Kefauver-Harris Amendment of 1962.	7 and s	NC1-00-7	
	Destroy 10 years after submission.			
15. (D-24)	Drug Listing Labeling File		-	
	Labels and advertising material on certain drugs submitted in accordance with the Drug Listing Act 1972 and the Survey of Marketed Drugs.	of	NC1-88-7	8–1/D–24
	Destroy 10 years after submission.			
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 le extensive than NDA's (see item D-5).	r 255		WITHDRAWN
× j	(Disposal instructions for these records will be submitted separately.)			
17. (D-27)	Form A File			
	Drug container labels and evidence submitted by manufacturers to substantiate the efficacy of drug first approved during the period 1938-1962. Mater is used to evaluate the efficacy of these products light of improved analytical methods.	ial	NC1-88-7	8–1/D–27
	Destroy 5 years after completion of DESI project a any resulting litigation.	Ind		
18. (D-28)	Drug Experience Reports			
	Original and duplicate (pink) copies of FD 1639, D Experience Report, describing effects and circumst of adverse reactions on users of drug products. A microform copies of these reports made by FDA. Re	ances Iso.	NC1-88-7	-1/D-28
115-203	Four copies, including original, to be submitted to the National A	Archives	STANDARI Revised Ju	D FORM 115-A
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Request fo	or Records Disposition Authority-Continuation	JOB NO.	PAGE OF 8 11
7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retantion Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
	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 c 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 communit	<u>y</u>	
	Destroy after initial processing, including microfilming.	×	
	c. <u>Duplicate Copies</u> Destroy after initial processing.		
	d. <u>Microform copies</u>		
	Destroy 30 years after submission of report unle needed for further study.	SS	
l.(D-29)	Advertisements and Promotional Labeling		
	Copies of nonviolative advertisements and promotiona labels for prescription drugs, including reminders, which may be on film or tape. Also, Form FD 2253, Transmittal of Advertisements and Promotional Labeli for Drugs for Human Use.	and -	-1/D-29
	Destroy 2 years after completion of review.		
(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, a status of drug applications. Used to generate repor which aid in the IND/NDA review process and for compliance purposes.		-27D-30
115-203	Four copies, including original, to be submitted to the National Arci	Revised Jul	by General Service

Administration FPMR (41 CFR) 101-11.4

Request f	or Records Disposition Authority-Continuation	0.	PAGE OF	11
7. ITEM NO	B. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKE	EN
	Destroy (by erasure) individual data elements 10 years after entry.			
2 <u>(</u> D-31)	<u>New Drug Evaluation Management Information System (ADP)</u> This system maintains information relative to the receipt and review of investigational new drugs (IND's),	NC1-88-79	-2/D-31	
	new drug applications (NDA's), and related types of submissions.	• .	-	
	Destroy (by erasure) individual data elements 10 years after entry.			
2 2 (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.	NC1-88-79	-2/D-32	
	Destroy (by erasure) individual data elements 10 years after entry.			
?3(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.	NC1-88-79	-2/D-33	
	Destroy (by erasure) individual data elements 10 years after entry.			
4 (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.	NC1-88-79	-2/D-34	
	Destroy (by erasure) individual data elements as they are updated or 10 years after entry, whichever is sooner.			
115-203	Four copies, including original, to be submitted to the National Archives	STANDARD Revised Jul	FORM 115-A	
			by General Servi	ice

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7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)		9. Sample or Job No	10. ACTION TAKE
25 (D-35	OTC Information System (ADP)	-		
	This system will maintain data on regulatory acti correspondence with drug manufacturers and review panels, comments on proposed monographs, and bibliographic citations relative to the establish of OTC drug monographs.	-	NC1-88-79	-2/D-35
	Destroy (by erasure) individual data elements 10 after entry.	years		
26 (D - 36	Drug Experience Information System (ADP)			
	This system maintains data files consisting of adv reactions to marketed drugs as reported by manufacturers, hospitals, and physicans. Tables a generated showing adverse reaction and/or drug interactions, as well as other reports in response specific requests.	ire	NC1-88-7	9-2/D-36
	Destroy (by erasure) individual data elements 30 y after entry.	ears		
D-37	Drug Efficacy Study Implementation Data System (AD	P)/		
	This system maintains data related to drug product studied by the National Academy of Science/Nationa Research Council as a result of the 1962 amendment the Food, Drug, and Cosmetic Act. Reports are generated to assist the Agency with administration the Drug Efficacy Study Implementaction (DESI) pro	s 1 s to	NC1-88-79	2/D-37
	Destroy (by erasure) entire file 5 years after termination of DESI program, and any resulting litigation.			
7 (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 ab treatment programs. The file includes historical d the results of periodic Agency inspections, staffin and annual report information.	use	NC1-88-79	-2/D-38
115-203	Four copies, including original, to be submitted to the National Arc	hives	Revised July	by General Servi

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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
	Destroy (by erasure) individual data elements 10 y after entry.	ears		orer.
2 8(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 applications (ANDA's) and Antibiotic forms 5 and 6 have completed biopharmaceutical review.	drua	NC1-88-79	-2/D-39
	Destroy (by erasure) individual data elements 10 ye after entry.	ears		
29(D-40)	<u>Poison Control System (ADP)</u> 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 yea after entry.		NC1-88-79	-2/D-40
D-41	Deleted.		•	
146, 200	Four copies instudios original to be submitted to the National Ar		STANDADO	FORM 115-A
115-203	Four copies, including original, to be submitted to the National Arc Gittl: 1975 () = 579-387	L111∓€ 3	Revised Jul Prescribed Administr	y 1974 by General Services