Records Schedule Number: DAA-0088-2018-0007

Status: INACTIVE
Date Approved: 07/12/2019

General Information

Agency or Establishment	Food and Drug Administration
Record/Scheduling Group	0088 - Records of the Food and Drug Administration
Records Schedule Applies to	Agency Subdivision
Major Subdivision	CBER (Center for Biologics Evaluation and Research)
Schedule Subject	Records Related to the Development of a Safe and Effective Poliovirus Vaccine.
Additional Schedule Information	Under the Biologics Control Act of 1902 and Section 351 of the Public Health Service Act of 1944, approval and licensing is required for any vaccine to be marketed or distributed in the United States. In the 1950s that provision was assigned to the Laboratory of Biologics Control (LBC) of the National Institutes of Health (NIH). The LBC became the Division of Biologics Standards (DBS) within the NIH in late 1955. DBS was then transferred from NIH to the Food and Drug Administration (FDA) in 1972 and with various reorganizations and renaming is now the Center for Biologics Evaluation and Research (CBER). Records in this collection refer to CBER and its previous organizational names. Records Related to the Development of a Safe and Effective Poliovirus Vaccine (hereinafter, “the collection") contains correspondence, meeting summaries, test data and reports, limited clinical trials, lot release test results, marketing files and the applications for licenses to manufacture inactivated and oral polio vaccine (IPV and OPV, respectively) created or received by the FDA between 1950 and 1996. The collection supported Department of Justice litigation from approximately 1956 through the early 2000s.

The collection contains all documents necessary for the FDA's regulatory requirements for licensing and marketing a biologic product. This includes the original license application, licensing supplements and amendments and supporting correspondence. The collection also includes correspondence and meeting documentation related to post-approval and marketing issues. The licensing application contains manufacturing process descriptions, validation methodology, and chemical and animal testing data used in support of product release for human use. The licensing application also includes summary clinical data, physician package inserts and product labeling. The collection contains internal and external correspondence documenting meetings, as well as government and manufacturer testing for regulatory review to justify release and approval of individual lots/batches based on previously determined standards and values.

The collection contains licensing information for two poliovirus vaccines. Inactivated poliovirus vaccine (IPV) using a killed virus administered by injection was developed by Dr. Jonas Salk, approved in 1955, and licensed to six companies. Oral poliovirus vaccine (OPV) using a live virus and administered orally, was developed by Dr. Albert Sabin, approved in 1961 and 1962, and licensed to three companies. The collection contains the applications and associated documentation and lot release protocols for both IPV and OPV from 1955 to 1996.

The lot release protocols present a summary of all manufacturer testing documenting that the vaccine was safe, effective and met the criteria set forth in the regulations. The protocols contain important neurovirulence testing for the absence of live virus or for SV40 virus, a virus normally found in monkeys, but a contaminant for this vaccine.

	The collection contains documents related to the “Cutter Incident.” The incident centered on 56 children who developed paralytic poliomyelitis with five deaths and hundreds more exposed after receiving the newly licensed Cutter Laboratories inactivated polio vaccine. In April 1955 Cutter produced 120,000 doses of inactive polio vaccine that contained the live virus, despite passing product lot release testing. The Cutter Incident resulted in lawsuits against Cutter and the resignation of several government officials including the Secretary of Health, Education, and Welfare. The produced finding aid describes the materials at a summary level by series; OPV Protocols (100); IPV Protocols (200); OPV Correspondence, Meeting Reports, and Testing (300); IPV Correspondence, Meeting Reports, and Testing (400); OPV Applications (500) and IPV Applications (600); Please note: Correspondence and testing are identified in the finding aid by company name. The records control schedule is separated into two items: Lot Release Protocols (file codes 100 and 200); and the other record types (300-600) including depositions, license applications, laboratory and manufacturer test results, laboratory notebooks, laboratory and manufacturer correspondence, meeting minutes, publications, and reports. Parts of the collection contain trade secret or confidential commercial information under provisions of 21 CFR 20.61. Other parts of the collection contain personal privacy information (PII) under provisions of 21 CFR 20.63. These records are covered under the Freedom of Information Act 5 U.S.C. 552(b)4 and (b)6. The boxes or folders containing confidential commercial information or PII are identified in the finding aid. A comprehensive list of known acronyms or abbreviations as found in the records will be enclosed in the finding aid.
Is there a classified version of this form?	No
Is consultation and coordination with Tribal Governments required?	Predate requirement

Records Schedule Number: DAA-0088-2018-0007

Status: INACTIVE
Date Approved: 07/12/2019

Item Count

Total number of disposition items: 2
Number of Temporary disposition items: 1
Number of Permanent disposition items: 1
Number of Items with Disposition Not Approved: 0
Number of Inactive disposition items: 2

Records Schedule Number: DAA-0088-2018-0007

Status: INACTIVE
Date Approved: 07/12/2019

Outline of Records Schedule Items for DAA-0088-2018-0007

Item #	Title	Disposition
0001	Lot Release Protocols Related to the Development and Use of a Safe and Effective Poliovirus Vaccine.	Temporary
0002	Correspondence Related to the Development of a Safe and Effective Poliovirus Vaccine.	Permanent

Records Schedule Number: DAA-0088-2018-0007

Status: INACTIVE
Date Approved: 07/12/2019

Records Schedule Items

DAA-0088-2018-0007-0001	STATUS: INACTIVE - NOT FOR USE
ITEM GENERAL INFORMATION	
Item Title	Lot Release Protocols Related to the Development and Use of a Safe and Effective Poliovirus Vaccine.
Item Description	This item includes materials numbered with the File Codes 100 and 200: OPV Protocols (100) and IPV Protocols (200). Files consist of materials dating from 1956-1996. Lot release protocols are submitted by manufacturers for each lot/batch of product and contain results of all chemical and animal testing in various stages of manufacture. Information in the lot release protocols may be linked to correspondence in the letters and memoranda records found elsewhere in this collection. Neurovirulence test results in the protocols show the absence of SV 40 (Simian Virus 40), a monkey virus that has been found to cause tumors in rodents. Manufacturer testing is required by Regulations and the test results are part of the approved product license application which is required by law to distribute the vaccine. Documents in the correspondence and protocols section have been used extensively in litigation against the government or where the government has had to testify. These results are reviewed by FDA staff reviewers to ascertain compliance with regulations. Results are also compared with or used as a determination for selection of lot/batch for conformity testing by the NIH/FDA. A comprehensive list of known acronyms or abbreviations as found in the records will be enclosed in the finding aid.
Is this item media neutral?	Yes
Is this item a Big Bucket?	
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	
Does this item supersede existing disposition authorities?	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Retention Period	Destroy immediately after approval of this schedule.
ADDITIONAL INFORMATION	

Records Schedule Number: DAA-0088-2018-0007

Status: INACTIVE
Date Approved: 07/12/2019

Are any of the records covered by this item national security classified?	
GAO Approval Required	No

DAA-0088-2018-0007-0002	STATUS: INACTIVE - NOT FOR USE
ITEM GENERAL INFORMATION	
Item Title	Correspondence Related to the Development of a Safe and Effective Poliovirus Vaccine.
Item Description	This item includes materials numbered with the File Codes 300 - 600: That is, OPV correspondence, meeting, and reports (300); IPV correspondence meeting, and testing records (400); OPV Applications (500) and IPV Applications (600) from the Polio Files. Files consist of materials dating from 1950-1996. The materials include applications, clinical trials, depositions, NIH/FDA laboratory and manufacturer test results, laboratory notebooks, internal and external correspondence, product license applications, lot release tests, marketing files, meeting minutes, publications, and summary reports. A comprehensive list of known acronyms or abbreviations as found in the records will be enclosed in the finding aid.
Is this item media neutral?	Yes
Is this item a Big Bucket?	
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	
Does this item supersede existing disposition authorities?	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Permanent
Cutoff Instructions	Other: N/A
Are there multiple instructions for this item?	No
Transfer Instruction	Transfer to the National Archives immediately after approval of this schedule.
ADDITIONAL INFORMATION	
Approximate first year of records covered by this authority	1950

Records Schedule Number: DAA-0088-2018-0007

Status: INACTIVE
Date Approved: 07/12/2019

	End year of records covered by this authority	Year: 1996
	Date span of the initial transfer	From: --/--/1950 To: --/--/1996
	Are any of the records covered by this item subject to a FOIA exemption?	

Records Schedule Number: DAA-0088-2018-0007

Status: INACTIVE
Date Approved: 07/12/2019

Signatory Information

Action	User	Date
Accept	Data Migration	05/23/2018
Approve	David Ferriero	07/12/2019