

REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER N1-88-99-2 - P	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NWML) WASHINGTON, DC 20408		DATE RECEIVED 12/27/99	
1. FROM (Agency or establishment) Department of Health and Human Services		NOTIFICATION TO AGENCY	
2. MAJOR SUBDIVISION Food and Drug Administration		In accordance with the provisions of 44 U.S.C. 3303a, the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	
3. MINOR SUBDIVISION			
4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra	5. TELEPHONE 301-827-4274	DATE 4-20-00	ARCHIVIST OF THE UNITED STATES <i>John W. Paul</i>
6. AGENCY CERTIFICATION I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached ___ page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO manual for Guidance of Federal Agencies, <input type="checkbox"/> is not required; <input type="checkbox"/> is attached; or <input type="checkbox"/> has been requested.			
DATE 12/21/99	SIGNATURE OF AGENCY REPRESENTATIVE <i>Seung Ja Sinatra</i>	TITLE <i>Agency Records Officer</i>	
7. Item No.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
	Record Group 88 WNRC Project: Records of the Food and Drug Administration This schedule provides one-time disposition authority for unscheduled Food and Drug Administration records that are stored at WNRC. SEE ATTACHED SCHEDULE		

Agency
NR NWMO

**RECORD GROUP 88: RECORDS OF THE FOOD AND DRUG ADMINISTRATION
(FDA) WNRC PROJECT**

Items 1-9 provide one-time disposition authority for the specific accessions listed.

1. Division of General Services. Records Section. Krebiozen Files, 1949-66. 103 cu. ft.

These records consist of patient case files, physicians' notes, transcripts, testimonies, correspondence, memorandums, U.S. Federal District Court exhibits, legal files, and other documents used in a 1965 Chicago court case concerning the drug Krebiozen. Northern District Court of Illinois case number 64CR668, Stevan Durovic vs. Robert N. Palmer, R.D. Sherman, R.W. Case, et. al., involved Durovic's petition to market Krebiozen in the United States as a cancer therapy drug. Included are photographic exhibits from the court case, microfilm, glass vials which may contain drug residue, medical résumés of people involved with the Krebiozen study, transcripts of Krebiozen hearings conducted in Illinois in 1953 and in California in 1958, inspectors' notebooks, computer printouts with names of physicians and patients, coding sheets of patient histories, punch cards, drug shipment lists, news clippings, magazine articles, charts, subpoena lists, court testimonies, and interviews with Dr. Andrew Ivy, who sponsored the development of Krebiozen by Stevan and Marko Durovic, two Yugoslavian immigrants. The records relate to such subjects as inspections of labs and suppliers, bogus treatment claims, the use of horses to develop the Krebiozen serum, and background materials to establish the FDA's right to investigate bogus claims and shut down companies if necessary.

Disposition: PERMANENT. Transfer to NARA in FY2001.

Justification: These files complement the small amount of Krebiozen records in RG 21, Records of District Courts of the United States, in the Chicago Regional Archives. The staff at NRDC have reported that there is an ongoing interest in the Krebiozen issue. While the National Cancer Institute has concluded that there is no evidence of Krebiozen-induced therapeutic effects in cancer patients, Krebiozen is still used as a controversial alternative cancer therapy. These records significantly document one of the FDA's primary functions, which is the evaluation of the safety and efficacy of medicines. The files consist of materials generated and collected by FDA inspectors to establish that Krebiozen was being sold with unsupportable claims of effectiveness as a cancer treatment. These records are also important because they provide complete documentation of the investigatory process. Earlier materials (State legislative hearings) from prior inquiries into the controversial use of this drug have been collected. Original notebooks from the regional FDA inspectors are present, along with original Federal District Court exhibits.

WNRC Acc. No.: 88-70A-6263 (Boxes 1-97); 88-70-6264 (Boxes and bundles numbered 1-5, total of 6 cu. ft.)

2. Division of General Services. Records Section. Thalidomide Files, 1958-63. 8 cu. ft.

Thalidomide was initially prescribed in Europe in the late 1950s to ease insomnia and morning sickness among pregnant women. When taken during the first trimester of pregnancy, the drug caused fetal death or such birth defects as deafness, blindness, disfigurement, cleft palate, many major internal disabilities, and phocomelia (the shortening of or the absence of limbs). Thalidomide was never marketed in the United States, but William S. Merrell Company of Cincinnati distributed samples under the brand name "Kevadon" to doctors, who gave the medication to their patients. These records relate to the findings of Dr. Frances Kelsey's thalidomide study and subsequent teratology reports. Included are correspondence, memorandums, invoices and questionnaires to physicians concerning patient reactions to thalidomide and volume distributed, investigations, inventories of shipments to physicians, some patient case files, and a Saturday Evening Post story (October 1962) concerning the effects of thalidomide on unborn babies. Other files contain investigative summaries relating to Federal destruction of thalidomide supplies, correspondence concerning drug testing, copies of drug labels, correspondence regarding thalidomide investigations in Canada and Europe, and information on pharmaceutical companies that did not distribute thalidomide.

Disposition: PERMANENT. Transfer to NARA in FY2001.

Justification: These files document the FDA's efforts to track down supplies of a drug that belatedly revealed itself as the cause of severe birth defects. Although thalidomide was withdrawn from world markets in the early 1960s as a medication for insomnia and morning sickness, it is currently being tested, and in some cases, used, to treat conditions associated with leprosy, HIV, AIDS, and certain types of cancer.

WNRC Acc. No.: 88-70-6263 (Boxes 98-105)

3. Division of General Services. Records Section. Subject Files, 1962-71. 83 cu. ft.

These files may be connected to records accessioned under the P95 project, NN3-088-94-001 (D82 General Subject Files), which consist of correspondence and reports arranged according to a decimal filing scheme. The records in this accession are arranged by subject. Included are patient case files, physicians' records, investigation materials, transcripts of hearings, court decisions, correspondence, telegrams, FDA and other agency publications, reports, and studies. Subjects covered include such drugs as thalidomide and Dimethyl-sulfoxide (DMSO), controversial and bogus therapies, FDA investigations of drug companies and laboratories concerning their testing procedures, Congressional investigations of the national drug industry by the Kefauver-Fountain Committee, interagency coordination studies, labeling and promotional literature, distribution of drug samples to physicians, and drug efficacy studies.

Disposition: PERMANENT. Transfer to NARA in FY2001.

Justification: These records document the FDA's efforts to investigate bogus medical treatments, to enforce standardized testing procedures, and to promote truthful advertising about the safety and effectiveness of drugs. The files also complement Congressional hearings files on drug pricing and advertising, and supplement the information in Congressional legislation files

currently held in the Center for Legislative Archives. FDA files on thalidomide (a drug initially prescribed in Europe for insomnia and morning sickness but which caused severe birth defects), for example, were supplied to the Kefauver-Fountain Committee, which ultimately led to the 1962 Kefauver-Harris Amendment to the Food, Drug, and Cosmetics Act.

WNRC Acc. No.: 88-71A-5373 (Boxes 1-83)

4. Survey Reports, 1968-70. 5 cu. ft.

These files relate to the treatment of obesity and deaths connected with the use of diet pills. Included are deceased patient case files, correspondence, physicians' vitae, published articles, transcripts of hospital records, news clippings, testimonies, and memorandums. The records relate to obesity, investigations into injuries and deaths involving diet medication, coroners' findings, and adverse reactions to diet medication.

Disposition: ~~TEMPORARY. Destroy immediately on approval of this schedule.~~
 PERMANENT. Transfer to NARA in FY2001.

Justification: [The records are a miscellaneous collection of documents regarding casualties that allegedly involved diet medications. There is no focus to the records and no final reports on particular drugs or manufacturers.] → See Attachment to Concurrence Form.

WNRC Acc. No.: 88-73A-0004 (Boxes 8-12)

Withdrawn per
 memo to file
 dated 3/28/00.
 LMB

5. Bureau of Biologics. Subject Files, 1954-73. 45 cu. ft.

These records are arranged chronologically by year, thereunder according to an alpha-numeric filing scheme. Included are correspondence, memorandums, reports, meeting files, statistics, and cross-reference sheets. The files relate to such subjects as polio, influenza, measles, rubella, reactions to the whole blood amendment, blood banks, regulation of biological products shipped in interstate and foreign commerce, creation and enforcement of standards, licensing to manufacture biological products, and evaluation of new investigational biological drugs.

Disposition: PERMANENT. ~~Transfer to NARA in FY2001.~~
 Return to FDA in Jan. 2000

Justification: The records document the creation and enforcement of standards, policies, research, and testing methods that influence the production, transport, and application of blood and other biological products in the U.S.

WNRC Acc. No.: 88-74-0008 (Boxes 1-29); 88-76-0033 (Boxes 1-16)

6. Regulatory Reform Policy Files, 1972-76. 4 cu. ft.

Withdrawn per
 memo to file
 dated 3/28/00.
 LMB

These records consist of the correspondence and policy files of Sam Fine, Associate Commissioner for Compliance. Included are meeting materials, drafts for the Code of Federal Regulations, reports, memorandums, proposed documents for publication, and critiques of recall regulations. The files relate to such subjects as policy decisions, the compliance regulation task

force, subcommittees, and criteria for prosecution.

Disposition: PERMANENT. Transfer to NARA in FY2001.

Justification: The records document the background of FDA policy and enforcement decisions regarding compliance by manufacturers.

WNRC Acc. No.: 88-82-0046 (Boxes 1-4)

~~7. Contracts and Reports on Dogs and Monkeys, 1970-76. 5 cu. ft.~~

~~These files consist of annual and semiannual reports concerning estrogen components used in oral contraceptives. The reports were produced under a HEW contract by the International Research and Development Corporation, in Mattawan, Michigan, as long-term oral studies for the Ortho Research Foundation. Such drugs as mestranol (a synthetic estrogen), MK-665 (a contraceptive steroid), Wy-4355, and ORF-1658 were administered to female dogs and monkeys, and the results were compiled on each individual animal. For the most part, the reports are quite technical and not intelligible to the non-scientific reader. The records contain charts, statistics, synopses, compounds, clinical studies (methods and results), procedures, drug administration, lab tests, and results relating to behavior, weight, female organs, food consumption, and pathological studies.~~

~~Disposition: TEMPORARY. ~~Destroy immediately on approval of this schedule.~~ History Office.~~ *Return to FDA immediately for review by FDA's History Office.*

~~Justification: The records consist of technical data that does not document the policies or functions of the FDA. The methodology and findings to which these highly technical data relate are undoubtedly well documented in scientific research publications.~~

~~WNRC Acc. No.: 88-77-0048 (Boxes 1-5)~~

*Withdrawn
per memo to file
date 3/28/00.
JMB*

8. Commissioners' "Special Files," 1954-81. 8 cu. ft.

These subject files may have been created by several commissioners to parallel the main decimal file series. Files with decimal classifications may have been withdrawn from the official file or maintained only in the commissioners' office due to sensitive contents. Included are original memorandums, correspondence, policy drafts, reports, meeting materials, and minutes. Other files relate to projects, litigation concerning drug approval, exhibits for environmental impact reports, Executive Secretariat reports, and memorandums between headquarters and field offices. Routine administrative files dealing with such subjects as travel, procurement, and personnel issues may be disposed of during initial processing.

Disposition: PERMANENT. Transfer to NARA in FY2001.

Justification: The records document standards, regulations, and significant program and policy decisions made at the highest levels of the FDA.

WNRC Acc. No.: 88-87-0013 (Boxes 1-2, 6-11)

9. Commissioner's Chronological and Subject Files, 1977-86. 24 cu. ft.

These records relate to the activities of the Commissioner of Food and Drugs, who is responsible for directing activities to protect the health of the Nation against impure and unsafe foods, drugs, and cosmetics. Included are original correspondence, routing slips, reports, committee nominations, briefings, memorandums, public calendars, meeting materials, and publications for the Federal Register. The files are arranged chronologically by year. Correspondence control numbers may be linked to the central decimal file.

Disposition: PERMANENT. Transfer to NARA in FY2001.

Justification: These files document significant policy decisions and program activities conducted at the highest level of the FDA.

WNRC Acc. No.: 88-87-0013 (Boxes 3-5); 88-88C-0034 (Boxes 44-47); 88-89C-0016 (Boxes 43-44); 88-90D-0043 (Boxes 35-40); 88-91B-0017 (Boxes 34-37); 88-92C-0016 (Boxes 27-31)