REQUEST FOR RECORDS DISPOSITION AUTHORITY
(See instructions on reverse)

Rec'd 5/21/79

LEAVE BLANK
JOB NO. NC1-88-79-2
DATE RECEIVED 7/13/79
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disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10

OCT 9 1979 Walter M. Steuder
Date ACTING Archivist of the United States

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
Publich Health Service

3. MINOR SUBDIVISION
Food and Drug Administration

4. NAME OF PERSON WITH WHOM TO CONFER	5. TEL. EXT.
Joseph Reiff	443-4055

6. CERTIFICATE OF AGENCY REPRESENTATIVE.

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposal of the agency's records; that the records proposed for disposal in this Request of 18 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified.

☐ A Request for immediate disposal.

☒ B Request for disposal after a specified period of time or request for permanent retention.

C. DATE	D. SIGNATURE OF AGENCY REPRESENTATIVE	E. TITLE
5/14/79	Norman E. Shipp	Chief, Management Methods Branch, DMS FDA Records Control Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
	This request describes the Agency's machine readable (ADP) records. Items are keyed to identify the organization responsible for each file and follow the system established in the Agency's paper and film records schedule approved by the Archivist of the United States on February 23, 1978.		

to 10/2/79 - Changes with 5 items approved per V. Reiff. (PL)

115-107

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

Copy to Agency NNRS NCN 10-17-79

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
A2-10	Correspondence/Document Control System provides location, name, subject, date, and other key data regarding important documents in general subject and other files. Used to control and locate these documents for immediate access. Destroy (erase) at same time referenced documents are destroyed (see FDA Records Schedule, Item 1).		
A5-3	Contract Management Information System System tracks status and location of contract information such as accounting data, work description, property and personnel involved, period of performance, and billing information. Used to provide status, expenditures, and location of each contract. Destroy data when corresponding contract is closed and sent to Federal Records Center (see General Records Schedule 3, Item 4). Retain in history file until that time.		

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-4	Cross Reference of Regulations Provides control and cross references to those regulations pertaining to FDA and appearing in 21 CFR. Used to give FDA control over regulatory material under its areas of responsibilities. Destroy obsolete data during supplemental annual and quarterly updating. Destruction to be executed by operational office (FRW).		
C-5	Document Reporting System contains a comprehensive listing of Federal Register notices, proposals, and rules on a bureau by bureau basis. Used to track and control FDA Federal Register document activities. Destroy obsolete entries when quarterly report is prepared. Destruction to be executed by operational office (FRW).		
C-6	Federal Register Document Processing System contains drafts including revisions of Federal Register documents prepared by FDA components. Used to accelerate the flow of Federal documents from time of initial draft to final issuance by computer editing techniques. Destroy on completion of file on each particular Federal Register document. Destruction to be executed by operational office (FRW).		

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
P-2	Statistical Survey System Questionnaire data resulting from surveys of the general public regarding consumer attitudes on various regulated products, how the products are used, and their knowledge and experience with these products. Also demographic data on persons surveyed. Surveys are conducted on an irregular basis and cover a wide range of regulated product areas where consumer awareness should be increased. Evaluate need for file annually. Destroy 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
0-22	Pesticide This system collects detailed statistical data on the collection and examination of samples for pesticides, metal contaminanats and polychlorinated biphenyl (PCB) in order to provide statistical reports on the analysis of contaminated samples for further action by FDA. It is also used for Bureau of Foods and Bureau of Veterinary Medicine Compliance Program Evaluation, and Freedom of Information requests. Data needed for analysis was collected on or before September 30, 1977. Destroy 5 years after data has been collected and analyzed. (September 30, 1982).		

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-15	Blood Establishment Inspection and Registration System Names, addresses, products and other key data on blood establishments. Also inspection findings and collection and distribution data. Used to produce reports and statistics on types of products, functions, and discrepancies. Destroy on repeal of enabling legislation.		
B-16	Adverse Experience Reports Data consisting of product, producer, lot number, location, etc., on adverse biological experiences submitted by manufacturers and physicians. Used for adverse experience report preparation. Destroy on repeal of enabling legislation.		
B-17	Biological Products Lot Release Data extracted from lot release forms consisting of manufacturer, lot number, protocol receipt date, test results and action taken on each lot of biological products released, except swine flu lots. Used to prepare reports of actions taken and lots rejected. Destroy 10 years after report is prepared.		
B-18	Swine Flu Clinical Trials and Lot Release Similar to Biological Products Lot Release file (B-17) but also includes analyses of swine flu clinical trial results. Used to compare and analyze lot dosages, clinical reactions, and antibodytiters. Destroy on September 30, 1989.		
B-19	Histocompatability Research Names, blood types, and HLA (human leukocyte antigens) lab results of tested patients. Use for research analyses. Destroy 20 years after analysis 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
D-30	ASTRO-4 Drug Information System This system maintains a file of data on new drug applications (NDA) and investigational new drugs (IND) which includes such items as drug manufacturers, drug names, drug usage information, and status of drug applications used to generate reports to aid in the IND/NDA review process and for compliance purposes. Destroy on repeal of enabling legislation.		
D-31	New Drug Evaluation Management Information System This system maintains information relative to the receipt and review of investigational new drugs (IND), new drug applications (NDA), and related types of submissions. Destroy on repeal of enabling legislation.		
D-32	Radioactive Drug Research Information System This system maintains information relative to the receipt and review of submissions from radioactive drug research committees. Destroy on termination of program.		
D-33	Drug Product Defect This system maintains a comprehensive file of problem data collected on drug products to determine whether the problem is peculiar to the product itself, might occur in other products made by that company, or if the problem is an industry-wide phenomenon. Destroy 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-34	Bioresearch Monitoring Information System This system maintains data files on clinical investigators and will maintain data on clinical and nonclinical facilities associated with an investigational new drug (IND). Data will be updated periodically and reports prepared which will facilitate the monitoring of human drug trial efforts by the Division of Scientific Investigations. Destroy on repeal of enabling legislation.		
D-35	OTC Information System This system will maintain data on regulatory actions, correspondence with drug manufacturers and review panels, comments on proposed monographs, and bibliographic citations relative to the establishment of OTC drug monographs. Destroy on repeal of enabling legislation.		
D-36	Drug Experience Information System This system maintains data files consisting of adverse reactions to marketed drugs as reported by manufacturers, hospitals, and physicians. Tables are generated showing adverse reactions and/or drug interactions, as well as other reports in response to specific requests. Destroy on repeal of enabling legislation.		
D-37	Drug Efficacy Study Implementation Data System This system maintains data related to drug products studied by the National Academy of Science/National Research Council as a result of the 1962 amendments to the Food, Drug, and Cosmetic Act. Reports are generated to assist the Bureau of Drugs with administration of the Drug Efficacy Study Implementation (DESI) project. Destroy 5 years after termination of 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-38	Drug Abuse Treatment Monitoring Information System This system maintains data files on the use of methadone and other treatment modalities in drug abuse treatment programs. The file includes historical data, the results of periodic FDA inspections, staffing, and annual report information. Destroy on termination of program.		
D-39	Biopharmaceutical Review Management Information System This system maintains a data base of information pertaining to all new drug applications (NDA), investigational new drugs (IND) abbreviated new drug applications (ANDA) and Antibiotic Forms 5 and 6 that have completed biopharmaceutical review. Destroy on repeal of enabling legislation.		
D-40	Poison Control System This system provides immediate response to selected poison control centers using cathode ray tubes (CRT) on questions concerning the accidental ingestion of approximately 10,000 household products and medicines. Destroy on termination of program.		
D-41	Medically Oriented Data System (MODS) This system contains data on the nature and cause of injuries resulting from use of drugs, medical devices, and other products under FDA jurisidiction as reported by hospitals. Used to collect data showing what products are especially dangerous. Destroy on termination of 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
F-58	Internal Research Reports Results of scientific research studies in the Bureau of Foods containing title and author of report, subject, key words, program, and location of report. Provides information on on-going research for use of other Agency scientists, reviewers, and program managers. Destroy individual items when superseded by new data.		
F-59	Scientific Manuscript Bibliography Retrievable records of scientific documents created by Agency authors. Includes authors, titles, key words, bibliographic data, and accession number. Used to provide an index on Agency created documents. Destroy individual items when superseded by new data.		
F-60	Automated Dictionary Services Descriptions of new chemical and food terms and index codes. Used to produce dictionaries of these terms to facilitate information retrieval. Destroy items when superseded by new data.		
F-61	Food Defect Action Level Simulator Reports of analysis of sampled foods giving specific type(s) of defect (insect fragments, mold, etc.). Used to illustrate the impact of different action levels to aid in establishing the levels of defects FDA will accept in the tested product. Destroy items when superseded by new data.		
F-62	Total Diet Sampling of food intakes, region, season, and date. Used to produce the Market Basket Summary Report for food contamination by pesticides and chemicals. Destroy items 3 years after superseded by new data.		

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-63	Low-Acid Canned Food Data consisting of a registry of low acid canned food processors and processes to assure that all processes are in compliance with 21 CFR, Part 90. Destroy items when superseded by new data.		
F-64	Compliance Program Evaluation Reporting on the status of compliance program evaluations for the purpose of tracking the status of the review. Destroy items when superseded by new data.		
F-65	Imported Foods System contains the results of sample analyses of imported foods. Information is analyzed in order to monitor import food quality. Destory on completion of evaluation of the program.		
F-66	Food Information Storage and Retrieval System consists of retrieval of citations and indexing of documents covering Bureau of Foods' documents in files, compliance program evaluation reports, contract reports, technical plan project descriptions, and internal research reports. Used to provide Bureau scientists and managers with systematic access to historical data. Destroy when items superseded by new data.		
F-67	Heavy Metals This system records results of sample analyses performed in the field to monitor the maximum levels of lead and cadmium leached from ceramic dinnerware. The reports are used in evaluating the effectiveness of the compliance program. Destroy items when superseded by new data.		

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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
F-68	Animal History Data This system records information on laboratory animals tested in the Bureau of Foods for animal condition, weight, and food consumption to provide history and simple statistics in a meaningful manner. Destroy items when superseded by new data.		
F-69	Voluntary Registration of Cosmetic Product Establishments This system registers all cosmetics establishments, manufactured products, raw materials, ingredients and adverse reactions in order to facilitate industrial surveillance, provide the ability to associate the chemical hazards with specific products and relate adverse reactions to ingredients. Destroy items when superseded by new data.		
F-70	Chick Embryo This system maintains historical data from a screening program to teratogens. It provides summaries and detailed statistical analyses on chick embryos in order to screen potentially teratogenic compounds and identify those which are more likely to be teratogens. Destroy items when superseded by new data.		

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-13	Medical Device Classification This system maintains a file of medical device classification data obtained through the use of Food and Drug Administration (FDA) Advisory Panels. System information is used to (1) track progress of the advisory panel; (2) assess the number and types of devices in the various classification categories; (3) respond to public inquiries regarding specific device classification levels, and (4) help establish priority ranking for device standard development. Destroy individual data items as they became inactive or are updated.		
K-14	Medical Device Experience Monitoring Network This system maintains a file of laboratory product defect information collected from multiple sources such as laboratories, druggists, and hospitals in order to target FDA field resources at device defect problems. Destroy on repeal of enabling legislation.		
K-15	National Standards Survey This system maintains medical device standard development information. Used to produce the National Standards Survey Directory compiled from standards development organizations in order to produce a Standards Directory (National). Destroy individual data items as they became inactive or are updated.		
K-16	International Standards Survey This system maintains medical device standard development information. Used to produce the International Standards Survey Directory compiled from standards development organizations in order to produce a Standards Directory (International). Destroy individual data items as they became inactive or are updated.		

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

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
K-17	Document Control This system maintains a file of data from manufacturers. Used to track and maintain a histroy of correspondence submitted to meet legal requirements. Destroy individual data items as they became inactive.		

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-20	Drug Experience Report This system, which is the Drug Experience Report (DER), monitors approved new animal drug aplications. This information is in regard to marketed quantities and adverse reactions encountered in the use of approved drugs. Destroy 2 years after data has been collected and analyzed.		
V-21	New Animal Drug Applications This system is the new animal drug applications index which provides data regarding applications for approval to market new animal drugs, which are distributed periodically throughout the Bureau. Destroy 2 years after data has been collected and analyzed.		
V-22	Investigational New Animal Drug Index This system is the investigational new animal drug (INAD) index which provides information related to activities associated with the investigation of new animal drugs. Quarterly distribution of index is forwarded to all divisions in the Bureau. Destroy 2 years after data has been collected and analyzed.		

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-17	Compliance Activities Planning and Evaluation This system will assist the Bureau in control, analysis and decision making with respect to data submitted under requirements of Public Law 90-602, and will identify manufacturers or assemblers in potential low-compliance, and assist in inspection and resource allocation. Destroy 5 years after termination of program.		
X-18	Nationwide Evaluation of X-ray Trends (NEXT) This system provides a mechanism for monitoring x-ray use trends, and allowing states to evaluate radiation protection progress. Destroy 20 years after termination of project.		
X-19	Radiation Registry of Physicians This system compares age specific and age adjusted morbidity, incidence and mortality rates between radiologists and pathologists in order to determine the difference between radiation effects on the two groups of physicians. Permanent. Transfer to NARS 10 years after completion of survey. ~~Transfer to FRC 10 years after completion of program.~~ ~~Destroy 10 years after date of transfer.~~		
X-20	Social Security Administration Disability Study This system determines differences of radiation effects between occupationally exposed persons and a control group. ~~Permanent~~ ~~Offer to National Archives when no longer needed for Agency use. Include magnetic tapes (do not release data to public until 50 years after date of transfer) and one copy of source document, code sheet, and record layout.~~ Destroy 1 year after termination 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
X-21	Radiation Protection - Personnel Monitoring This system monitors the occupational radiation exposure of Federal employees and maintains these records for possible health effects, evaluation, and administrative and/or judicial proceedings. Dispose of when and as authorized by the Nuclear Regulatory Commission (10 CFR 20.401)		

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
HFI-25	Diagnostic Data This system provides an automated data collection and retrieval system on environmental microbiological surveillance testing and experiments for microbiological surveillance support. Destroy on repeal of enabling legislation.		