REQUEST FOR AUTHORITY
TO DISPOSE OF RECORDS
(See Instructions on Reverse)

LEAVE BLANK	
DATE RECEIVED 3 OCT 1977	JOB NO.
NC1 88 78 1	

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

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

5. TEL. EXT.
443-4055

6. CERTIFICATE OF AGENCY REPRESENTATIVE:

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disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10.

2-23-78 (Date) James B Rhoads Archivist of the United States

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 _____ page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified.

8/4/77 Date — Norman E. Shipp (Signature of Agency Representative) — Chief, Management Methods Br., DMS FDA Records Control Officer (Title)

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.		
1	General Subject		
	Record copies of outgoing correspondence, incoming correspondence, memoranda for record, plans, reports, speeches, agendas and minutes of meetings and conferences, and essential backup material.		
	a. Material relating to foods, drugs, and other regulated products. Also material of long-range, agency-wide significance. (400, 500, and 600 series of the FDA Files Manual).	B-600, #1	
	*PERMANENT.	Copies: NNR, NNF, NNU, NNB, WNRC.	
	Transfer to Federal Records Center (FRC) 5 years after cutoff date. Offer to National Archives 20 years after cutoff date.		
	* Files not accepted by NARS at time of offer are disposable without further agency concurrence.		

115-106

STANDARD FORM 115
Revised January 1973
Prescribed by General Services Administration
FPMR (41 CFR) 101-11.4

2/8/78 - All changes with approval of J. Reiff (PL) Sent to agency. NCW - NNB, NNF & NNU - 2/22/78

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
	b. Administrative and routine material. (and all records not covered by "a")		
	Destroy 7 years after cutoff date.		
	Note: Certain documents described above which relate to specific subjects will be placed in files relating to these subjects and disposed of according to the disposition instructions for these files. Correspondence and other items having limited or no record value such as acknowledgements, thank you letters, and replies to routine requests should not be included in The General Subject files.		
2	Correspondence		
	Nonrecord copies of the above documents. Also known as chronological, transitory, reading, snoop, or day files.		
	Destroy when circulation is completed, or after 1 year. Note: If necessary, these files may be retained for longer periods of time on an exception basis and destroyed when no longer needed for administrative purposes.		
3	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 1 year after cutoff date.		
	b. Indexes used for other purposes.		
	Destroy at same time as referenced documents.		
4	Administration Files		
	Nonrecord copies of documents relating to positions, staffing, training, travel, hiring, payroll and other personnel matters, including consultants. Also space, equipment, procurement, budgeting, planning and general management document copies.		

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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
	a. Position documents. Destroy 1 year after position abolished. b. Employee documents. Destroy 1 year after employee leaves FDA. c. Planning documents. Destroy 1 year after plan is completed. d. Other documents. Destroy 1 year after cutoff date unless needed for further reference.		
5	References Nonrecord material maintained by offices and individuals including regulations, procedures, guidelines, precedent material, publications, articles, catalogs, correspondence copies not described above, and related material. Destroy when superseded or after 1 year unless needed for further reference.		
6	Working Papers Notes, memoranda for record, initial drafts, comments, and similar material collected by employees in the course of their work. Destroy 6 months after completion of project or assignment unless needed for further reference.		
7	Directives Drafts, working papers, clearances, comments, camera copies, and record and extra copies of Staff Manual Guides, Compliance Policy Guides, Compliance Program Guidance Manual, Regulatory Procedures Manual, Data Processing Manual, Field Management Directives and other Agency issuances.		

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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
	a. Record copy of each issuance. except issuances relating routine administration and internal management. PERMANENT. Offer to National Archives 1 year after issuance is superseded or revoked in 5 year increments. b. Other material, ~~and~~ copies., and issuances not covered in "a". Destroy 1 year after issuance is superseded or revoked unless needed for further reference.		
8	Forms Printouts, storage orders, record and extra form copies, suggestions, and surveys related to forms. a. Record copy of each form. PERMANENT. Offer to National Archives 1 year after issuance is superseded or revoked in 5 year increments. b. Other material and copies. Destroy 1 year after form is cancelled.		

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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
	Equal Employment Opportunity Office Develops affirmative action programs in the EEO area. Investigates and resolves discrimination complaints.		
E-1	EEO Complaint File Affidavits and other documents collected by an EEO investigator in the course of investigating complaints concerning discrimination. Destroy 5 years after complaint has been resolved and no further action is expected.		

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
	Office of Legislative Services Advises the Commissioner concerning legislative needs and in the analysis of pending congressional legislation which may affect FDA. Prepares and clears FDA position papers and Departmental reports on proposed legislation for approval of the Commissioner. Coordinates and assists in the development and preparation of FDA legislative proposals for the Commissioner's review. Assists in the preparation of testimony for presentation to Congressional committees; monitors hearings and Congressional activities affecting FDA; and distributes legislative materials. Directs or coordinates the preparation of data requested by Congressional investigative committees; provides technical and other assistance to Members of Congress, Congressional and other correspondence.		
L-1	House and Senate Hearings Background material such as Position Papers, correspondence, briefs, and copies of acts used by HEW and FDA officials who testify at Congressional investigative ("oversite") hearings. a. Original material. Destroy original material when put on microfilm (2 years). b. Microfilm copies. Destroy microfilm copies when 20 years old. (To be microfilmed per FPMR 101-11.507(c)(1).		
L-2	Congressional Original correspondence from Congressmen and copies of FDA replies. Includes routine constituent mail as well as more substantive letters initiated by Congressmen and their staffs. Transfer to FRC 1 year after Congressman leaves office. Destroy 7 years after Congressman leaves office.		

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
L-3	Special Committee Committee hearing correspondence, fact sheets, and background information for use by committees on Judiciary, Aging, Small Business, and others concerned with FDA operations. Transfer to FRC 1 year after committee dissolves. Destroy 7 years after committee dissolves.		
L-4	Pending Legislation Copies of proposed legislation initiated both by FDA and other parties introduced in Congress that is of interest to the Agency. Destroy 1 year after legislation is enacted or disposed of unless needed for further reference.		
L-5	Legislation of Interest to FDA Copies of legislation that have been passed by the Houses of Congress. Destroy when microfilmed. Destroy microfilm copies 5 years after filming unless needed for further reference.		
L-6	Congressional Legislative Hearings Background material similar to House and Senate Hearings file (L-1) for legislative hearings. Destroy 1 year after completion of hearing unless needed for further reference.		

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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
	Office of Compliance Coordinates FDA compliance programs and international relationships with foreign firms, international groups, and other nations; coordinates the preparation of international travel plans and the Annual International Travel Plan for the Commissioner's approval. Functions as principal advisor to the Commissioner on regulations, and compliance-oriented matters which impact on policy and direction, and long-range program goals. Evaluates and coordinates FDA's overall compliance efforts to assure optimum use of FDA and other Federal, State, and local resources, a balance between voluntary and regulatory compliance, and FDA responsiveness to consumer needs. Stimulates an awareness within FDA of the need for prompt and positive action to secure compliance by regulated industries. Directs and coordinates the regulation-making activities of FDA and the preparation of Federal Register material.		

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
C-1	Visitor Files. Lists of persons from foreign countries visiting FDA. Includes names, countries of origin, facilities visited, and purpose of visits. Destroy 1 year after visit or when no longer needed for reference.		
C-2	Master Files for Foreign Travel. Names, places visited, purpose, itineraries, correspondence, and trip reports of foreign travel by FDA personnel attending foreign meetings and conferences. Transfer to FRC 3 years after cutoff date. Destroy when 8 years old.		
C-3	Hearing Clerk Records. Legal briefs, exhibits, transcripts of hearings, judges' orders, notices, comments, final orders, objections, hearing requests and other legal documents used in legal proceedings before the FDA Administrative Law Judge. Transfer to FRC 3 years after final action is taken. Destroy on repeal of enabling legislation (Administrative Practices and Procedures Act; Title 21, CFR, Part 2).		

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

OFFICE OF SCIENCE

Functions as the principal advisor to the Commissioner on scientific matters which impact on FDA policy and direction and long-range program goals.

Provides leadership and direction on scientific and environmental matters and stimulates scientific and technological achievement in FDA.

Participates with the Division of Contracts and Grants Management in the development of FDA policy concerning the use of scientific grants and contracts; develops science policy for the acquisition of extramural research studies and supporting scientific data and/or innovative scientific equipment and instrumentation under the grants and contracts mechanism.

Serves as the focal point for preaward coordination and scientific review of FDA's extramural research, training, and fellowship activities; for the development of Agency scientific research, environmental impact policies, and procedural guidelines; and for technical liaison activities concerning scientific matters, environmental impact, research grants, and science-oriented contracts.

Chairs an internal science advisory council, composed of scientists representing the bureaus, which advises the Agency on scientific policy and environmental impact of Agency actions.

Appraises the technical aspects and relative contributions of FDA's intramural and extramural science programs. Evaluates the adequacy of scientific resources available to the Agency. Initiates action as appropriate to enhance the FDA scientific posture by promoting optimum utilization of the grants and contracts mechanism, interagency agreements, and international scientific collaboration under Public Law 480 and related statutes.

Provides a focal point for committee management activities within FDA.

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
S-1	Environmental Impact File Environmental impact statements, effluent limitation guidelines, analysis and assessment reports and comments on chemicals, construction, recalls, etc. Transfer to FRC 3 years after date of last action. Destroy when 7 years old.		
S-2	Advisory Committee Records Public Advisory Committees are appointed to provide the FDA Commissioner with specific advice and recommendations on scientific and regulatory matters such as, uniform purity standards and evaluations of chemical safety, which supplement information generated by FDA staff members. Committees include the Toxicology Advisory Committee, Panel on Review of Antigens, Arthritis Advisory Committee, and others. a. Committee files. Rosters of committee members, committee charters, and recommendations of committees. PERMANENT. Transfer to FRC 5 years after cutoff date. Offer to National Archives 20 years after cutoff date. b. Reports. Reports required by the Federal Advisory Committee Act (Annual Reports to Congress, Annual Reports by Committees which held Closed Meetings, and Annual Review of Committee Activities) as well as any other reports that may be required. PERMANENT. Transfer to FRC 5 years after submission of report. Offer to National Archives 20 years after submission. c. Minutes. Complete and accurate descriptions of matters discussed and conclusions reached by the Advisory Committees. PERMANENT. Transfer to FRC 5 years after cutoff date. Offer to National Archives 20 years after cutoff date.		

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
	d. Verbatum Transcripts. Word-for-word recordings of Advisory Committee meetings. (1) Steno tapes, tape recordings and other recording devices. Destroy when type copies (verbatum transcripts) have been prepared. (2) Typed copies (verbatum transcripts) from (1) above. PERMANENT. Transfer to FRC 5 years after cutoff date. Offer to National Archives 20 years after cutoff date. (3) Verbatum records that have never been transcribed. PERMANENT. Transfer to FRC 5 years after cutoff date. Offer to National Archives 20 years after cutoff date.		
S-3	Departmental and Interagency Committee Files These committees, which are no longer involved with FDA activities, performed the same functions as the Advisory Committees (item S-2) and have similar type records. Destroy files 7 years after Committee is no longer monitored by FDA.		
S-4	Special Foreign Currency Program Contracts, correspondence, reports, and background data related to the Program which is concerned with allocating counterpart funds (PL-480) for payment of scientific projects done in foreign countries for FDA. Transfer to FRC 10 years after completion of program. Destroy when 15 years old.		

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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
S-4 (Con't)	a. Final reports. PERMANENT. Transfer to FRC 10 years after completion of program. Offer to National Archives when 15 years old. b. Other material. Transfer to FRC 10 years after completion of program. Destroy when 15 years old.		

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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

OFFICE OF PLANNING AND EVALUATION

Advises and assists the Commissioner and other key officials concerning the performance of FDA long-range program planning, development, and evaluation activities.

Develops program and planning strategy through analysis and evaluation of issues affecting policies and program performance.

Develops, installs, and monitors the Agency-wide planning system including the Five-Year Plan and the Strategic Plan.

Conducts operations research, and economic and special studies as a basis for forecasting trends, needs, and major problems requiring solution; and provides assistance and consultation in these areas to operating units.

Evaluates impact of external factors on FDA programs, including industry economics, consumer expectations, and protective legislation. As necessary, recommends new programs or changes in existing programs and program priorities.

Develops FDA evaluation programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.

Evaluates impact of FDA programs on consumer protection.

Develops and coordinates an Agency-wide system for the collection of medical data from hospitals, clinics, and other reporting units.

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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
P-1	Project Files Proposals, source data, working papers, draft reports, evaluations, clearances, and final reports by MODS (Medical Oriented Data Systems) and other studies and projects conducted by the Office of Planning and Evaluation. MODS is a system of reporting by hospitals, etc., or injuries and illness caused by eyeglass lenses, foods, cosmetics, and drugs to FDA. Reports are used to pinpoint specific problem areas for concentrated study. a. Final reports. Transfer to FRC 10 years after completion of project. Destroy 20 years after completion of project. b. Other material. Destroy 5 years after completion of project.		

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
	OFFICE OF PROFESSIONAL AND CONSUMER PROGRAMS Serves as principal advisor to the Commissioner on development and implementation of effective policies and programs to convey important health protection concepts and practices to consumers and to the medical and scientific professions. Develops and coordinates a program of liaison with the medical and scientific professions designed to promote understanding of and support for FDA efforts to protect the public health. Develops and conducts consumer education programs through a nationwide network of consumer affairs officers and through other broad education efforts. Provides FDA central control for and processes all FDA public correspondence. Compiles, coordinates, and edits the FDA Drug Bulletin.		

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
G-1	Information Retrieval Copies of material used to respond to public inquiries such as public laws, regulations, speeches and testimony by FDA officials, freedom of information material, correspondence, reports plans, studies, publications, etc. Destroy when obsolete or superseded or 1 year after date of receipt unless needed for further reference.		
G-2	Audio Visual Closed circuit television tapes and other audio visual materials used for training FDA, state agency, and other personnel in various aspects of FDA programs. Also, similar material used to familiarize the general public with FDA's mission and functions and to alert them to specific health hazards. a. Training tapes. (1) Erase 1" training tapes when course is revised or terminated. (2) Erase 1/2" training tapes 5 years after revision or termination. b. Public use tapes. Erase 1" public use tapes on completion of their intended use. PERMANENT. ~~Transfer 1/2" public use tapes to FRC 3 years after completion. Offer to National Archives 10 years after completion.~~ Offer to NARS the original or master tape or the earliest generation of the program upon completion of intended use or when 5 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
	OFFICE OF PUBLIC AFFAIRS Serves as principal advisor to the Commissioner on all public affairs activities. Develops, implements, and monitors policies and programs regarding media communications and relations; acts as focal point for disseminating news concerning FDA activities. Provides editorial and graphic arts services for Agency publications and public affairs activities. Produces and publishes the FDA Consumer, the Agency's official, general-circulation magazine, the FDA Public Calendar, the FDA Enforcement Report, the FDA New Drug Approval List, and FDA Today. Oversees FDA's implementation of the provisions of the Freedom of Information Act. Maintains liaison with the Office of the Assistant Secretary for Public Affairs.		

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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
I-1	Press Releases Information given to communications media advising of FDA's position on various matters and actions taken, including reports on recalls and approvals. a. Record copy. PERMANENT. Transfer FRC 7 years after cutoff date. Offer to National Archives 20 years after cuttoff date. b. Other material. Destroy other copies, drafts, and back-up material 1 year after cutoff date.		
I-2	Talk Papers Background material for use of the press staff and field offices when communicating with the public. Destroy 7 years after cutoff date.		
I-3	Publications Proofs, prints, manuscripts, and supporting material for FDA Papers, FDA Consumer, and similar publications. a. Record copies. PERMANENT. Transfer to FRC 4 years after publication. Offer to National Archives 20 years after publication. b. Non record copies. Destroy when no further need is expected. c. Other material. Destroy supporting material 1 year after publication.		

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
I-4	FDA Public Calendar Listing of meetings and/or events involving top policy-makers of FDA with individuals outside the Executive Branch of the Federal Government. (Weekly) a. Record copy. ~~PERMANENT.~~ Transfer to FRC 7 years after cutoff date. ~~Offer to National Archives 20 years after cutoff date.~~ Destroy 20 years after cutoff date. b. Non record copies. Destroy when no further need is expected. c. Other material. Destroy 1 year after publication.		
I-5	FDA Enforcement Report Listing of all FDA regulatory actions and recalls, seizures, prosecutions and injunctions. (Weekly) a. Record copy. ~~PERMANENT.~~ Transfer to FRC 7 years after cutoff date. ~~Offer to National Archives 20 years after cutoff date.~~ Destroy 20 years after cutoff date. b. Non record copies. Destroy when no further need is expected. c. Other material. Destroy 1 year after publication.		
I-6	FDA New Drug Approval List Listing of all new drugs approved by FDA (human drugs, veterinary drugs, biological products). (Weekly)		

-6
Con't)

a. Record copy.

~~PERMANENT~~

Transfer to FRC 7 years after cutoff date. ~~Offer to National Archives 20 years after cutoff date.~~
Destroy 20 years after cutoff date.

b. Non record copies.

Destroy when no further need is expected.

c. Other material.

Destroy 1 year after publication.

I-7

FDA Today

Newsletter to all FDA employees - issued monthly.

a. Record copy.

~~PERMANENT~~

Transfer to FRC 7 years after cutoff date. ~~Offer to National Archives 20 years after cutoff date.~~
Destroy 20 years after cutoff date.

b. Non record copies.

Destroy when no further need is expected.

c. Other material.

Destroy 1 year after publication.

I-8

Audio-Visual

Motion picture films, photographs, slides, tapes, and exhibit materials produced inhouse and under contract to publicize the Agency's mission and operations. Also related specifications, requisitions, and copies of contracts.

a. Record copies of each item as follows:

1. Still pictures: the original negative and a captioned print for each black and white image and the original color transparency or color original, a captioned print, and an internegative if one exists for each color image.

PERMANENT. Break file every five years and offer to NARS when 10 years old.

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN

2. Motion pictures: the original negative or color original plus optical sound track, an intermediate master positive or duplicate negative plus optical sound track, and a sound projection print.

3. Sound recordings: the master tape, matrix or stamper, and one disc pressing for each conventional mass-produced multiple copy disc recording and the original tape or the earliest generation of each magnetic audiotape recording.

4. Video recordings: the original or the earliest generation of the recording or a kinescope of the recording.

(2,3, and 4): PERMANENT. Offer to NARS when no longer needed for administrative use or when 5 years old.

5. Finding aids necessary or helpful for the proper identification, retrieval, and use of the above, such as indexes catalogs, and caption lists and production files which include contracts, scripts and other documentation bearing on the origin, acquisition, release, and ownership of the above audiovisual records.

PERMANENT. Offer to NARS along with the audiovisual records to which they relate.

b. Non-record copies.

Destroy when no further use is expected.

c. Other material.

Destroy one year after publication.

STANDARD FORM 115-A
Revised July 1974
Prescribed by General Services Administration
FPMR (41 CFR) 101-11.4

GPO : 1975 O - 570-387

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
	Policy Management Staff Directs and coordinates a multidiscipline team of administrative and/or program specialists who conduct scheduled reviews of field and Headquarters elements of the Agency to determine adherence to existing managerial policy and practices; assures that recommendations resulting from the review findings are implemented. Evaluates the Agency's physical security program and provides professional leadership and authoritative guidance in this area. Formulates policy and procedures necessary to maintain the integrity of privileged information submitted by industry. Serves as FDA representative and liaison with the Office of Internal Security, OS, and participates with them in developing and implementing intra-agency policy and procedures for security related matters. Provides a centralized Agency-wide investigative capability for top management.		

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
A-1	Critical-Sensitive Positions Requests for National Agency checks of employees occupying sensitive positions, employee data forms, determinations of eligibility, updates, and related correspondence. Destroy 5 years after termination of employment or when no longer needed for reference.		
A-2	Administrative-Investigative Case Files Notification of possible impropriety by FDA employees. Decisions to investigate, reports of investigation, and action taken as a result. Physical security information such as reports, inspection records, etc., regarding all headquarters and field installations. Also, on-site review program and administrative operations documents in the security area. a. Investigative material Destroy 5 years after termination of employment or when no longer needed for reference. b. Physical security material Destroy 3 years after submission of final report or when no longer needed for reference.		
A-3	Document Security Classified documents containing national defense security information of interest to FDA. Also logs and receipts for these documents. Destroy or return to issuing agency when FDA action is completed.		

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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
	DIVISION OF MANAGEMENT SERVICES Provides leadership and guidance to headquarters staff offices, headquarters operating activities, and field activities for all general service programs, including procurement, personal property management and accountability, real property management, space management and utilization, construction and engineering services, communications, printing and reproduction, microfilm management, files, and records management. Responsible for maintaining effective liaison with the Government Printing Office, and for the centralized clearance and coordination of all printing and publication services. Coordinates the development of Agency-wide policies and procedures for such services and plans and executes and adjusts efforts in these activities.		
A2-1	Administrative Files Documents relating to specific regulated firms and their products. Includes Establishment Inspection Reports (EIR's), giving the results and comments of FDA officers inspecting production plants; surveillance, investigation, and miscellaneous reports made by FDA officers following up on suspected violations to the Food, Drug, and Cosmetic Act; copies of violations and corrective/enforcement action taken; cross references to applications and petitions for new products; and related correspondence with and about the firms. a. Out of business firms. Transfer to FRC 2 years after firm has gone out of business or date of last action, whichever is later. Destroy on repeal of enabling legislation. b. Non-current records. Transfer to FRC 7 years after documents are no longer current. Destroy on repeal of enabling legislation.	B-604 #3	

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
A2-2	Case (Recall Files) Materials on each action taken regarding the recalling of unsafe, impure, or mislabeled products from the market initiated by the producer or FDA. Includes legal documents, summaries of the extent and effectiveness of the recall, and related documents. Transfer to FRC 8 years after case is closed in batches by letter series. Destroy 24 years after closure.		
A2-3	Injunction Procedings Documentary evidence and requests for an injunction against a firm and/or its products forwarded to the Office of the General Counsel for legal action. Transfer to FRC 5 years after termination of final action. Destroy 20 years after final action.		
A2-4	Import Detention Notices Documents related to the detention of possibly violative imported products. Includes forms FD 772, Notice of Refusal for Admission; FD 777, Notice of Detention and Hearing; and FD 779, Notice of Release. Transfer to FRC 5 years after final action taken. Destroy 15 years after final action.		
A2-5	Sample Seizure and/or Criminal Prosecution Records. Records pertaining to product samples that have resulted in seizure, prosecution, or been placed in permanent abeyance by administrative action before or after citation. Includes collection records, sample records, labels, promotional material, seizure and analytical reports, notices and records of hearings, recommendations, termination of action notification, and related correspondence. a. Seizure and/or criminal prosecution records including permanent abeyance case files that have resulted in seizure or prosecution. Transfer to FRC 5 years after final action taken in batches of letter series. Destroy on repeal of enabling legislation.	B-600, #2	

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
A2-5 (Con't)	b. Other permanent abeyance folders. Transfer to FRC 5 years after final action taken in batches of letter series. Destroy on repeal of enabling legislation.		
A2-6	Correspondence. Instructional material for correspondence preparation and supporting papers. Also samples of letterhead, etc. Destroy 1 year after supersession.		
A2-7	Employee Suggestion File. Suggestions, evaluations, awards, letters of adoption or rejection, and supporting material. Destroy 2 years after suggestion is adopted or rejected.		
A2-8	Employee Locator File. Lists of employees with organization, room, and telephone numbers. Destroy when superseded.		
A2-9	Monthly Stock Reports. Reports on equipment and supplies ordered, on hand, and distributed. Also forms FD-1780, Stock Requisition. Used for reimbursement and accounting purposes. Destroy 2 years after submission of report.		

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

DIVISION OF MANAGEMENT SYSTEMS AND POLICY

Provides leadership and direction in the effective and efficent use of Agency resources; provides Agency-wide consulting services in organization and operations analysis and in the analysis, design, implementation, and maintenance of operating systems and procedures.

Provides central FDA control for delegations of authority and maintains control files of delegations to and within the Agency.

Conducts Agency-wide organization, management, and manpower studies; designs and recommends systems, procedures, and policy to implement study conclusions.

Provides computer systems analysis and applications programming services for the staff offices of the Commissioner and data base management services for the Agency.

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
A3-1	Project File (Management Surveys) Reports made on projects undertaken on a one-time basis without initiating a formal survey. a. Record report copy. Destroy 5 years after completion of project. b. Supporting material and other report copies. Destroy 1 year after completion.		
A3-2	Project File (Management Engineering and ADP) Reports on various management studies. Also supporting material such as interview notes, analyses, and report drafts. a. Record report copy. Destroy 10 years after date of submission. b. Other report copies. Destroy 2 years after submission. c. Supporting material. Destroy 1/2 year after completion of project or, if no final action, after 3 years.		
A3-3	Survey File Reports and supporting material on various management studies. a. Major surveys affecting important policy, procedures and planning. PERMANENT. Offer record copy to National Archives 10 years after submission of report. b. Other surveys. Destroy record copy of report 10 years after submission of report. c. Supporting material for major and other surveys. Destroy 2 years after submission of report.		

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
A3-4	Recurring Reports Copies of reports submitted on a regular basis to other activities such as Manpower Management Report, Quarterly Activities Report, Training Needs Summary Report, and other management reports. Also, instructions, source data, computations, drafts, and extra copies. a. Final report copy. Destroy report 5 years after submission. b. Other material. Destroy 2 years after submission.		
A3-5	Organization Proposals, clearances, functional statements, organization charts, and reports on OPB studies relating to FDA organization. a. Approved organizational statements. PERMANENT. Transfer approved statements to FRC 10 years after superseding reorganization. Offer to National Archives 20 years after superseding reorganization. b. Unapproved organizational statements. Destroy 10 years after preparation. c. Other material. Destroy 10 years after preparation.		
A3-6	Delegations of Authority Proposals, clearances, drafts, and final statements of delegations of authority.		

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
A3-6 (Con't)	a. Final statements. ~~PERMANENT.~~ ~~Offer to National Archives~~ Destroy 10 years after cutoff date. b. Other material. Destroy 10 years after cutoff date.		

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
	DIVISION OF PERSONNEL MANAGEMENT Plans and develops a comprehensive personnel management program for FDA, including programs in manpower planning, skills, utilization, position analysis, career development and training, upward mobility, occupational health and safety, employee services, and employee-management relations. Provides staff assistance to servicing personnel offices performing recruitment, position classification, employee service, and personnel action processing functions. Implements and administers centralized FDA staff development and occupational health and safety programs; performs employee-management relations activities and other services not provided by servicing personnel office. Assists executive and operating management in expeditiously and effectively achieving program objectives while assuring applications of the Federal Merit System.		
A4-1	Supergrade Positions Position descriptions, grade justifications, staffing papers, organization charts, and correspondence relating to each supergrade position. Destroy 3 years after position is abolished or when no longer needed for reference.		
A4-2	Grievance and Appeal Cases Correspondence, completed forms, and other material relating to employee grievances. Destroy 2 years after date of final action or when no longer needed for reference.		
A4-3	Outside Activity Forms DHEW 520 and 521 prepared by employees having an outside job. Destroy 2 years after employee terminates outside employment or leaves FDA.		

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
A4-4	Honor Awards Nominations, selections, and correspondence concerning awards given employees. Destroy when employee leaves FDA.		
A4-5	Program Review and Evaluation - Safety Documents relating to the employee safety program including issuances, reports, and correspondence. Destroy 10 years after cutoff date unless needed for further reference.		
A4-6	Position Classification Standards Standards developed to classify FDA job descriptions. Destroy when superseded.		
A4-7	Training Request File Requests for employee training, course evaluations, and long-term training records. Destroy 4 years after completion of training unless needed for further reference.		
A4-8	Individual Training Program Participants Assignments, activities, and training of each employee participating in the program. Destroy 3 years after participant completes program.		

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

DIVISION OF CONTRACTS AND GRANTS MANAGEMENT

Provides leadership, direction, and staff advisory services for the FDA negotiated contracts and grants management programs. Coordinates activities of FDA bureaus and offices to insure proper development of grants and contracts program requirements.

Plans, develops, and coordinates the issuance of FDA-wide negotiated contracting policies and procedures.

Participates with the Office of Science in the development of FDA policy concerning the use of research grants and grants funds. Serves as the Agency focal point for developing, coordinating, and implementing FDA policies and procedures pertaining to grants management; serves as the primary point of liaison with the management staff of grantee institutions for the general interpretation of grants management policies.

Directs and coordinates all administrative functions associated with grants management after technical review and approval are complete. Directs and conducts negotiations with grantee institutions.

Executes all negotiated contracts and grants awards.

Analyzes, evaluates, and reports selected statistical and financial data pertaining to the grants and contracts program.

Maintains liaison with the Office of the Assistant Secretary for Administration and Management on contracts and grants management policy, and procedural and operating matters. Serves as FDA focal point for the processing of audit reports and for liaison with the HEW Audit Agency.

Provides price/cost analysis and related services for contracts and grants.

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
A5-1	Interagency Agreements/Memoranda of Understanding Agreements and understandings with other agencies, both technical and administrative, for work done by or for FDA. They include exact descriptions of the work to be done, time frames, costs or other renumeration, and details of the personnel and equipment involved. Also, subsequent amendments, comments, approvals, and related correspondence. a. Final Agreement/Understanding documents. ~~PERMANENT.~~ Destroy ~~Offer to National Archives~~ 2 years after termination of entire agreement/understanding ~~in 5 year increments.~~ b. Other material. Destroy 2 years after termination.		
A5-2	Grants Applications, opinions, comments, approvals or declinations funding documents, progress and expenditure reports, published materials, and correspondence concerning grants awarded by FDA for research. Destroy 6 years after termination of grant or date of final payment, 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
	BUREAU OF BIOLOGICS Administers regulation of biological products shipped in interstate and foreign commerce under the biological product control provisions of the Public Health Service Act. Inspects manufacturers' facilities for compliance with standards, tests products submitted for release, establishes written and physical standards, and approves licensing of manufacturers to produce biological products. Plans and conducts research related to the development, manufacture, testing, and use of both new and old biological products to develop a scientific base for establishing standards designed to insure the continued safety, purity, potency, and efficacy of biological products. Administers applicable provisions of the Federal Food, Drug, and Cosmetic Act as they pertain to human drugs that are biological products. In carrying out these functions, cooperates with other bureaus of FDA, other PHS organizations, governmental and international agencies, volunteer health organizations, universities, individual scientists, non-governmental laboratories, and manufacturers of biological products.	NC-174-237 (10/4/74)	

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
B-1	Consumer Complaints Original complaint letters from consumers and others including copies of those submitted on forms FD 1239, Drug Experience Report. Also, correspondence with firms involved concerning the complaints and corrective action taken as well as memos for record regarding the complaint. Transfer to FRC 5 years after the complaint is resolved; ~~Destroy after 20 years except offer a sample not to exceed 3% to National Archives at time of destruction.~~		Destroy when 7 years old.
B-2	Manufacturers' Correspondence and Data One portion of the file contains copies of correspondence from manufacturers on various subjects. The other consists of raw data developed by Bureau of Biologics personnel regarding the testing of vaccines. Destroy 5 years after action has been completed.		
B-3	Correspondence Cross Reference (Salmon) Carbon copies of correspondence sent out arranged alphabetically by individual or firm name for cross reference. Destroy after 3 years.		
B-4	Pending Licenses and Applications Copies of form NIH 523 or FD 2671, License Application Reference Number Notification, cover letters to the firm involved and related correspondence. a. Approved licenses. Place documents in Establishment or Product License file jackets (see B-6 and B-7). b. Disapproved licenses. Destroy application and supporting material 5 years after disapproval, ~~except offer a sample not to exceed 3% to National Archives at time of destruction.~~		

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
B-5	License Application Notices Similar to above file but contains other copies of form NIH 523 or FD 2671 and correspondence with firm concerning approval or disapproval and follow-up documents. Destroy 1 year after completion of action.		
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, 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. (1) License folder. Disposal not authorized at this time. Review for disposal 10 years after revocation, suspension, or supersession. When reviewed, ~~select a sample to be eventually offered to National Archives~~ Do not transfer to FRC. (2) License establishment supporting material. Same as above.		
B-7	Product Licenses Licenses and supporting material authorizing production of specific products consisting of application copies, changes in production methods, questions and answers with firms, cover and follow-up letters, and related material. a. Active licenses. Retain in Agency space until license is revoked, suspended, or superseded.		

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
	b. Revoked, suspended, or superseded licenses.		
	(1) License folder.		
	Disposal not authorized at this time. Review for disposal 10 years after revocation, suspension, or supersession. ~~When reviewed, select a sample to be offered to National Archives.~~ Do not transfer to FRC.		
	(2) License product supporting material.		
	Same as above.		
B-8	Import Permits.		
	Copies of forms NIH 1395 or FD 2502, Permit for Importation of Licensed Biological Products.		
	Destroy 5 years after expiration of permit.		
B-9	Protocol Releases.		
	Approvals granted for batches of biologicals. Copy of the protocol, forms NIH 289 or FLH 2558, Release/Reject Letter, forms NIH 837 - 845, Completed Check List, forms NIH 30 or FLH 2568, Receipt Letter, and related correspondence such as cover letters, requests for more information and replies concerning the release of specific batches of a product.		
	Transfer to FRC 4 years after date of release. ~~Disposal not authorized at this time. Review for disposal 10 years after date of release.~~ Destroy when 20 years old.		
B-10	Investigational New Drugs (INDs) - Biologicals.		
	IND in triplicate indicating approval for testing of product on humans and supporting material consisting of supplements (amendments), form NIH 1770, Clinical Trial Outline, and related correspondence with producers.		
	a. Original IND.		
	1. Unlicensed products:		
	Transfer to FRC 10 years after completion of final action. ~~On transfer, review for disposal and select a sample not to exceed 3% which will eventually be offered to National Archives.~~ Destroy when 20 years old.		
	2. Licensed products. Retain until no longer needed. Do not send to FRC.		

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
B-10 (Con't)	b. IND copies and supporting material. Destroy 5 years after completion of final action.		
B-11	Efficacy Reviews Documents submitted by manufacturers regarding product efficacy, reviews and evaluations of product made by Bureau of Biologics' professionals, and reports on results of review by the professionals. Note: Efficacy reviews are conducted by prominent scientists on all products manufactured during the period 1903 thru 1972. Products are evaluated by panels (e.g., toxoids and toxins panel, allergenics panel, etc.). a. Reports. Offer to NARS ~~Offer to National Archives~~ after publication in the Federal Register or when no longer needed for reference. b. Supporting material. Destroy ~~Offer to National Archives~~ within 20 years after termination of review.		
B-12	Efficacy Review Committee Members. Documents relating to the members of the Efficacy Review Committee such as appointments and travel papers. Destroy 1 year after member leaves committee.		
B-13	Inspection Reports on Firms of Regulatory Interest ~~Records on firms that have gone out of business or are of no further regulatory interest.~~ ~~Transfer to FRC 2 years after inspection. Review for disposal 10 years after inspection. Offer a sample not to exceed 3% to National Archives at time of review.~~ Transfer to FRC 2 years after firm is out of business. Destroy 8 years thereafter.		

Four copies, including original, to be submitted to the National Archives 16—59428-1 GPO

B-14

Laboratory Test Records

Laboratory notebooks, records of results of clinical tests, evaluations, experimental findings, control test results, and related correspondence. Also card files containing summaries of test results and receipt of samples.

a. Inspection Sample Test Results.
b. Control Test Results.
c. Poliovirus Neurovirulance Experiment Findings.
d. Individual Animal Study Record Cards.

Transfer to FRC 5 years after completion of test. Destroy 20 years after test completion.

e. Animal Test Cards.
f. Sterility Test Cards.
g. Sample Cards.

Destroy 1 year after completion of test.

Four copies, including original, to be submitted to the National Archives 16—59428-1 GPO

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
	Bureau of Drugs Develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs for human use. Reviews and evaluates new drug applications (NDA's) and notices of claimed investigational exemption for new drugs (IND's). Develops and implements standards for the safety and effectiveness of all over-the-counter (OTC) drugs. Monitors the quality of marketed drugs through product testing, surveillance, and compliance programs. Develops and promulgates guidelines on current good manufacturing practices for use by the drug industry. Develops and disseminates information and educational material dealing with drugs to the medical community and the public. Conducts research and develops scientific standards on the composition, quality, safety, and efficacy of human drugs. Collects and evaluates information on the effects and use trends of marketed drugs. Monitors prescription drug advertising and promotional labeling to assure their accuracy and integrity. Analyzes data on accidental poisonings; disseminates toxicity and treatment information on household products and medicines. Evaluates applications for operation of methadone treatment centers and other activities using methadone or other drugs. Directs the FDA antibiotic and insulin certification program.		

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
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. a. Original reports. Transfer to FRC 5 years after completion of study. Destroy 20 years after completion of study. b. Report copies. Destroy when no longer needed for reference.		
D-2	Deleted		
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. Transfer to FRC 5 years after all action completed. Destroy 25 years after action completed. b. Other material. Destroy at same time as corresponding DESI folder.		
D-4	Clinical Investigator File Documents used to evaluate the quality of work performed by clinical investigators. Destroy after 5 years unless needed for further reference.		

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
D-5	New Drug Applications Applications from drug producers for approval to market new drugs (form FD 356H). Includes clinical data, test results, labeling, promotional material, progress and other reports, adverse reactions, notices of terminations, withdrawals or approvals, FDA evaluations and recommendations, supporting material, and related correspondence. a. Original: Transfer to FRC when no longer needed for reference. Destroy on repeal of enabling legislation. b. Duplicate: Destroy when action completed. c. Triplicate: Transfer to appropriate District Office when action completed.	B-600	#30
D-6	Investigative New Drugs (INDs) Applications from drug producers to ship drugs in interstate commerce and test new drugs on human subjects (form FD 1571). Includes amendments, formulations, progress and other reports, changes, FDA evaluations and recommendations, and related correspondence. a. Original: Transfer to FRC when no longer needed for reference. Destroy on repeal of enabling legislation. b. Duplicate and Triplicate: Destroy when action completed.		
D-7	Drug Master File Confidential information concerning drug producers such as personnel involved, facilities, drug formulations and production methods. a. Original: Transfer to FRC when no longer needed for reference. Destroy on repeal of enabling legislation. b. Duplicate: Destroy when no longer needed for reference. c. Triplicate: Transfer to appropriate District Office after initial review.		

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
D-8	Laboratory Services Monthly Reports Work count data for Program Management System reports. Consists of production regarding animal housing, glass- Destroy 1 year after order has been filled.		
D-9	Media Requests Orders from FDA professionals for culture media (form FD 1979). Destroy 1 year after order has been filled.		
D-10	Glassware Orders Orders from FDA professionals for laboratory glassware (form FD 1903). Destroy 1 year after order has been filled.		
D-11	Chemcial and Microbiological Assay Results Reports on assays (tests to determine amounts and strengths of components) of various substances performed by FDA professionals. Destroy 5 years after termination or when no longer needed for reference.		
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. ~~PERMANENT~~. Transfer to FRC 5 years after supersession by a later standard. ~~Offer to National Archives~~ Destroy 20 years after supersession.		

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
D-13	Assays Turbidimetric assay standard curve plots, zone reader data, plate assay zone readings, biological test data results and related raw data compiled both by various items of laboratory machinery and manual observations. Destroy 1 year after completion of assay unless needed for further reference.		
D-14	Certification Records (NCAA) Analytical data used in certification of drugs. Destroy when no longer needed for reference.		
D-15	Regulatory Testing Records Laboratory data sheet on testing of USP, NF, and IND sampels used for completion of analysts' work sheets. Destroy 5 years after preparation or when no longer needed for back-up.		
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.		
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 correspondence and documentation. Transfer to FRC 5 years after recall action completed. Destroy on repeal of enabling legislation. Destroy copies when no longer needed for reference.		

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
D-18	Drug Seizures Collection records, labeling, analytical reports, certificates and affidavits, seziure reports, termination of action reports, notices and records of hearings, recommendations, criminal prosecution records, and related documents pertaining to individual seizure actions. Transfer to FRC 5 years after completion of action or end of letter series. Destroy on repeal of enabling legislation.		
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.		
D-20	Defect and 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 Pharmaceopeia to ascertain what drugs and categories of drugs have above normal defects and laboratory testing difficulties. Transfer to FRC when no longer needed for reference. Destroy when program is abolished.		
D-21	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 of inspection reports, and other reports. Transfer to FRC when no longer needed for reference. Destroy on repeal of enabling legislation or when of no further use to FDA.		

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
D-22	Methadone Hospital Files Jackets from each hosptial receiving shipments of methadone containing applications to administer methadone, related correspondence, and reports on use and results of the drug. Transfer to FRC when no longer needed for reference. Destroy on repeal of enabling legislation or when of no further use to FDA.		
D-23	Registration File Official establishment registration forms (FD 1597 and FD 2656) from all drug producers and distributors submitted annually in compliance with the Kefaufer-Harris Amendment of 1962.		
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 when no longer needed to comply with the provisions of the Act.		
D-25	Batch and Production Data Files. Coding sheets of batch and production data submitted in compliance with the Drug Listing Act. Destroy when no longer needed to comply with the provisions of the Act.		
D-26	Abbreviated New Drug Applications. Applications to produce drugs already approved for other manufacturers. File contents similar but less extensive than NDA jackets (see D-5). Original. Transfer to FRC 2 years after date of last action. Destroy on repeal of enabling legislation.		

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
D-26 (Con't)	Duplicate. Destroy when action completed. Triplicate. Transfer to appropriate District Office when action is completed.		
D-27	Form A File (Original Reports). 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. Transfer to FRC 5 years after completion of final action. Destroy on repeal of enabling legislation.		
D-28	Drug Experience Reports Original and duplicate (pink) copies of Form 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 submitted by drug manufacturers and suppliers in conjunction with their NDAs (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. 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 10 years after submission of report unless needed for further study. (To be microfilmed per FPMR 101-11.507(c)(1		

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
	BUREAU OF FOODS Develops FDA policy with respect to the safety, composition, quality (including nutrition) and labeling of foods, food additives, colors, and cosmetics. Conducts research and develops standards on the composition, quality, and safety of foods, food additives, colors, and cosmetics. Conducts research designed to improve the detection, prevention, and control of contamination that may be responsible for illness or injury conveyed by foods, food additives, colors, and cosmetics. Develops and promulgates Current Good Manufacturing Practices for the food processing industry and Model Regulations for State and local government use in assuring food safety and quality. Plans FDA surveillance and compliance programs and evaluates progress toward objectives of planned program and regulatory activities relating to foods, food additives, colors, and cosmetics. Reviews industry petitions and recommends promulgation of regulations for food standards and for the safe use of color and food additives. Collects and interprets data on nutrition, food additives, and environmental factors affecting the total chemical insult posed by direct and indirect food additives. Analyzes regulatory samples as necessary to support Bureau complianc programs. Participates in training of FDA field personnel and provides guidance to the regulated industries in the application of the most effective procedures to assure food safety and quality. Studies consumer experience with expectation of and exposure to Bureau-regulated products and maintains a nutritional data bank. Recommends to the Office of the Commissioner new or revised legislation pertinent to the Bureau's responsibilities.		

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
F-1	Program Management Plans containing feasibility studies, time frames, and personnel and other resources required to conduct specific projects on such subjects as the effect of heavy metals in fish. Also, briefing material, supporting documentaton, notice of approval or rejection of plans, and interim and final reports with supporting material on the progress and results of approved projects. a. Final reports: Destroy 10 years after submission of report. b. Other material: Destroy 2 years after submission of report.		
F-2	Food Additive Petitions Formal requests from producers of vitamins, preservatives, etc., for approval for use of additive, notification of FDA approval, and documentation in support of approval. Transfer to On-Site Storeroom 6 years after final action taken. Destroy on repeal of enabling legislation.		
F-3	Food Additive Master File Supporting material from producers for food additive petitions such as test results, protocols, and correspondence between producers and FDA. Transfer to On-Site Storeroom 6 years after final action taken. Destroy on repeal of enabling legislation.		
F-4	Food Additive Subject File Correspondence with producers, industry, consumers, and other agencies concerning safety and efficacy of additive. Also advisory opinions, data reports, and evaluation results. Transfer to On-Site Storeroom 6 years after additive withdrawn from market. Destroy on repeal of enabling legislation.		

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
F-5	Food Standard Petitions Petitions received from various sources proposing to establish or amend standards of identity or container fill. Results of actions taken and supporting material. Also, food standards initiated within FDA. Transfer to On-Site Storeroom 6 years after final action taken. Destroy on repeal of enabling legislation.		
F-6	Color Additive Petitions and Diluent Petitions Formal requests from producers of color additives and diluents for use of their product. Notification of FDA approval and documentation in support of action taken. Transfer to FRC 6 years after action completed or when no longer needed for reference. Destroy on repeal of enabling legislation.		
F-7	Color Additive Master File Supporting material from producers for color additive petitions including test results, protocols, and correspondence between producers and FDA. Transfer to FRC 6 years after action completed or when no longer needed for reference. Destroy on repeal of enabling legislation.		
F-8	Color Additive Manufacturing and Process File Documents relating to manufacturing procedures: controls, testing equipment used, sanitation, capabilities of personnel, etc. Destroy 10 years after change of production process, when manufacturer has gone out of business, or when no longer needed for reference.		
F-9	Color Additive Certification Records of analyses of color additive samples submitted for certification. Destroy 1 year after certification is made or when no longer needed for reference.		

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
F-10	GRAS Petitions Requests from producers for approval of continued use of substances (additives and colors) in foods and cosmetics that are generally recognized as safe (GRAS). Notification of FDA approval and documentation in support of FDA action. Transfer to On-Site Storeroom 6 years after action is completed. Destroy on repeal of enabling legislation.		
F-11	Petitions Reviews Reviews of petitions received from producers of additives that have been rejected giving reason for rejection. Transfer to On-Site Storeroom 6 years after completion of review. Destroy on repeal of enabling legislation.		
F-12	Temporary Marketing Permits Application, permit copy, back up papers, and related correspondence concerning issuance of permits. Destroy 6 months after expiration of permit.		
F-13	Temporary Permits (test foods) Application for permit to market test foods deviating from standards, copy of permit, and supporting documents. Destroy 1 year after expiration of permit.		
F-14	Import Milk Act File Herd testing reports, milk import permits, reviews and related correspondence. Destroy 3 years after expiration of permit.		
F-15	Equipment Reviews Correspondence and publication references used to review and approve sanitation and food processing equipment proposed for use on interstate carriers. Correspondence with manufacturers and carriers. Reports and back-up material on acceptability of equipment. Destroy on completion of review unless needed for further reference.		

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
F-16	Vessel Plans Blueprints of ships, evaluations, and related correspondence with builders and suppliers detailing sanitation and food preservation equipment. Destroy on completion of ship.		
F-17	Sewage Treatment Plants Construction criteria, review of plant projects, cholorination studies, reports with recommendations for improvement or acceptability. Destroy 10 years after final action taken.		
F-18	State Assistance Reports Requests from state agencies for shellfish sanitation assistance, records of evaluation of request, and reports on denial and extent of assistance given. Destroy all material 10 years after preparation of report.		
F-19	Growing Area Surveys (shellfish sanitation) Raw bacteriological data, data interpretation reports on finding, follow-up documentation and recommendations. a. Data interpretation reports: Destroy 10 years after preparation. b. Other material: Destroy 3 years after preparation.		
F-20	Review of State Shellfish Labs Original data supplied by inspectors and state agencies, evaluation of data, reports on evaluation findings, recomendations for corrections, results of implementation of recommendations. Destroy 3 years after implementation of recommendations.		

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
F-21	Market Shellfish Raw bacteriological data, interpretation of data, staff reports of acceptability or need for corrective action. a. Staff reports: Destroy 10 years after preparation. b. Other material: Destroy 3 years after preparation.		
F-22	Recalls Materials on each action taken regarding the removal of unsafe, impure or mislabeled products from the market for destruction or return to producer for correction. Recalls can be initiated by the producer (voluntary) or FDA (involuntary). Includes recall summaries, internal reports, and correspondence pertaining to voluntary and involuntary recalls of unsafe products. Transfer to FRC 10 years after recall completed. Destroy 20 years after recall completed.		
F-23	Establishment Inspection Reports (Hazard Analysis Critical Control Point (HACCP) only) Investigational, surveillance, and miscellaneous reports made of plants and their products. Also related correspondence and documentation regarding corrective action taken. This is a program to make in-depth inspections of food producing plants which pose or may pose special health problems such as low acid canned foods. Transfer to FRC 15 years after reports have been given final review. Destroy 20 years after final review.		
F-24	Deleted		
F-25	Cosmetic Injury Complaints Original of complaint, action taken, final action, and related correspondence. Destroy 1 year after final action taken or when no longer needed for reference.		

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
F-26	FPLA State Survey Reports Reports submitted by state agencies indicating need for issuance of specific regulations under the Fair Packaging and Labeling Act. Transfer to FRC when regulation is promulgated. Destroy 10 years after regulation is promulgated.		
F-27	Deleted		
F-28	Referee Records and Correspondence Accuracy, development, and name of testing data; collaborative studies; methods of analyses; and name of chemist for subject under study. Also, appointment letters, adoption of methods, summarized topics and need for methodology on subject. Referees are chemists who develop and validate analytical methods for testing chemicals found in foods such as microtoxins or metals. These analytical methods become the procedure for testing individual food samples. Destroy 8 years after study is completed or referee's appointment is terminated.		
F-29	Referee Subject File Appointment dates and subjects assigned, status of studies, and reports on collaborative work. Destroy 8 years after termination of subject project or referee's appointment.		
F-30	Cooperative Quality Assurance Program (CQAP) CQAP is a self certification project between FDA and industry whereby producers of certain products enforce their own standards for purity, potency, etc., with minimum FDA supervision. Includes files on participants of Program icluding plant's production specifications, exception reports, and complaints. Also lists of abstentions, applications, candidates, deferred prospects, evaluations, nominees, rejectees, and terminees. Destroy 5 years after termination of program project.		

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
F-31	DELETED		
F-32	Data and Test Results Results of biochemical tests made to measure effects of various substances on animals. Also data on dose description, change to organs, total weight of subject, and description of litters. Transfer to FRC 15 years after completion of test. Destroy 30 years after completion of test.		
F-33	Assays - Biochemical and Clinical Procedures and methods used in performing assays, purpose of assay, and results of assay. Destroy 10 years after completion of assay.		
F-34	Analytical Worksheets Worksheets on the analysis made of cosmetic samples received from producers. Also labels with comments and changes for cosmetic products. Destroy 5 years after completion of analysis.		
F-35	Research Project Worksheets (data & correspondence only) Records of the results of research projects. Includes data sheets and description of experiments. Transfer to FRC 15 years after completion of project. Destroy 30 years after completion of project.		
F-36	Laboratory Notebooks and Experimental Data Records of tests made, assays, procedures, methods, samples used, and results. Transfer to FRC 15 years after completion of project. Destroy 30 years after completion of project.		
F-37	Progress Reports Summaries of laboratory notebook contents. Destroy 10 years after completion of report.		

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
F-38	Quarterly and Annual Reports Technical summary reports of projects being performed in laboratories in support of various projects. Transfer to FRC 5 years after completion of project. Destroy 12 years after completion of project.		
F-39	Sample Control Forms FD-421, Sample Accountability Record, used as basis for testimony given in legal actions and to account for regulatory and food additive samples received from District Offices. Transfer to FRC 7 years after preparation of form. Destroy on repeal of enabling legislation.		
F-40	Sample Files Sample worksheets and records of results of analyses or experiments on samples. Destroy 5 years after action is completed.		
F-41	Sample Record Books and Studies Reports on results of studies made to validate Canadian Food and Drug Directorate methods to detect salmonella in foods; to determine if Canadian methods are acceptable for use. Sample record books contain raw data pertaining to the samples used in the study. Transfer to FRC 5 years after completion of study. Destroy 10 years after completion of study.		
F-42	Chick Embryo Studies Records and reports on studies of the effects of drugs, food additives, and pesticides on chick embryos. Also evaluation of these studies as to possible toxic trends. Transfer to FRC 15 years after completion of study. Destroy 30 years after completion of study.		

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
F-43	Aflatoxins Studies Records and reports on findings of materials containing aflatoxins. Also, summaries of these reports. Destroy 5 years after completion of study.		
F-44	Swine Studies Results of studies on the generic effects of various substances on swine. Transfer to FRC 15 years after completion of study. Destroy 30 years after completion of study.		
F-45	Heavy Metals Study (Technical Plan) Laboratory notebooks and program material concerning the toxic effects of chemicals and metals injested in food. Transfer to FRC 15 years after completion of study. Destroy 30 years after completion of study.		
F-46	Use Data on FD & C Red #2 Data received from producers and trade associations re: use of Red #2 color additive in drugs, foods, and cosmetics. Used to help determine what restrictions will be placed on use of this color additive. Destroy 10 years after final action is completed, including settlement of legal suits and complete withdrawal of substance from market.		
F-47	Anaerobes Experiment record books containing data on clostridia experiments to test oxygen-producing bacteria for botulism poisionng. Destroy 10 years after completion of experiment.		
F-48	Sensitization Potentials Tests Results of tests and experiments made on various substances used in cosmetics for eye and skin irritation. Destroy 10 years after completion of tests.		

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
F-49	Food Additive and Pesticide Studies Results of toxicological tests and experiments made on various substances possibly found in foods. Used to determine safety levels of these substances in food for human consumption. Transfer to FRC 15 years after completion of study. Destroy 30 years after completion of study.		
F-50	Pathology Project Studies Study outline, description, objective, protocol, observations and report giving results and conclusions on the effect of toxic compounds in foods and additives on test animals. a. Final study reports: Transfer to FRC 15 years after completion of study Destroy 30 years after completion of study. b. Other material: Destroy 10 years after completion of study.		
F-51	Pathological & Histopathology Laboratory Record Books Notebooks used for referencing and indexing samples worked on in course of studies. Transfer to FRC 15 years after completion of study. Destroy 30 years after completion of study unless needed for further reference.		
F-52	Bionetics (Contract #71-268) Reports on bionetics studies made under contract. Back-up material and related correspondence. Transfer to FRC 1 year after acceptance of report Destroy 10 years after acceptance of report.		

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
F-53	GRAS Monographs and Evaluations Statements on historical use of GRAS (Generally Recognized as Safe) substances and evaluation procedures. Used as ad hoc text book and reference. The GRAS project is a reevaluation with improved techniques of chemicals previously found safe for use of foods. a. Monographs: Transfer to FRC on completion. Destroy 5 years after completion. b. Laboratory tests and scientific evaluations: Transfer to FRC when approved or denied. Destroy 10 years after denial or, if approved, after withdrawal of substance from market. c. Consumer comsumption data: Destroy when new ADP printout is available. d. Abstract cards: Transfer to FRC when no longer needed for reference. Destroy 4 years after transfer.		
F-54	GRAS Testing Mutagenicity reports on the results and summaries of tests made on GRAS substances under contract. Transfer to FRC 15 years after completion of test. Destroy 30 years after completion of test.		
F-55	GRAS Review of Literature EMIC (Environmental Mutagen Information Center)/GRAS lists of books and periodicals and some actual publications containing references to mutagenesis and teratogenesis. Transfer to FRC 10 years after completion of review. Destroy 15 years after completion of review.		

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
F-56	GRAS List of Contract Evaluations Reports, evaluations, and correspondence relating to contracts for the evaluation of the interagenicity of GRAS compounds. Transfer to FRC 5 years after completion of evaluation. Destroy 10 years after completion of evaluation.		
F-57	Contract Information Interim and final reports prepared by outside laboratories under contract for testing mutagenecity in GRAS chemicals. Transfer to FRC 1 year after action completed. Destroy 20 years after completion of action.		

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
	BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS Develops FDA policy regarding the safety, efficacy, and labeling of medical devices and in vitro diagnostic products. Collects and evaluates data on significant hazards to the public health which may be caused by the use of medical devices and diagnostic products; develops and recommends regulations and changes in or additonal to FDA legislative authority necesary to protect the public health. Evaluates the safety, efficacy, and labeling of medical devices and diagnostic products and recommends their classification into regulatory categories. Conducts research and coordinates the development of standards for appropriate categories of medical devices and diagnostic products; publishes approved standards and regulations specifying good manufacturing practices in the Federal Register. Develops, plans, coordinates, and evaluates FDA surveillance and compliance programs for medical devices and diagnostic products, and initiates compliance actions as necessary. Provides assistance in the handling of legal actions on medical device and diagnostic product matters. Operates a National Medical Device Experience Monitoring System. Provides the Commissioner with authoritative advice on significant existing and anticipated problems in the area of medical device and diagnostic product safety. Develops and disseminates educational materials on medical device and diagnostic product problems in conjunction with the Office of the Assistant Comissioner for Public Affairs.		

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
K-1	Seizure Files Copies of memos sent to General Counsel for seizure of unsafe or ineffective medical devices or diagnostic products. Destroy 1 year after action is completed unless needed for further reference.		
K-2	Recall Files Copies of requests for recalls sent to producers and distributors of defective medical devices or diagnostic products and supporting material. Destroy 1 year after action is completed unless needed for further reference.		
K-3	Regulatory Letter Files Copies of letters to District Offices requesting issuance of Regulatory Letters to producers. Destroy 1 year after action is completed unless needed for further reference.		
K-4	Assignment Log Copies of Assignment Memos to District Offices requesting inspections of certain firms. Destroy 1 year after action is completed unless needed for further reference.		
K-5	Establishment Inspection Reports (EIR) - Medical devices and diagnostic products only. Inspection forms, summary reports, findings, recommendations and related correspondence on inspections of producers' facilities. Transfer to AF jacket in Records Section, ACA, when study is completed (see item A2-1).		
K-6	Regulatory Material Weekly lists of detentions, recalls, seizures, injunctions, and prosecutions. Destroy 2 years after cutoff date unless needed for further reference.		

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
K-7	Regulatory Requests, surveys, programs, and legislation concerned with devices and diagnostic product enforcement activities. Destroy when superseded or cancelled, or 5 years after cutoff date.		
K-8	Deleted		
K-9	Litigation Sample jackets, legal drafts, witness' statements, correspondence, and other trial preparation material concerning medical device and diagnostic product court hearings. a. Sample jackets and official correspondence: Transfer to appropriate files (item 1 and A2-1) after completion of project. b. Other material: Destroy 1 year after completion of project or when no longer needed for reference.		
K-10	Investigation New Drugs (IND) and New Drug Applications (NDA) - medical devices and diagnostic products only Applications from manufacturers to test and market medical devices and diagnostic products consisting of clinical data, test results, amendments, supplements, labeling, promotional material, progress reports, adverse reactions, and related correspondence. Also, notices of termination, withdrawal, and approval. This project is concerned with determining the safety, effectiveness, and accuracy of apparatus such as electrocardiograms and blood pressure equipment used to diagnose illness from outside the body.		

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
K-10	a. Original: Transfer to FRC 5 years after date of last action. Destroy when enabling legislation is repealed. b. Duplicate: Destroy when final action is taken. c. Triplicate: Transfer to District Offices when final action is taken.		
K-11	Form FD 2687 File Copies of Notification of Shipment of In Vitro Diagnostic Product for Investigational Use form submitted by producers. Transfer to FRC 5 years after cutoff date. Destroy 10 10 years after cutoff date.		
K-12	Manufacturers' Submissions Replies from producers to requests for various items of information concerning their products for use in developing product standards. Includes equipment diagrams, production methods, quality controls, instructions for use and other data requested by the Agency to obtain adequate information to develop safety and performance standards. a. Original: Transfer to FRC when product standard is put into effect. Destroy 20 years after standard is put into effect. b. Copies: Destroy when no longer needed for reference or transfer to other activities.		

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

BUREAU OF RADIOLOGICAL HEALTH

Develops and carries out a national program designed to control unnecessary exposures of man to and assure the safe and efficacious use of potentially hazardous ionizing and nonionizing radiation.

Conducts an electronic product radiation control program including the development and administration of performance standards.

Plans, coordinates, and evaluates surveillance and compliance programs relating to radiation exposure.

Plans, conducts, and supports research on the health effects of radiation exposure through contracts and grants; and provides institutional support through training grants.

Develops criteria, recommendations, and standards relative to radiation use and exposure.

Develops and promotes improved procedures, techniques, and users' qualifications for reducing unnecessary radiation exposure.

Provides technical and scientific support, including training, to other bureaus within FDA and to other agencies having radiological health responsibilities.

Participates in development of model codes and recommendations for guidance of industry and of national, state, and local radiation-control and standard-setting agencies in order to optimize radiation control practices.

Maintains appropriate liaison with other Federal, state, and international agencies, with industry, and with consumer and professional organizations.

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
X-1	State Training Programs. Reports and recommendations from Regional Training Committees giving specific training courses needed, number of persons involved, projected number of trainees, and unique problems expected (e.g. state law provisions) for the training of state agents in radiological health enforcement. Destroy 10 years after termination of program.		
X-2	College/University Contracts. Contract copies and supporting material for training in educational institutions in X-ray science and engineering and in radiological technology. Destroy 1 year after termination of contract unless needed for further reference.		
X-3	Radiological Health Training and Medical Applications. Committee meetings and agendas, correspondence, progress reports, pilot project information, training packages, descriptions of training courses, studies and recommendations, regulations, licensing material, performance standards, studies and other material on radiological health applications to dentistry, podiatry, chiropractry, and other medical fields. This file documents developments of standard training procedures for lab technicians, paramedics, and other users of regulated equipment. Also, efforts to have procedures adopted by state agencies, medical schools, etc. a. Training packages and course descriptions, and "end product" items such as reports, on training effectiveness and training objective standards. Permanent - Offer to National Archives 5 years after termination of program. b. Other material. Destroy 5 years after cutoff date.		

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
X-4	Survey Activities Final reports and evaluations on X-ray exposure studies, X-ray trends, the Advanced X-ray Survey, and AEC Facility Inspections. Also, supporting material. Surveys are conducted to determine program effectiveness, areas needing greater attention, and effects of program implementation. a. Final Reports. Permanent - Offer to National Archives 10 years after completion of survey or when no longer needed for reference. b. Other Material. Destroy 10 years after completion of survey or when no longer needed for reference.		
X-5	Manufacturers File Plant visit reports and background information on makers of all regulated products. Destroy when plant ceases operations or when documents are no longer needed for reference.		
X-6	Standards and Regulations File Accident and incident data, dosage and exposure information, correspondence, documentation from outside sources, reports, position and summary statements, drafts of standards and legislation, and related material concerning radiological exposure. Also, appointments of Agency and outside members to the Medical Radiation Advisory Committee, the Technical Electronic Product Radiation Safety Standards Committee and other committees established to develop product standards and regulations. Destroy 3 years after cutoff date unless needed for further reference.		

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
X-7	Accidental Radiation Reports Letters from various sources reporting alleged cases of exposure to excessive radiation. Destroy 5 years after cutoff date unless needed for further reference.		
X-8	Defect Actions Correspondence concerning electronic products that do not comply with FDA safety standards. Destroy 5 years after cutoff date unless needed for further action.		
X-9	Electronic Products Correspondence Incoming and outgoing correspondence, telephone communications, memoranda and other information exchanged with manufacturers and others concerning the Radiation Control for Health and Safety Act of 1948 (PL 90-602). This Act is the enabling legislation for the Bureau of Radiological Health, granting authority to set standards and regulate producers of possibly hazardous radiation emitting products. a. Original documents (arranged alphabetically by originator) Destroy when microfilm proves to be an adequate substitute. b. Microform copies (arranged alphabetically by manufacturer.) Transfer to FRC after 5 years. Destroy when 20 years old. (To be microfilmed per		
X-10	Deleted FPMR 101-11.507(c)(1).		
X-11	Radiation Control Policy and Procedures (a/k/a Policy Statements, Interpretations, and Significant Correspondence Documents supporting the development of FDA regulations, policies, and procedures for setting safety and effectiveness standards for radiological products. Includes advisory opinions from General Counsel, minutes and reports of meetings, conferences, and hearings. Also correspondence with producers, trade and professional associations, and Federal and state agencies. Transfer to FRC 3 years after final action is taken; destroy 7 years after transfer.		

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
~~X-11 (Con't)~~	~~PERMANENT.~~ ~~Offer to National Archives on repeal of enabling legislation.~~		
X-12	Electronic Products Reports Exemption requests, variance requests, initial and annual reports, and reports of model changes filed by manufacturers of electronic products pursuant to the Radiation Control for Health and Safety Act. a. Exemption Requests. Transfer to FRC 1 year after termination of action. Destroy 5 years after transfer. b. Initial Reports. Transfer to FRC 1 year after final review is completed and no further action is required. Destroy 7 years after transfer. c. Annual Reports and Reports of Model Changes. Transfer to FRC 1 year after final review is completed and no further action is required. Destroy 7 years after transfer. d. Variance Requests. Transfer to FRC 1 year after expiration of variance or termination of action. Destroy 5 years after transfer.		
X-13	Electronic Products Microfiche Report File Microfilm copies of all exemption requests, variance requests, initial reports, annual reports, and reports of model changes filed by manufacturers of electronic products. Transfer to FRC 5 years after final action is completed. Destroy on repeal of enabling legislation.		

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
X-14	Compliance Case Files Compliance actions, defect rulings, corrective action plans, reports of accidental radiation occurrence, and supporting documents and materials. Transfer to FRC 5 years after completion of final action. Destroy on repeal of enabling legislation.		
X-15	Field Survey Forms Reports (forms FD 2783-2786 and 2536) resulting from field inspections of regulated products. Transfer to FRC 2 years after date of receipt or termination of action, whichever is later. Destroy 6 years after date of receipt or termination of action, whichever is later.		
X-16	Assembler Certification Forms Forms FD 2579 on which a diagnostic X-ray installation is reported and certified by the installer (assembler). Transfer to FRC 1 year after date of receipt. Destroy 6 years after date of receipt.		

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
	BUREAU OF VETERINARY MEDICINE Develops and recommends the veterinary medical policy of the Food and Drug Administration with respect to the safety and efficacy of veterinary preparations and devices. Evaluates proposed use of veterinary preparations for animal safety and efficacy. Coordinates the veterinary medical aspects of the FDA inspection and investigational programs and provides veterinary medical opinion in drug hearings and court cases. Plans, directs, and evaluates FDA's surveillance and compliance programs relating to veterinary drugs and other veterinary medical matters.		
V-1	Veterinary Investigative New Animal Drugs (VIND) and New Animal Drug Applications (NADA) including Medicated Feeds, Dosages, Pre-mixes, Master Files and Antibiotics ("65/55"). Applications from producers to test and market animal drugs and medicated feeds consisting of clinical data; amendments; supplements; labeling; promotional material; progress reports; adverse reactions; notices of termination, withdrawal, and approval; FDA evaluations and recommendations; acknowledgements and related correspondence and data. Original. Transfer to FRC 5 years after date of last action. Destroy when enabling legislation is repealed. Duplicate. Transfer to District Office when final action taken. Triplicate. Destroy when 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
V-2	Charge and History Cards Form FD 1702 for each VIND and NADA showing receipt of documents and action taken. Destroy when enabling legislation is repealed.		
V-3	Distributor Cards Form FD 1702 listing all distributors of each drug and drug component. Destroy when superseded or no longer needed for reference.		
V-4	Labels Additional copies of labels, inserts, and promotional material for each approved drug and feed additive. Destroy when product is withdrawn from the market or no longer needed for reference.		
V-5	Recalls Documents relating to the recall of unsafe, ineffective, unapproved, mislabeled, or adulterated animal drugs and medicated feeds. Includes requests for recall action with explanations, extent of recalls (wholesale or retail level), recommendations to approve results, approvals or denials, and effectiveness of results of the approved actions. a. Closed recalls. Transfer to FRC 3 years after action completed. Destroy 10 years after action completed. b. Open recalls. Transfer to Administrative File (AF) jacket 3 years after action completed.		
V-6	Draft Regulations Drafts of regulations concerning approval of animal drugs and feeds, changes, and clearances. Destroy 5 years after publication of regulation.		

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
V-7	Specific Drug and Industry File Copies of correspondence replying to producers; inquiries on drugs and feeds, regulations and studies. Destroy 4 years after cutoff date.		
V-8	Guidelines Procedures developed by the Bureau explaining and clarifying regulations for submission of applications. Destroy when superseded by new guide.		
V-9	Investigations Reports from District Offices on investigations of finding heavy metals, pesticides, and other harmful residues in animal feeds. Destroy 2 years after cutoff date unless needed for further reference.		
V-10	Investigation Summaries Summary sheets of investigation reports described above (V-9) and correspondence with investigators. Destroy 2 years after cutoff date unless needed for further reference.		
V-11	Industry Items Mailing lists and procedures for distributing Animal Drug Memos and BMV Memos to industry. Destroy when superseded.		
V-12	Special Project (Salmonella) Correspondence, working papers, committee minutes, reports, and other data on control of salmonella.		

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
V-12 (Con't)	a. Final report. Permanent. Transfer to FRC 5 years after completion of project. Offer to National Archives 20 years after completion. b. Other material. Destroy 1 year after completion of project.		
V-13	Pesticide File Comments and opinions forwarded to Environmental Protection Agency on applications to market drugs and pesticides. Destroy when superseded by later comments and opinions.		
V-14	Adverse Drug Reactions Reports received from public, Bureau Analyses, and recommendations. Transfer to appropriate NADA jacket when action completed.		
V-15	Adverse Drug Reaction Cards Abstracts of Drug Reaction Reports. Destroy 1 year after cutoff date or when no longer needed for reference, whichever is later.		
V-16	Drug Experience Reports Reports from producers on labeling, manufacturing, production, and clinical studies. Transfer to appropriate NADA jacket when action is completed.		
V-17	Intermural Projects Protocols, lab notebooks, EKG and other machine tracings, quarterly and semi-annual reports, project correspondence, and final manuscripts on tests and evaluations		

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
V-17 (Con't)	of animal drugs done by the Agency. Projects include evaluating the effects on animal metabolisms of drugs done in vivo, liver contamination by DES, and others done in support of NADA reviews. a. All original material. Transfer to FRC 5 years after completion of project. Destroy 20 years after completion. b. Copies. Destroy 1 year after completion of project unless needed for further reference.		
V-18	Contract (Extramural) Projects Contract copies, invoices, reports, correspondence, research papers and final manuscripts on tests and evaluations of chemicals done under contract with university labs in support of NADA reviews. Includes projects on T-2 toxins, cooking residues, and other substances which cannot be done inhouse. a. All original material. Transfer to FRC 5 years after completion of project. Destroy 20 years after completion. b. Copies. Destroy 1 year after completion of project unless needed for further reference.		
V-19	Colony Files Data on the effects of substances on test animals. Transfer to FRC 10 years after completion of test. Destroy 20 years after completion.		

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

EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS

Executes direct line authority over all FDA field operations; develops, issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within FDA through which Headquarters offices obtain field support services.

Provides direction and counsel to Regional Food and Drug Directors in the implementation of policies and operational guidelines which form the framework for management of FDA field activities.

Establishes FDA's field compliance and enforcement posture, based on Agency policy.

Develops and/or recommends to the Commissioner policy, programs, and plans for activities between FDA and State and local agencies; administers the Agency's overall Federal-State program and policy; coordinates the program aspects of FDA contracts with State and local counterpart agencies.

Evaluates the overall management and capabilities of FDA's field organization; initiates action to improve the management of field activities and coordinates the formulation and management of career development plans.

Implements nationwide information storage and retrieval systems for data originating in field offices.

Develops and/or recommends to the Commissioner policy programs, and plans for applied research which relates to FDA enforcement problems and which will be conducted by field installations; coordinates such research efforts with concerned bureaus and the Office of Science.

Provides other FDA components with laboratory support in various highly specialized areas.

Recommends priorities for all field construction, repair, improvement, and renovation and recommends short- and long-range field facility utilization plans.

Operates FDA emergency preparedness and civil defense programs.

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
0-1	Comprehensive Inspection of Chronic Violators (CICV) Background data, compliance action plans, reports, and correspondence on firms that are frequent violators of FDA regulations. Destroy ~~Permanent. Offer to National Archives~~ 3 years after cutoff date.		
0-2	Import Detention Notices Detention notices, hearing documents (including lab work sheets), and Release or Referral Notices. Transfer to FRC 3 years after issuance of Release or Refusal Notice. Destroy 8 years after issuance.		
0-3	Commercial Detention Lists Monthly lists of products detained by FDA for possible violation. a. Original list. Destroy 10 years after issuance. b. Copies. Destroy 3 years after issuance.		
0-4	Import Alerts and Circulars Notifications sent to field offices advising of importation of violative products. a. Original notifications. Destroy 10 years after issuance. b. Copies. Destroy 3 years after issuance.		

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
0-5	Import Detention Lists. Lists of detained violative products. a. Original lists. Destroy 10 years after issuance. b. Copies. Destroy 3 years after issuance.		
0-6	Recall File. Recommendations for recall of violative products from the market, notifications of recall actions taken, concurrences, effectiveness checks, distribution information, and recall summaries. Destroy 3 years after recall action is completed.		
0-7	Emergency Operations. Reports received of injuries caused by products and product complaints. Destroy 3 years after final action taken.		
0-8	Action Plans. Plans developed by field offices for allocating resources to achieve increased and improved surveillance of products and their producers used internally by the Executive Director of Regional Operations. Destroy 10 years after firm is in compliance.		
0-9	Radiation Inventory. Reports from state agencies on costs, equipment, and personnel involved with radiation programs. Destroy 10 years after receipt unless needed for further reference.		

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
0-10	Quality Assurance. Inspection reports and other investigational activity records for the Quality Assurance Group used to monitor the effectiveness of inspections of regulated firms and of other field office activities. a. Inspection reports. Transfer to appropriate Administrative File (AF) jacket 2 years after action has been completed. b. Other material. Destroy 2 years after action has been completed.		
0-11	Foreign Inspection Program. Correspondence, inspection reports, drug information, and related data on firms importing drugs into this country. Destroy 5 years after approval unless needed for further reference.		
0-12	Project IDEA. Final reports, clearances, and related correspondence with field offices on tryouts of new programs and procedures. The project is concerned with testing and evaluating worthwhile recommendations for improving field office procedures. Destroy 1 year after completion of project unless needed for further reference.		
0-13	Project IDEA Inspection/Analytical Reports. Inspection and analytical reports from field offices as part of pilot studies under project IDEA. Destroy 3 years after publication of final report.		

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
0-14	Program Oriented Data System (PODS) ADP file of inspections made, samples analyzed, enforcement activities, establishments and products involved, and other field activities. Used to measure program effectiveness and indicate problem areas. Destroy when superseded or no longer needed for reference.		
0-15	Consultants' Files Interim and final reports, comments, correspondence and supporting material for a management consultant study of EDRO operations prepared by Booz-Allen-Hamilton. Destroy 5 years after termination of contract unless needed for further reference.		
0-16	Commissioning Files Correspondence, personal history statements, and approvals pertaining to the commissioning of state officials to enforce FDA regulations. Destroy 10 years after commission is revoked.		
0-17	State Contracts Contracts and related correspondence with state agencies for enforcement of FDA regulations. Destroy 5 years after revocation of contract.		
0-18	Salmonella Reports Weekly reports from field offices giving the number, category, etc., of food samples examined for traces of salmonella poisoning and the results of the examinations. Also summaries of these reports prepared at headquarters. Used to determine extent and patterns of salmonella poisoning. Transfer to FRC 3 years after cutoff date. Destroy 6 years after cutoff date.		

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
0-19	Consumer Complaints Copies of forms FD 2516 and 2516a prepared by field offices on reports of adverse reactions received from the public, medical community and state agencies. Includes complaint letters from consumers. Also follow-up reports on action taken and related correspondence. Use to pinpoint problem areas and for reference. Transfer to FRC 3 years after cutoff date. Destroy 6 years after cutoff date.		
0-20	Government-Wide Quality Assurance Files Comments by FDA inspectors visiting firms selling drugs to Defense Department regarding their adherence to Good Manufacturing Procedures (GMP). Used to determine firm's ability to produce adequate quantities of pure and efficacous drugs (firm profiles). Transfer to Administrative File (A2-1) after completion of review and any necessary action taken.		
0-21	Civil Defense Plans, reports, instructions, and correspondence on relocation, evacuation, and security. Destroy when superseded or no longer needed for reference.		

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
	NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH Conducts research programs to study the biological effects of potentially toxic chemical substances found in man's environment, emphasizing the determination of the adverse health effects resulting from long-term, low-level exposure to chemical toxicants; the determination of the basic biological processes for chemical toxicants in animal organisms, the development of improved methodology and test protocols for evaluating the safety of chemical toxicants; and the development of data that will facilitate the extrapolation of toxicological data from laboratory animals to man. Conducts such additional research programs as may make appropriate use of facilities and expertise of the Center and contribute to its overall scientific capability. Develops, as a national resource, Center programs in close cooperation with other agencies such as the National Institutes of Health and the Department of Agriculture. Operates with the advise of a Policy Board, consisting of members appointed by the Secretary of Health, Education, and Welfare and by the Administrator, Environmental Protection Agency. The Policy Board recommends program priorities, reviews program and research results, reviews budget requirements and allotments, recommends management policies, reviews qualifications of applicants for key positions, and advises agency heads on matters concerning the Center.		

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
HFH1-1	Protocols. Proposals to conduct various experiments containing outline of experiment, objectives, rationale, format, time frames, methodology, resources needed, and expected results. a. Approved protocols. Destroy 5 years after completion of experiment. b. Disapproved protocols. Destroy 5 years after disapproval.		
HFH1-2	Raw Data. Findings on tests for pathogens in bacteria, mold, and in samples of animals and air. Includes weekly reports on the findings. a. Specific pathogen free animal tests. Destroy when no longer needed for research purposes. b. Quarantined animal tests. Destroy when vendor goes out of business. c. All others. Destroy when final report (item 21) is issued.		
HFH1-3	Experimental Data. Laboratory notebooks and other documents containing assays, observations, and scientific or technical raw data on various experiments. a. If experiment results published. Destroy 1 year after date of publication. b. If not published. Destroy when no longer needed for research purposes with a maximum of 5 years.		

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
HFH1-4	Breeding Information System (manual). Data on genealogy, productivity, number and size of litters, intervals between litters, weight, food consumption, and abnormalities of test animal entered in log books. a. Breeding animal data. Destroy after 5 years. b. Experimental animal data. Destroy when no longer needed for research purposes. Note: These records may also be destroyed when the file (Item 12) is proven reliable.	BIS	
HFH1-5	Experimental Data Collection. Log books indicating which test animals have been assigned to which experiment. Destroy when no longer needed for research purposes or reliability of BIS file is proven.		
HFH1-6	Allocation System. Log books giving data detailing what animal colonies were assigned to which experiment, combining information in the Breeding Information System (item 4) and Experimental Data Collection (item 5). a. Breeding animal data. Destroy after 5 years. b. Experimental animal data. Destroy when no longer needed for research purposes. Note: These records may also be destroyed when the BIS file (item 2) is proven reliable.		

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
HFH1-7	Gross and Microscopic Pathology Reports Mark-sense forms containing raw data on experiment observations to be entered on magnetic tape reels. Destroy 1 year after completion of experiment unless needed for further research or reference purposes.		
HFH1-8	Tissue Slides and Blocks Glass slides and paraffin blocks containing organs of sacrificed animals used for microscopic examination. Destroy when no longer needed for research purposes.		
HFH1-9	Environmental Files Data on results of periodic testing of "clean" areas for possible contamination. Used to document healthfulness of work area. Transfer to FDA Safety Officer after 1 year. Destroy when no longer needed for reference.		
HFH1-10	Environment Monitoring System (JC-80X10) Data on temperature, humidity, and other laboratory conditions entered daily on magnetic tapes. Destroy after 5 weeks and when data entered on summary tapes (item 11).		
HFH1-11	Monthly EMS Summaries (JC-80110) Summaries of data on Environment Monitoring System tapes (item 10) entered on magnetic tapes. Destroy 5 years after completion of all experiments on tape reel.		
HFH1-12	Breeding Information System (B-12X0) Genealogical history and transactions of test animals used used in various experiments entered daily on magnetic tape. Destroy after 5 weeks and when data entered on summary tapes (item 13).		

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
HFH1-13	Monthly BIS Summaries (B-120H0). Summaries of data on Breeding Information System tapes (item 12) entered on magnetic tapes. Destroy when no longer needed for research purposes.		
HFH1-14	Experiment Information System (E-110H0). Data on gross observations such as changes in weight, tumor growth, appearance, and feed and water given to animals undergoing tests entered daily on magnetic tape. Destroy after 5 weeks and when data entered on summary tapes. (See item 15)		
HFH1-15	Monthly EIS Summaries (E-110H0). Summaries of data on Experiment Information System tapes (item 14) entered on magnetic tapes. Destroy when no longer needed for reference purposes.		
HFH1-16	Pathological Information System (P-110X0). Data regarding pathological observations of test animals entered as needed on magnetic tapes. Destroy after 14 days and when data entered on summary tapes (item 17).		
HFH1-17	Monthly PIS Summaries (P-200H0). Summaries of Pathological Information System tapes (item 16) entered on magnetic tapes. Destroy when no longer needed for research purposes.		
HFH1-18	Correction Tapes (B-141X0). Updates and corrections made to BIS System tapes (item 12). Destroy after 5 weeks and when data entered on summary tapes (item 13).		
HFHI-19	Monthly Correction Tape Summaries (B140H0). Summaries of Correction Tapes (item 18) entered on magnectic tapes. Destroy when no longer needed for research purposes.		

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
HFH1-20	ADP Printout files. Hard page copies of data contained in magnetic tape files (items 10-19). Destroy on completion of experiment or when no longer needed for reference.		
HFH1-21	Manuscripts/Publications. Final reports on findings and results of various experiments with key supporting data in summary form such as assays, observations, methodology, etc. May also contain conclusions and recommendations. Permanent - Offer original (official) copy to National Archives 20 years after issuance. Destroy other copies when no longer needed.		
HFH1-22	Monthly and Periodic Status Reports. Summaries of memoranda from project and experiment leaders giving findings and results of various experiments. Also, advise as to status of work in process and work completed. Destroy after 5 years unless needed for further reference.		
HFH1-23	Program Planning and Evaluation files. Copies of Monthly Status Reports, Quarterly Reports, Annual Reports, Quarterly EPA Reports, and feeder reports from NCTR activities. Reports contain highlights of accomplishments and events at NCTR in narrative format. Destroy 1 year after submission of report unless needed for further reference.		
HFH1-24	Engineering Plans. Diagrams of buildings and facilities occupied by NCTR showing plumbing, wiring, etc. Destroy or return to Corps of Engineers when superseded, building is demolished, or no longer needed by NCTR.		

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
	CINCINNATI TRAINING FACILITY Develops and directs a wide range of training and educational programs conducted by FDA for other Federal, State, and local personnel. Maintains an awareness of new developments in all FDA program areas and relates such developments to corresponding training needs of State and local personnel. Participate in or coordinates the conduct of training courses or education workshops within the Regions. Develops or coordinates the development of manuals, course materials, publications, and audiovisual aids needed for the effective conduct of classroom, correspondence, and on-the-job training programs; operates facilities appropriate to the needs of these training operations. Serves as the focal point of coordination of the Agency's Federal-State training program.		
H2-1	Training Files Names of attendees and instructors, travel documents, critiques, and miscellaneous correpondence and material relating to courses conducted by the Cincinnati Training Facility, EDRO. Destroy 5 years after completion of course.		