Schedule Number: NC1-088-79-01

Some items in this schedule are either obsolete or have been superseded by new NARA approved records schedules.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These items, unless subsequently superseded, may be used by the agency to disposition records.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SUPERSEDED AND OBSOLETE ITEMS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 They are superseded, obsolete, filing instructions, non-records, or were lined off and not approved at the time of scheduling.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Item R-6 is superseded by N1-088-06-003, item 4.1.
Items R-8a, R-8b, R-16, and R-18 are superseded by N1-088-09-003, item 1.3.
Item R-9 is superseded by N1-088-09-001, item 1.5.
Item R-10 is superseded by N1-088-09-002, item 3.1.
Item R-11 is superseded by N1-088-05-001, item 6.
Items R-14a, R14b, R15a, R-15b, and R-17 are superseded by N1-088-09-003, items 3.2.1 3.2.2.
Item R-19 is superseded by N1-088-09-003, item 3.3.3.
Items R-20a and R-21a are superseded by N1-088-09-003, item 2.1.1 and 2.1.3.
Item R-20b is superseded by N1-088-09-003, item 2.1.3.

(See Instructions on reverse) Rec'd NCI 10 Jul 79 NF

LEAVE BLANK

JOB NO. NC1-88-79-1

DATE RECEIVED 11 JUL 1979

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

1. FROM (AGENCY OR ESTABLISHMENT)
Department of Health, Education, and Welfare

2. MAJOR SUBDIVISION
Public Health Service

3. MINOR SUBDIVISION
Food and Drug Administration - Field Offices

4. NAME OF PERSON WITH WHOM TO CONFER
Joseph S. Reiff

5. TEL. EXT.
443-4055

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disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10.

7-17-79
Date

James E. O'Neill
acting 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 13 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
6/13/79	Norman E. Shipp	Chief, Management Methods Branch, DMS FDA Records Control Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
	The mission of the Food and Drug Administration (FDA) is to protect the public health of the Nation as it may be impaired by foods, drugs, biological products, cosmetics, medical devices, ionizing and nonionizing radiation-emitting products and substances, poisons, pesticides, and food additives. FDA's regulatory functions are geared to insure that: foods are safe, pure, and wholesome; drugs, medical devices, and biological products are safe and effective; cosmetics are harmless; all of the above are honestly and informatively packaged; and that exposure to potentially injurious radiation is minimized. FDA's field operation is organized into ten Regional Field Offices. When warranted by workload or geographic size, a region may be further organized into District Offices, and Resident Inspection Posts. A field office may execute some or all of the following functions: 1. Obtain compliance with laws and regulations enforced by FDA, and initiate and conduct educational and voluntary compliance programs. 45 items.	B-620 See attached sheet for corresponding items	

115-107

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

sent to all FRC's, NNF & Agency 8-2-79

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
	2. Conduct investigations and inspections, and analyze samples of foods, drugs, and other commodities for which FDA has regulatory responsibility. 3. Conduct administrative hearings on alleged violations, and initiate appropriate enforcement action. 4. Recommend legal action and assist in implementing approved action. 5. Provide analytical and inspectional support in programs for which FDA has responsibility. 6. Provide assistance to States and localities in the event of a national disaster or other emergency requiring FDA assistance.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-1	General Subject Record copies of outgoing correspondence, incoming correspondence, memoranda for record, plans, reports, speeches, agendas, minutes of meetings and conferences, and essential backup material. Note: Certain of these documents which relate to specific firms, products, persons, or events will be placed in other files as appropriate and disposed of according to the disposition instructions for these files. Correspondence and other material having limited or no record value such as acknowledgements, thank you letters, and replies to routine requests will not be placed in the General Subject file. Cut off file at the end of each fiscal year and destroy 10 years after cutoff date.		
R-2	Correspondence Nonrecord copies of the above documents. Also known as chronological, reading, snoop, or day files. Destroy when no longer needed for reference, not to exceed 1 year after action completed.		
R-3	Transitory Correspondence and other material having limited value for short periods of time thereafter. Destroy 1 year after creation.		
R-4	Indexes Cards and logs listing various documents for cross referencing, locating, control, report preparation, and proof of action taken. a. Indexes used for control and report preparation: Destroy when no longer needed for action, not to exceed 1 year. b. Indexes used for other purposes: Destroy at same time as referenced documents.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-5	References Nonrecord material maintained by offices and individuals including regulations, procedures, guidelines, precedent material, publications, articles, catalogs, correspondence not described above, and related material. Review annually. Destroy all material no longer needed at time of review.		
R-6	Working Papers Drafts of reports, correspondence, and other papers, rough and informal notes, comments, and preliminary worksheets which are not part of any official records or do not represent significant basic steps in their preparation. Destroy at such time as the user determines they are no longer needed, not to exceed one year after action is completed. Note: In any discrepancy between this instruction and Agency or other regulations, the disposal instructions in the regulations shall apply.		
R-7	Establishment Files Jacketed records containing material on each firm and facility in the geographic area over which FDA has jurisdiction. Contains copies of licenses and registrations; Establishment Inspection Report (Form FD 481CG) and other reporting forms with attachments; Notices of Inspections (Form FD 482); Lists of Observations (Form FD 483); Receipts for Samples (Form FD 484); narrative reports, exhibits; photographs; collection reports and Analyst's Work Sheets for Factory Samples; and Interstate Travel Checklist Reports. Also may contain correspondence relating to the firm or facility; consumer complaints (Forms FD 2516 and 2516a or narrative formats); Investigational Reports; Surveillance Reports; Information Letter copies and firms' responses; Regulatory Letter copies including copies of firms' responses and FDA final decisions; copies of seizure recommendations including Headquarters responses; Reports of Seizure Accomplishment and Notice of Status of Decree;		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-7 (Continued)	copies of memoranda to Headquarters recommending citation and including Headquarters responses; Notices of Hearing (Form FD 466) and Records of Hearing; copies of cover memoranda for prosecution recommendation including Headquarters responses; Termination of Prosecution Reports; copies of cover memoranda for injunction recommendations and Headquarters responses; copies of temporary abeyance letters; and copies of recall summaries. a. Documents pertaining to firms that have gone out of business or are of no further regulatory interest: Transfer to Federal Records Center 2 years after occurrence. Destroy 10 years after occurrence. b. Documents pertaining to firms of continuing interest that are used in day-to-day operation: Destroy 10 years after date of creation. Maintain in the active files until destroyed. c. Documents pertaining to firms of continuing interest that are not used in day-to-day operation: Transfer to Federal Records Center 1 year after date of creation or receipt, whichever is later. Destroy 10 years after date of creation or receipt.		
R-8	Potential Obligation Firms Documents relating to firms that are not presently under FDA surveillance but may be at a future date. Includes state or local government inspection material, compliance, and correspondence relating to the firms. a. Material on firms that are brought under FDA surveillance: Transfer to Establishment Files (R-7) at time surveillance begins. b. Material on firms that are not brought under FDA surveillance: Review file annually. Destroy material over 3 years old.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-9	Foreign District Files Material relating to firms located outside the boundaries of the filing office. Includes recall information, recall effectiveness checks, information on consumer complaints, assignments, and sample summaries and worksheets. Break file at end of each fiscal year. Destroy 2 years after file is broken.		
R-10	Diary Notes Initial, longhand Establishment Inspection Report and supporting material (see R-7) prepared on site by inspector while making the inspection. Destroy 10 years after date of inspection or until no legal action resulting from inspection is possible, whichever is later.		
R-11	Closed Recalls Material relating to the recall of unsafe, impure, mislabeled, or ineffective products from marketplace. a. Class I Recalls (consumer/user level): Transfer to Federal Records Center 5 years after action completed. Destroy 10 years after action completed. b. Class II Recalls (next level above consumer/user level: Transfer to Federal Records Center 2 years after action completed. Destroy 10 years after action completed. c. Class III Recalls (manufacturer level): Transfer to Federal Records Center 2 years after action completed. Destroy 5 years after action completed.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-12	Consumer Complaints Yellow copies of Form FD 2516, 2516a, and letter format complaint copies. Break file at end of each fiscal year. Destroy 1 year after file is broken.		
R-13	Closed Legal Files Various legal documents relating to enforcement actions taken. Includes original (white) Collection Report copies, labeling, analytical worksheets, sample summaries, Regulatory Letters, firms' response, and statement of final decision; seizure recommendations, Headquarters response, Reports of Seizure Accomplishment, and Notice of Status of Decree; citation recommendation, Headquarters responses, Notices of Hearing (Form FD 466), and Records of Hearing; prosecution recommendation, Headquarters responses, and termination of prosecution reports; injunction recommendations and Headquarters responses; temporary abeyance letters. Also exhibits and other supporting material and copies of court documents, testimony, decisions, and other legal papers. Transfer to Federal Records Center 3 years after legal action is completed and file is closed. Destroy 10 years after action is completed and file closed.		
R-14	No Action Indicated (NAI) Sample Files Collection Reports (white copies), analysts worksheets, labels, shipping documents, and if relevant, consumer complaints on regulated products shipped in interstate commerce, including survey samples not analyzed and samples that were inspected and found to be nonviolative. a. NAI Sample Files used as basis for defining product standards: Destroy when all questions involving standards are resolved or 2 years after date of collection, whichever is later.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-11 (Continued)	b. Other NAI Sample Files: Break file at end of each fiscal year. Destroy 2 years after file is broken.		
R-15	Collection Reports Reports detailing the procurement of samples of regulated products for testing and examination. a. Official (original white) copies: If sample is analyzed and found violative, transfer to Legal File (R-13) along with corresponding analyst's worksheet. If sample is analyzed and found nonviolative, transfer to NAI File (R-14) in company with corresponding analyst's worksheet. If sample is not analyzed, transfer to NAI File (R-14). b. Duplicate (pink) copies: Break file at end of each fiscal year. Destroy 1 year after file is broken. c. Fiscal (green) copies: Destroy 6 years and 3 months after end of accounting period during which sample was collected.		
R-16	Sample Accountability Records (Closed Samples) Copies of Form FD 421 giving identification and processing data on samples of regulated products. Destroy between 1 and 3 years at the discretion of each Field and District Office after disposal of corresponding sample.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-17	Sample Package Identification Copies of Form FD 525 used to identify and forward samples of regulated products to Agency laboratories that were collected by inspectors. Destroy when decision is made to test or not to test sample, not to exceed 1 year from date of receipt.		
R-18	Laboratory Management System (LMS) #3 and #4 Code Sheets Forms used to enter location data for worksheets, collection reports, etc., into the LMS. Destroy on completion of in-house Program Oriented Data System (PODS Mini) audit for appropriate year.		
R-19	Laboratory Control Documents Instrument monitoring records such as log books, thermographs and other machine tracings, and instrument charts measuring the performance of incubators, freezers, and other laboratory equipment used in testing and examining samples of regulated products. Transfer to Federal Records Center 2 years after test/examination is completed. Destroy 5 years after test/examination is completed.		
R-20	Import File Material related to regulated products imported into the country. Includes Importers Entry Notice (Form FD 701), Import Collection Reports (Form FD 715), Land Port Entry Notices (Form FD 720), Mail Entry Collection Reports (Form FD 725), Tea Import Chop Lists, sample summaries and analysts worksheets on imported products, Import Detention Notices, Release Notices, and Refusals of Admission. a. No Action Indicated (NAI) product samples: Break file at end of each fiscal year. Destroy 2 years after file is broken.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-20 (Continued)	b. Violative (detained) product samples: Transfer to Federal Records Center 3 years after legal action is completed and file is closed. Destroy 10 years after legal action completion and file closed.		
R-21	Importers Entry Notices Authorization to unload imported regulated products (Form FD 701, yellow copies). a. When samples are collected: Place in Import File (R-20). b. When samples are not collected: Destroy 6 months after date of receipt.		
R-22	Document History Records Form FD 2360 used as worksheets to transcribe financial data from contracts, requisitions, etc., onto computer input media. Destroy 6 years and 3 months after end of accounting period during which data was transcribed.		
R-23	Earning and Leave Statements Green copies of Form OS-340 containing employee pay and leave data. Break off at end of fiscal year. Destroy 3 years after file is broken.		
R-24	New Drug Applications (NDAs), New Animal Drug Applications (NADAs), and Investigational New Animal Drug Applications (INADs) Triplicate copies of applications from producers for approval to test and market new drugs (Form FD 356H). Includes test results, labeling, promotional material, progress and other reports, adverse reactions, notices of termination, withdrawals, or approvals, FDA evaluations and recommendations, supporting material, and		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-24 (Continued)	related correspondence. May occasionally include clinical data. a. Clinical data: Destroy on receipt. b. Other material. Destroy 10 years after receipt from Headquarters.		
R-25	Drug Master Files Triplicate copy of privileged information forwarded from Headquarters containing data from firms and FDA reviews used to ascertain capabilities of firms to produce and market regulated products. Includes qualifications of key personnel, facilities, production methods, protocols, and drug formulations. Destroy 10 years after receipt from Headquarters unless needed for further reference.		
R-26	Antibiotic Certificates Approvals granted by FDA for firms to market antibiotics. Includes Applications for Exemption for Storage (Form FD 1671), Processing (Form FD 1672), Labeling (Form FD 1673), Manufacturing Use (Form FD 1674), Testing (Form FD 1677), Repacking (Form FD 1678), and Supplemental Certification (Form FD 1679) as well as the basic Antibiotic Application (Form FD 1675). a. Copies of Certificates: Destroy 3 years after date of issuance. b. Application forms and other material: Destroy 10 years after application is approved.		
R-27	Color Additive Certificates Copies of Form 3000 showing Agency approval of each batch of colors used in regulated products. Break off at end of fiscal year. Destroy 3 years after file is broken.		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-28	Patient Identification Names and other personal data on methadone treatment patients collected in the course of methadone treatment inspections. Destroy when no longer needed for investigational uses, not to exceed 2 years after date of inspection.		
	MILK, FOOD SERVICE, AND SHELLFISH SANITATION PROGRAMS (MFS & SSP)		
R-29	MFS & SSP State and Local Programs Evaluations Reports made on audits of State and local programs to determine their effectiveness. Also background material and related correspondence. Break file at end of each fiscal year. Transfer to Federal Records Center 5 years after file is broken. Destroy 10 years after file is broken.		
R-30	MFS & SSP Technical Consultants and Assistants Studies, correspondence, and data providing technical guidance to State and local agencies and firms in regulated industries. Break file at end of each fiscal year. Transfer to Federal Records Center 5 years after file is broken. Destroy 20 years after file is broken.		
R-31	MFS & SSP Training Training materials, instructions, attendance rosters, and related items concerning National Consultant Program (NCP) courses given to FDA, State, local, and regulated industry personnel. Break file at end of each fiscal year. Transfer to Federal Records Center 5 years after file is broken. Destroy 10 years after file is broken.		

Promulgated 9-1-49 by
General Services Administration
The National Archives

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-32	MFS & SSP Meetings and Conferences Agendas, minutes, lists of members, members' biographical data, and correspondence pertaining to meetings with State, local, and regulated industry officials. Break file at end of each fiscal year. Transfer to Federal Records Center 5 years after file is broken. Destroy 10 years after file is broken.		