Schedule Number: NC-174-00-237

All items in this schedule are inactive. Items are either obsolete or have been superseded by newer NARA approved records schedules.

Description:

Superseded by NC1-088-78-001 #B1-14

INACTIVE - ALL ITEMS SUPERSEDED OR OBSOLETE

U. S. GOVERNMENT PRINTING OFFICE: 1973-524-748

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS

(See Instructions on Reverse)

29 items 8688

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

LEAVE BLANK	
DATE RECEIVED: AUG 29 1974	JOB NO.: NC 174-237

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disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10.

10-4-74 (Date) Wayne Robert Jr. Acting Archivist of the United States

1. FROM (AGENCY OR ESTABLISHMENT)
Department of Health, Education, and Welfare
2. MAJOR SUBDIVISION
Food and Drug Administration
3. MINOR SUBDIVISION
Bureau of Biologics
4. NAME OF PERSON WITH WHOM TO CONFER: Joseph Reiff
5. TEL. EXT.: 153-34055
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 6 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified.

(note change to item # 90)

8-28-74 (Date) Joseph S. Reiff (Signature of Agency Representative) Acting Chief Management Methods Br. DMS, ACA (Title)

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

The Food and Drug Administration is responsible for assuring the safety, efficacy, potency, and purity of foods, cosmetics, medical devices and drugs including biological products. The Bureau of Biologics is particularly concerned with administering regulation of biological products and blood shipped in interstate and foreign commerce. To this end, the Bureau plans and conducts research related to the development, manufacturing, testing, and use of biological products; establishes written and physical standards; approves licensing of manufacturers to produce biological products; inspects manufacturers' facilities for compliance with standards; and tests products submitted for release.

81 General Subject

Basic correspondence series of incoming correspondence of trade and professional associations, government agencies, and the general public, other than complaints. Contains official copy of the reply. Arranged by subject and chronologically.

PERMANENT. Transfer to Washington National Records Center after 7 years. Offer to National Archives 20 years after cutoff.

82 Consumer Complaints

File contains original complaint letters from consumers and others including copies of those submitted on forms FD 1639

Copy to Agency 10/10/74 MD.

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
	Drug Experience Report. Also correspondence with firms involved concerning the complaint and corrective action taken as well as memos for record regarding the complaint. a. Transfer to Washington National Records Center 5 years after complaint is resolved; destroy after 15 years in FARC except b. Offer a sample not to exceed 3% to National Archives, 15 years after complaint is resolved.		
83	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 personnel regarding the testing of vaccines. Destroy 5 years after action has been completed.		
84	Correspondence Cross Reference (Salmon) File contains carbon copies of outgoing correspondence arranged alphabetically by individual or firm name for cross reference. Destroy after 3 years.		
85	Pending Licenses and Applications A. Approved licenses: Place documents in Establishment or Product License files (items 87 and 88). B. Disapproved License Applications: Destroy application and supporting material 5 years after disapproval, with the exception of a sample, not to exceed 3%, Offer to National Archives the sample 5 years after disapproval. File contains copies of form NIH 523 or FD 2671, License Application Reference Number Notification, cover letters to the firm and miscellaneous correspondence.		
86	License Application Notices File is similar to Pending Licenses file (item 85) but contains other copies of form NIH 523 or FD2671, and correspondence with firm concerning approval or disapproval and follow-up documents. Destroy after 1 year.		

Standard Form No. 115-A
Revised November 1951
Prescribed by General Services Administration
GSA Reg. 3-IV-106
115-202

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
87	Establishment Licenses Active License: Retain in agency space until license is revoked, suspended, or superseded. Revoked, Suspended, or Superseded License: a. 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 eventually to National Archives. b. license establishment supporting material: Disposal not authorized at this time; review for disposal within 10 years after revocation, suspension, or supersession. When reviewed, select a sample to be offered eventually to the National Archives. File contains copies of the license and supporting material consisting of application copies; resumes of responsible officials; changes of officials, production methods, plant layouts, and procedures; new equipment; cover and follow-up letters; questions and answers; and related notes and correspondence. Establishment- manufacturer.		
88	Product Licenses Active License: Retain in agency space until license is revoked, suspended, or superseded. Revoked, Suspended, or Superseded License: a. 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 eventually to National Archives. b. license establishment supporting material: Disposal not authorized at this time; review for disposal witnin 10 years after revocation, suspension, or supersession. When reviewed, select a sample to be offered eventually to National Archives. File consists of the licenses and supporting material consisting of applications, changes in production methods, questions and answers with firms, cover and follow-up letters,		

GPO: 1963—O-711-917

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8. DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9.9 SAMPLE OR JOB NO.	10. ACTION TAKEN
	and related material concerned with manufacturing a product.		
89	Import Permits File contains copies of forms NIH 1395 or FD 2562, Permit for Importation of Licensed Biological Products. Destroy 5 years after expiration of permit.		
90.	Protocol Releases. Protocol release- approval granted for a batch of ~~antibiotics.~~ biological. File contains a copy of the protocol; forms NIH 837-845, completed check lists; forms NIH 289 or FLH 2558, Release/Reject Letter; 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 a specific batch of the product. Arranged by number; indexed. Transfer to Washington National Records Center after 4 years. Disposal not authorized at this time; review for disposal 10 years after date of Release.		
91	Investigational New Drugs (INDs) File consists of IND(approval for testing of drugs on humans) in triplicate and supporting material consisting of supplements (amendments); form NIH 1770, Clinical Trial Outline; and related correspondence with firms. Arranged by number; indexed. Transfer to Washington National Records Center 10 years after completion of final action. On transfer, review for disposal and select sample, not to exceed 3%, which will eventually be offered to the National Archives. Destroy IND copies and supporting material after 5 years.		
92	Efficacy Reviews File contains documents submitted by manufacturers regarding product efficacy, reviews and evaluations of product made by Bureau of Biologics professionals, and reports on results of review made by the professionals. Efficacy reviews are conducted by prominent scientists on all products manufactured during the period 1903-72. Products are evaluated by panels e.g. toxoids and toxins panel, allergenics panel, etc.		

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. Reports: Offer to National Archives after publication in Federal Register, or when no longer needed for reference. b. Supporting material: Offer to National Archives within 20 years after termination of reviews. PERMANENT.		
93	Efficacy Review Committee Members File contains documents relating to the members of the Efficacy Review Committee such as appointment and travel papers. Destroy after 1 year.		
94	Inspection Reports File contains original copies of reports made on inspections of biological and blood processing establishments. Includes follow-up and related correspondence. a. Records on firms that have gone out of business or are of no further regulatory interest. Transfer to FARC after 2 years; review for disposal in 8 years after transfer; offer sample to National Archives, Select sample, not to exceed 3%, when reviewed. b. Records on other firms. Transfer to FARC after 7 years; review for disposal in 8 years after transfer; offer sample to National Archives. Select sample, not to exceed 3%, when reviewed.		
95	Laboratory Test Records Files contain laboratory notebooks, records of results of clinical tests and evaluations, experimental findings, control test results, and related correspondence. Card files contain summaries of test resulta 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 Washington National Records Center 5 years after completion of test; Destroy 15 years after transfer.		

Standard Form No. 115-A
Revised November 1951
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115-202

Job No. _____

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
	e. Animal Test Cards f. Sterility Test Cards g. Sample Cards Destroy 1 year after completion of test.		

GPO : 1963—O-711-917