A GUIDE TO RESOURCES ON THE HISTORY OF THE FOOD AND DRUG ADMINISTRATION

1995

Food and Drug Administration
History Office

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CONTENTS

This guide is designed to familiarize FDA staff, other government employees, historians, the press, regulated industry, students, and anyone else interested in regulatory history with the various resources on the history of the FDA. Included are both core sources useful for specific inquiries into the agency's past and information for those pursuing extensive historical research on the FDA. In addition, the guide discusses the structure, functions, and some of the programs of the FDA History Office. The office has a wide range of functions and offers various types of assistance to staff and outsiders, as reflected in some of the programs and activities mentioned at the end of this guide. The FDA is the oldest federal agency that has as its principal purpose the protection of consumer health; this guide will help those who want to learn more about the evolution of this agency.

BACKGROUND: FDA'S ORIGINS AND FUNCTIONS

The origins of the Food and Drug Administration can be traced back to 1862, when President Lincoln appointed chemist Charles M. Wetherill to head the Chemical Division in the new U. S. Department of Agriculture. In the following decade Wetherill's successor as chief chemist of the USDA, Peter Collier, began working on the ubiquitous problem of food adulteration. Harvey W. Wiley replaced Collier in 1883, leading the division as it grew into the Bureau of Chemistry in 1901. The bureau was charged to enforce the first comprehensive federal statute of its kind, the Federal Food and Drugs Act, when that law was passed in 1906.

In 1927 Congress authorized the formation of the Food, Drug, and Insecticide Administration from the regulatory wing of the Bureau of Chemistry; the name of the agency was shortened to the Food and Drug Administration in 1930. FDA left the Department of Agriculture in 1940 for the Federal Security Agency, which was created a year earlier. In 1953 FDA joined the Department of Health, Education, and Welfare after Congress established that department to assume certain functions of FSA. In 1968 the agency became part of the Public Health Service within HEW. When the education function was removed from HEW to create a separate department, HEW became the Department of Health and Human Services in 1980.

FDA's responsibilities derive from statutes that date back to the early twentieth century. Harvey Wiley fought long and hard to unify disparate interest groups behind a federal law to deal with serious problems in the food and drug supply. Through Wiley's crusading, the support of the General Federation of Women's Clubs, the work of muckraking journalists, the efforts of state and local food and drug officials, cooperation from the American Medical Association and the American Pharmaceutical Association, and the impact of Upton Sinclair's *The Jungle*, a novel depicting the filth of the meat packing industry, Congress approved one of the landmarks of Progressive era legislation in 1906, the Food and Drugs Act. Among other provisions, this law charged the Bureau of Chemistry to control—albeit to a lesser extent than Wiley and others had hoped—adulterated and misbranded drugs and food in interstate commerce.

FDA initiated a movement to replace the problematical aspects of the 1906 act during the nascent New Deal. Again, the support of women's groups, journalists, and others was important to the final passage of a bill, as was the repercussion from a toxic preparation of the wonder drug, sulfanilamide. So-called Elixir Sulfanilamide employed an untested solvent for the drug, diethylene glycol, and eventually it killed over a hundred people, most of whom were children. The 1938 Food, Drug, and Cosmetic Act, which remains the basic law we have today, featured many provisions lacking in the 1906 act. For example, it mandated that all new drugs be proved safe before marketing, therapeutic devices and cosmetics become subject to regulation, and standards of identity and quality be instituted for foods. The law also formalized FDA's ability to conduct factory inspections.

Harvey Wiley, in top hat and tails, on his way to make one of his many speeches for a federal food and drugs law.

Over the following decades numerous amendments and other acts broadened FDA's responsibilities considerably. These include a mandate for agency testing of insulin and antibiotics; regulation of chemical pesticides and food and color additives; distinction between prescription and nonprescription medications; regulation of drug efficacy; ensuring of good manufacturing practices; control of prescription drug advertising; regulation of therapeutic agents of biological origin; and oversight of nutrition labeling. The realities of enforcing such broad statutes requires

FDA's interaction with a variety of political, economic, and social interests. Today, as in the past, FDA strives above all else to safeguard the health and well being of the American people.

SELECTED FEDERAL FOOD, DRUG, COSMETIC, AND DEVICE LAWS

Drug Importation Act	June 26, 1848
Tea Importation Act	March 3, 1883
Food and Drug Importation Act	August 30, 1890
Tea Importation Act	March 2, 1897
Food Importation Act	March 1, 1899
Biologics Control Act	July 1, 1902
Food and Drugs Act	June 30, 1906
Meat Inspection Act	June 30, 1906
Sherley Amendment	August 23, 1912
Federal Trade Commission Act	September 26, 1914
Harrison Narcotic Act	December 17, 1914
Food, Drug, and Cosmetic Act	June 25, 1938
Miller Amendment	June 24, 1948
Durham-Humphrey Amendment	October 26, 1951
Factory Inspection Amendment	August 7, 1953
Miller Pesticides Amendment	July 22, 1954
Food Additives Amendment	September 6, 1958
Pesticide Chemicals Amendment	June 29, 1960
Color Additive Amendment	July 12, 1960
Kefauver-Harris Drug Amendments	October 10, 1962
Drug Abuse Control Amendments	July 15, 1965
Child Protection Act	November 3, 1966
Vitamin-Mineral Amendments	April 22, 1976
Medical Device Amendments	May 28, 1976
Saccharin Study and Labeling Act	November 23, 1977
Orphan Drug Act	January 4, 1983
Safe Medical Devices Act	October 27, 1990
Nutrition Labeling and Education Act	November 8, 1990

RESEARCHING THE HISTORY OF FDA *

While research is a primary function of the FDA History Office, we also try to facilitate studies by historians and others. Often a person needs merely a reference or two to investigate a particular question on the history of regulation and FDA, and History Office staff will run a quick check of our internal reference sources to assist with such a query. However, some individuals have a much broader interest in FDA history, requiring more extensive research and resulting in lengthy articles and books. Some scholars devote entire careers to the study of FDA and related history. Many of the works listed under the "Selected Sources" below are grounded in large part on FDA records. The resources available for the study of this subject are extensive, and here we can indicate only some of the more basic places to begin. The majority of the published secondary sources should be easily obtainable at most university libraries, but many of the published primary sources would more likely be found in law libraries, general university libraries, or other facilities designated as government document depository libraries. If uncertain, check with a reference librarian. Locations of the unpublished records are mentioned below.

* Parts of this section are adapted from James Harvey Young and Wallace Janssen, "Food and Drug Administration: Sources of Historical Information," unpublished 29-page typescript, files, FDA History Office; see also Paul B. Dunbar's Introduction to *Federal Food, Drug and Cosmetic Act: Administrative Reports, 1907-1949* (cited in the bibliography below).

PUBLISHED PRIMARY AND SECONDARY SOURCES ON FDA HISTORY

PART I: PRIMARY SOURCES

General Sources

The *Food and Drug Review* began in 1917 as a means of communicating information privately to state food and drug officials to assist them in helping enforce the 1906 federal act. Soon the *Review* became a vehicle for FDA headquarters to inform field offices about relevant publications, speeches by FDA staff, personnel changes in the agency, the status of legislation, enforcement activities in other field offices, and so on. In many ways the *Review* is a sort of diary of activities at FDA, issued monthly with illustrations and indexed annually (except the last three volumes). A few research libraries have purchased microfilm copies of the *Review*, which ceased publication in 1966. Microfilms are still available through the Library of Congress. The cumulatively indexed *FDA Papers*—which changed its name to *FDA Consumer* in 1973—succeeded the *Review*, but its thrust was very different than the *Review*, emphasizing articles of interest to consumers, as the newer title suggests, and including the official summaries of agency enforcement activities (see below). *FDA Today*, a monthly employee newsletter with illustrations that began in 1974 and is still published, probably was closer in scope to the *Review*, but it was much less comprehensive than the *Review*.

An inspector drills into a container of frozen eggs to collect a sample.

The annual reports of the Bureau of Chemistry and the FDA are another useful source on agency activities. Earlier reports of the Chief Chemist of the Chemical Division and the Division of Chemistry were included in the annual report of the Secretary of Agriculture. The modern annual reports of the agency have been collected and published in two volumes: *Federal Food, Drug and Cosmetic Law: Administrative Reports, 1907-1949* (Chicago: Commerce Clearing House, 1951), and Food and Drug Administration, *Annual Reports, 1950-1974* (Washington: Government Printing Office, [1974]).

The first volume has a fairly short index, while the latter collection has a separate index, compiled by Edward M. Shoemaker and published in 1983 by the American Institute of the History of Pharmacy, Madison, Wisconsin. The reports from headquarters and field offices on which these annual reports are based are included in the decimal files in the FDA unpublished records (see below). The annual reports, which ceased publication in 1979, were succeeded by the *Quarterly Activities Reports*. The latter contain a straightforward factual account that includes internal reorganizations, executive personnel changes, enforcement highlights and statistics, major court decisions and laws, and so on.

One can glean the concerns and interests of regulated industry through the trade literature, which includes periodicals such as *Oil, Paint and Drug Reporter* (founded in 1871 and continuing after 1972 as *Chemical Marketing Reporter), FDC Reports* (1939 to the present), *Food Chemical News* (1959 to the present), and *Drug and Cosmetic Industry* (established in 1914 as *Weekly Drug Markets* and continuing under the present title after 1932). The *Food Drug Cosmetic Law Journal* (1946 to the present) provides useful insight on FDA history from a variety of viewpoints. This journal has a cumulative chronological listing of articles in broad subject areas.

Legal Sources

Several publications trace details of the evolution of food and drug legislation and how it played out in the courts. A publication of the U. S. Department of Agriculture, Mastin G. White and Otis H. Gates, *Decisions of Courts in Cases under the Federal Food and Drugs Act* (Washington, D. C.: Government Printing Office, 1934), identifies and analyzes major cases stemming from the 1906 act. An ongoing publication, *Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record* (Chicago: Commerce Clearing House, c. 1949-1992), assumes a similar task for the 1938 act and its amendments. An FDA publication comprised of 34 volumes, including appendices, *A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments,* is a documentary history of the 1938 act. It explains why the laws are couched the way they are. Peter Barton Hutt and Richard A. Merrill's *Food and Drug Law: Cases and Materials,* 2d ed. (Westbury, N. Y.: Foundation Press, 1991), is a more recent interpretation of the impact of court decisions on FDA policies; the authors reproduce a variety of primary and secondary sources as well.

Sources on Regulations and Enforcement

FDA has long pursued a policy of enforcing food and drug laws that relies on full and frequent notification of regulated industry and others about how statutes and regulations affect them. On 17 October 1906 the U. S. Department of Agriculture issued "Rules and Regulations for the Enforcement of the Food and Drugs Act" as Circular No. 21 from the Office of the Secretary. The forty rules and regulations published at that time underwent several revisions up to the time of the 1938 act; however, each of these revisions continued to be published as Circular No. 21.

Food Inspections Decisions (FIDs) were another published venue for notification of changes in regulations. These were formal statements issued over the signature of the Secretary of Agriculture or, in some cases, over the signatures of the Secretaries of Agriculture, Treasury, and Commerce. The first thirty-nine FIDs pertained to interpretations of the Imported Food Act of 1899, which the Bureau of Chemistry was charged to enforce. From 1906 to 1934, the Bureau of Chemistry and then the FDA issued FID 40 through 212 to explain regulation of the 1906 act. The agency published *Service and Regulatory Announcements* (SRAs) until shortly after the 1938 act, first as a monthly and later on an irregular basis. The SRAs included FIDs as well as other policy matter that did not have the formality of FIDs, subject to prompt change if developments warranted.

After the 1938 act, FDA issued informal opinions, known as Trade Correspondence, based on its daily correspondence with manufacturers. They contained excerpts from the replies to regulated companies' queries about regulations under the act. The issues of Trade Correspondence were not published, but rather were mimeographed and distributed to the staff to maintain uniformity in policy throughout the country. They were available for inspection in field offices and at FDA headquarters. The complete series of Trade Correspondence, which ran from 26 August 1938 to 4 April 1946, was published in Vincent A. Kleinfeld and Charles Wesley Dunn, *Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record, 1938-1949* (Chicago: Commerce Clearing House, c. 1949), 561-753, which is indexed. The agency's press releases and talk papers present FDA's viewpoints and policies on a wide variety of issues; the FDA Medical Library has many of these on microfilm, and a list of press release titles exists for those issued from about 1950 to 1965. The Office of Public Affairs has indexed the recent press releases and talk papers.

The most important source to track changes in FDA regulations, from 1936 to the present, is the annually indexed *Federal Register*; this is particularly the case after passage of the Administrative Procedure Act in 1946. The narrative preambles to final regulations in the *Federal Register* can be especially useful in discerning the agency's mindset behind its rulemaking.

An essential tool for researching enforcement actions taken by the agency are the *Notices of Judgment under the Food and Drugs Act* and the *Notices of Judgment*

under the Federal Food, Drug and Cosmetic Act, required by provisions of the laws. These were published in groups of fifty by the Department of Agriculture (and later by the Federal Security Agency and the Department of Health, Education and Welfare) beginning in 1908. They summarize the government's case against a product, including the evidence of a product's adulteration or misbranding; often the notice will include a chemical analysis of the offending product. The *Notices* report the outcome of the cases as well.

An analyst conducts a "flyo-assay," a biological assay for pesticides that employs house flies to determine the toxicity of a substance.

The first 10,000 notices are indexed, from 1908 to 1922, as are Notices of Judgment 10,000 to 20,000. Thereafter, indices covered 1000 notices at a time. The indices are especially useful in revealing recidivism. For example, the Pabst Chemical Company, purveyor of Pabst Okay specific drug, was cited in twenty-seven Notices of Judgment from 1915 to 1919. The published notices, which were distributed to government depository libraries, also provide keys to more detailed information in the manuscript records of FDA (see below). The separately published notices ceased in 1966; thereafter they were appended to *FDA Papers* (and later, *FDA Consumer*) in a significantly curtailed format.

Sources on Science and Research

The Bulletins and Circulars of the Bureau of Chemistry also are helpful on the history of the agency; these total hundreds of separate publications, from the late-nineteenth century origins of regulation to the 1920s. Most are just a few pages each, but Bulletin 13 and 84 are notable exceptions. The former, on *Foods and Food Adulterants*, was issued in ten parts in over 1500 pages, from 1887 to 1902. Bulletin 84, on *Influence of Food Preservatives and Artificial Colors on Digestion and Health*, was a five-part, 1500-page study from 1904 to 1908. Agency scientists did not publish their work in the Bulletins and Circulars exclusively. Indeed, many in the Bureau also published in the standard professional journals of the day. But the Bulletins and Circulars are the most significant single source to document science and research in the early history of FDA.

PART II: SECONDARY SOURCES **

The following bibliography is quite literally a list of selected sources that will be useful to anyone interested in the history of the FDA and related issues. Most of these are interpretive secondary sources with ample references—if not bibliographies—to additional literature in the field. This should be considered merely a good starting point to investigate the field.

General Sources

Young, James Harvey. *Pure Food: Securing the Federal Food and Drugs Act of 1906.* Princeton: Princeton University Press, 1989 (definitive history of this landmark Progressive era legislation, including an historiography of the subject).

The Medical Messiahs: A Social History of Health Quackery in Twentieth-Century America. Princeton: Princeton University Press, 1967 (indicative subtitle; includes much on FDA).

"Food and Drug Administration." In *Government Agencies*, ed. Donald R. Whitnah, 251-57. Westport, Conn.: Greenwood Press, 1983 (a brief but succinct history of FDA, with a short bibliography).

"The Pig That Fell into the Privy: Upton Sinclair's *The Jungle and the Meat Inspection Amendments of 1906,*" *Bulletin of the History of Medicine* 59 (1985): 467-80 (impact of the novel and subsequent investigation on this Progressive era law).

"From Oysters to After-Dinner Mints: The Role of the Early Food and Drug Inspector," *Journal of the History of Medicine and Allied Sciences* 42 (1987): 30-53 (fascinating study of the first FDA inspectors).

"Food and Drug Enforcers in the 1920s: Restraining and Educating Business." *Business and Economic History*, 2d ser., 21 (1992): 119-28 (enforcement policy under the 1906 act).

Anderson, Oscar E., Jr. *The Health of a Nation: Harvey W. Wiley and the Fight for Pure Food.* Chicago: University of Chicago Press, 1958 (masterful biography; also an excellent early history of the 1906 act and the predecessor agency of FDA).

Jackson, Charles O. *Food and Drug Legislation in the New Deal.* Princeton: Princeton University Press, 1970 (on the formation of the 1938 Food, Drug, and Cosmetic Act).

**Presented in random order.

O'Reilly, James T. *Food and Drug Administration*, 2d ed. 2 vols. Colorado Springs, Colo.: Shepard's/McGraw-Hill, 1993 (this useful, comprehensive resource summarizes legal history behind a wide variety of policies).

Christopher, Thomas W. "Articles on Food and Drug Law." *Food Drug Cosmetic Law Journal* 13 (1958): 487-98 (dated but useful bibliography drawn exclusively from legal periodicals, arranged by subject).

Wiley, Harvey W. *An Autobiography*. Indianapolis: Bobbs-Merrill, 1930 (an illustrated and indexed life and career of the father of FDA).

Lamb, Ruth deForest. *American Chamber of Horrors: The Truth about Food and Drugs*. New York: Farrar and Rinehart, 1936 (on the many shortcomings of the 1906 act, and why a new law was needed, by the Chief Educational Officer at FDA).

Brannon, Michael. "Organizing and Reorganizing FDA." In *Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law*, 135-73. Washington: Food and Drug Law Institute, 1984 (documents the myriad structural changes within the agency).

FDA Consumer 15, no. 5 (1981) (this issue commemorating the 75th anniversary of the 1906 act includes a variety of historical articles).

Sources on Drug, Biologics, and Cosmetics Regulation

Young, James Harvey. *The Toadstool Millionaires: A Social History of Patent Medicines in America before Federal Regulation*. Princeton: Princeton University Press, 1961 (the subtitle conveys the subject of this pioneering study).

"Sulfanilamide and Diethylene Glycol." In *Chemistry and Modern Society: Historical Essays in Honor of Aaron J. Ihde*, ed. John Parascandola and James C. Whorton, 105-25. Washington, D. C.: American Chemical Society, 1983 (on the key event in 1937 that precipitated statutory drug safety).

"Federal Drug and Narcotic Legislation." *Pharmacy in History* 37 (1995): 59-67 (summarizes the principal drug laws, with references to the primary and relevant secondary literature).

American Health Quackery. Princeton: Princeton University Press, 1992 (a collection of his published essays on this theme, with a new essay on AIDS quackery).

Janssen, Wallace. "Outline of the History of U. S. Drug Regulation and Labeling." *Food Drug Cosmetic Law Journal* 36 (1981): 420-41 (a useful overview, especially with respect to misbranding).

Temin, Peter. *Taking Your Medicine: Drug Regulation in the United States*. Cambridge, Mass.: Harvard University Press, 1980 (raises many interesting issues deserving further study, but this economist's interpretations of regulatory history are sometimes questionable).

Kondratas, Ramunas. "Biologics Control Act of 1902." In *The Early Years of Federal Food and Drug Control*, 8-27. Madison, Wis.: American Institute of the History of Pharmacy, 1982 (on the coming of the federal statute that brought vaccines, sera, and antitoxins under regulation).

Sonnedecker, Glenn. "Drug Standards Become Official." In *The Early Years of Federal Food and Drug Control*, 28-39. Madison, Wis.: American Institute of the History of Pharmacy, 1982 (how the United States Pharmacopoeia and the National Formulary became official drug compendia under the 1906 act).

McFadyen, Richard E. "Thalidomide in America: A Brush with Tragedy." *Clio Medica* 11, no. 2 (1976): 79-93 (good companion piece to Young's "Sulfanilamide," because thalidomide had a similar impact on the passage of major drug regulatory legislation, the Kefauver-Harris Drug Amendments of 1962).

"Estes Kefauver and the Drug Industry." Ph. D. diss., Emory University, 1973 (a background for the enactment of the drug amendments of 1962).

Hutt, Peter Barton. "Investigations and Reports Respecting FDA Regulation of New Drugs." *Clinical Pharmacology and Therapeutics* 33 (1983): 537-48, 674-87 (more descriptive than interpretive, this serves as an excellent reference source on the role of outsiders, such as advisory committees, in shaping drug regulation policy of FDA, from 1939 to 1983).

Ward, Patricia Spain. "Who Will Bell the Cat?: Andrew C. Ivy and Krebiozen," *Bulletin of the History of Medicine* 58 (1984): 28-52 (history of quack cancer drug, Krebiozen, and the strange story of the scientist, Andrew C. Ivy, who endorsed it and thus ended his professional career).

Van Winkle, Walton, Jr. et al. "Appraisal of New Drugs." *Journal of the American Medical Association* 126 (1944): 958-61 (significant because this is among FDA's earliest published policy statements on how to submit a New Drug Application).

Swann, John. "FDA and the Practice of Pharmacy: Presciption Drug Regulation to 1951." *Pharmacy in History* 36 (1994): 55-70 (reference to the basic drug laws from the 19th to mid-20th centuries, and cooperation and conflict between organized pharmacy and FDA).

Blake, John B., ed. *Safeguarding the Public: Historical Aspects of Medicinal Drug Control*. Baltimore: Johns Hopkins Press, 1970 (several useful papers and discussions thereof, including those on 19th century drug regulation, drug regulation under the 1906 act, and regulation after 1938).

Dowling, Harry F. *Medicines for Man: The Development, Regulation, and Use of Prescription Drugs*. New York: Alfred A. Knopf, 1970 (internalistic but very useful overview of the subject).

Marks, Harry Milton. "Ideas as Reforms: Therapeutic Experiments and Medical Practice, 1900-1980." Ph. D. diss., Massachusetts Institute of Technology, 1987 (a

detailed study of clinical investigations in the U. S., including FDA's involvement).

Maeder, Thomas. *Adverse Reactions*. New York: William Morrow, 1994 (good regulatory history of an early antibiotic, chloramphenicol, and its rare but fatal side effect, aplastic anemia).

Taylor, Michael R. "History of Cosmetic Color Additive Regulation: Creative Maneuvering by FDA Bodes Well for the Future." *Food Drug Cosmetic Law Journal* 37 (1982):152-62 (regulation under the 1938 Act, under the Color Additives Amendment of 1960, and the 1980 listing of lead acetate as a signal of future policy).

Sources on Food, Device, and Veterinary Medicine Regulation

Belasco, Warren J. *Appetite for Change: How the Counterculture Took on the Food Industry, 1966-1988.* New York: Pantheon Books, 1989 (discusses the countercultural critique of governmental policy towards food and food additives between the 1960s and the 1980s).

Bosso, Christopher J. *Pesticides and Politics: The Life Cycle of A Public Issue*. Pittsburgh: University of Pittsburgh Press, 1987 (good general history of pesticides regulation, but contains a few errors regarding regulation).

FDA officials examining seafood for possible contamination from atomic bomb testing in the Pacific during the 1950s.

Hutt, Peter Barton. "A History of Government Regulation of Adulteration and Misbranding of Medical Devices." *Food Drug Cosmetic Law Journal* 44 (1989): 99-117 (a good, succinct survey of the history of device regulation outside of quackery).

and Peter Barton Hutt II. "A History of Government Regulation of Adulteration and Misbranding of Food," *Food Drug and Cosmetic Law Journal* 39 (1984): 2-73 (complete overview of governmental food regulation).

Janssen, Wallace F. "Inside the Poison Squad: How Food Additive Regulation Began" *Association of Food and Drug Officials Quarterly Bulletin* 51, no. 2 (1987): 68-72 (the story of Wiley's famous experiment to illustrate the hazards of additives using volunteer subjects).

Levenstein, Harvey W. *Revolution at the Table: The Transformation of the American Diet*. New York: Oxford University Press, 1988 (discusses the changes in American eating habits as knowledge about nutrition has advanced over the century).

Paradox of Plenty: A Social History of Eating in Modern America. New York: Oxford University Press, 1993 (continuation of previous volume beginning with the Great Depression to the present)

Marcus, Alan I. *Cancer From Beef: DES, Federal Food Regulation, and Consumer Confidence*. Baltimore: Johns Hopkins Press, 1994 (history of diethylstilbestrol used in cattle).

Whitaker, Adelyne Hiller. "A History of Federal Pesticide Regulation in the United States to 1947." Ph.D. diss., Emory University, 1974.

Hochheiser, Sheldon. "Synthetic Food Colors in the United States: A History under Regulation." Ph.D. diss., University of Wisconsin, 1982.

Soave, Orland. "History of Veterinary Medicine in the Food and Drug Administration." *Journal of the American Veterinary Medical Association* 199 (1991): 38-42 (on the regulation of products for veterinary use, 1906 to 1990).

Okun, Mitchell. *Fair Play in the Marketplace: The First Battle For Pure Food and Drugs*. Illinois: Northern Illinois University Press, 1986 (discusses the shortcomings and ultimate failure of three early food and drug statutes in New York, Massachusetts, and New Jersey as a prelude to the the 1906 act).

Ihde, Aaron J. "Food Controls Under the 1906 Act." In *The Early Years of Federal Food and Drug Control*, 40-50. Madison, Wis.: American Institute of the History of Pharmacy, 1982 (enforcement policy under the 1906 act, including the role of outsiders).

Pendergrast, Mark. *For God, Country and Coca Cola: The Unauthorized History of the Great American Soft Drink and the Company that Makes It*. New York: Charles Scribner's Sons, 1993 (although a history of Coca-Cola, the early history and regulatory problems of the soft drink are of interest to FDA).

Foote, Susan Bartlett. *Managing the Medical Arms Race: Public Policy and Medical Device Innovation.* Berkeley: University of California Press, 1992 (mostly oriented toward contemporary policy, but much is on the history of medical device regulation).

White, Suzanne. "Chemistry and Controversy: Regulating the Use of Chemicals in Foods, 1883-1959." Ph. D. diss., Emory University, 1994.

Whorton, James. *Before Silent Spring: Pesticides and Public Health in Pre-DDT America.* Princeton. Princeton University Press, 1974 (definitive history of pesticides regulation before World War II; essential reading for every FDA employee).

Young, James Harvey. "The Science and Morals of Metabolism: Catsup and Benzoate of Soda," *Journal of the History of Medicine and Allied Sciences* 23 (1968): 86-104.

"Saccharin: A Bitter Regulatory Controversy." In *Research in the Administration of Public Policy*, ed. Frank B. Evans and Harold T. Pinkett, 39-49. (Washington D. C.: Howard University Press, 1975).

"Botulism and the Ripe Olive Scare of 1919-1920," *Bulletin of the History of Medicine* 50 (1976): 372-91.

UNPUBLISHED SOURCES ON FDA HISTORY

In general, agency records prior to 1938 are part of the National Archives and housed at the Archives II facility in College Park, Maryland. Thereafter, records are under FDA's jurisdiction and require permission of the agency to consult them; these are housed at the Federal Records Center in Suitland, Maryland, or at agency headquarters. The collection at the National Archives consists of about 1000 cubic feet of records, including general correspondence, seizure recommendations, proposed legislation, papers of the Board of Food and Drug Inspection, enforcement records for the Tea Importation Act of 1897, and milk inspection documents. The reference archivist with jurisdiction over this record group (RG 88) has various finding aids to the collection.

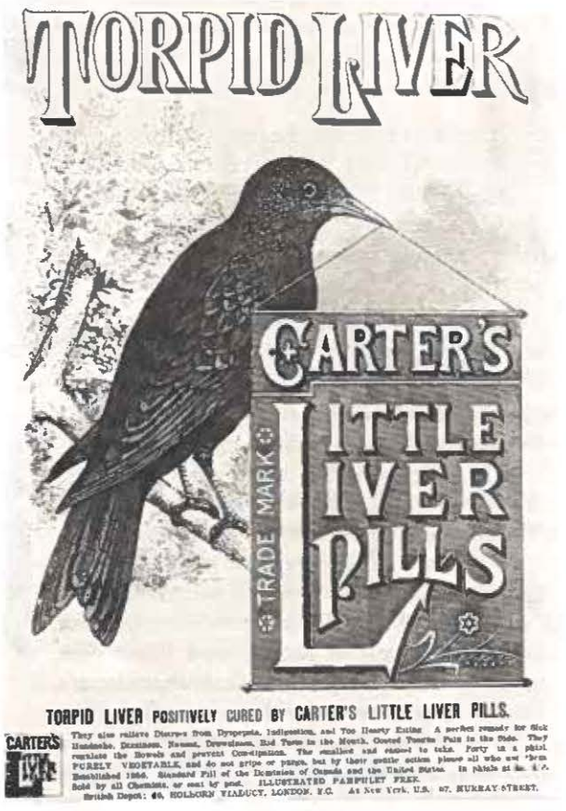
Non-FDA Records

Other collections in the National Archives might be useful in researching the history of product regulation that now falls under FDA. For example, the Public Health Service Records, RG 90, amply document the Hygienic Laboratory's (and later the National Institutes of Health's) supervision of the manufacture of antitoxins, serums, and other preparations following the Biologics Control Act of 1902. That function fell to FDA in 1972. Record Group 90 also houses some documents from a predecessor of FDA's Center for Devices and Radiological Health, the Bureau of Radiological Health of the PHS, which came to FDA in 1971. Responsibility for caustic poisons, unsafe toys, and other product safety concerns, which had resided in FDA since 1927, passed to the new Consumer Product Safety Commission in 1973.

The Federal Trade Commission (RG 122) began regulating advertising of drugs soon after its creation in 1914; it continued in this role under stronger legislation in 1938, when other products were added to its responsibilities, such as medical devices and cosmetics. The Post Office also had an active interest in regulation pertinent to FDA responsibilities. In fact, this department pursued drug fraud perpetrated through the U. S. mail prior to the 1906 act. The records of the Post Office Department in general (RG 28) and its Bureau of the Chief Inspector in particular (same record group) would be a valuable entree for the researcher interested in this line of inquiry.

Considering the roots of FDA, many records connected with agriculture in the federal government, such as the Records of the Office of the Secretary of Agriculture (RG 16), might be of use as well. The Records of the Bureau of Narcotics and Dangerous Drugs (RG 170), the agency that preceded the Drug Enforcement Administration, include material on the legitimate manufacture, illicit distribution, and abuse of narcotics, stimulants, and depressants—all products that the FDA regulated at one time or another.

Many collections other than those in government archives are relevant to the study of the regulation of foods, drugs, and so on. Certainly a useful place to begin would be either the *National Union Catalogue of Manuscript Collections* or the Research Library Information Network (RLIN) on-line database. A useful group of pre-1938 records are the Harvey Washington Wiley Papers at the Library of Congress Manuscripts Division. Nearly 250 boxes document the life and career of the man who



The FTC's protracted 16-year battle to remove "liver" from Carter's Little Liver Pills culminated in a favorable decision for the government in 1959.

headed the predecessor of FDA from 1883 to 1912. Included in the Wiley Papers are several diaries and a bibliography of publications of the Bureau of Chemistry from 1862 to 1924. The Library of Congress also houses the collected papers of Wiley's wife, Anna Kelton Wiley, which contains some papers of Harvey Wiley from about 1900 to 1930.

The American Medical Association's Historical Health Fraud and Alternative Medicine Collection is an excellent source of correspondence, circulars, clippings, and other matter on the history of quackery. This collection derives from the AMA's Department of Investigation and covers most of the twentieth century, including extensive material on Harry Hoxsey, Albert Abrams, rheumatism cures, and hundreds of quacks and quack products. The AMA published a very useful finding aid to the collection, Arthur W. Hafner et al., *Guide to the American Medical Association Historical Health Fraud and Alternative Medicine Collection* (Chicago: American Medical Association, 1992).

Researchers should be aware that the agency is bound by legislative fiat not to divulge confidential information such as trade secrets or patient information. Accordingly, for most records under FDA's control one must begin by filing a freedom of information (FOI) request with the agency. This is most efficiently done after consulting with the History Office about the sort of records that would most likely address the subject at hand. The FOI process must by law occur in a timely manner, but a person still should allow ample lead time so the FOI request can be processed, records can be identified and pulled, and so on.

Case Files

FDA has a variety of records, but most fall within the following groups: case files, AF files, decimal files, new drug applications, and the assortment of records under the Dockets Management Branch. Case files document the litigation stemming from violations of food and drug legislation, from the initial complaint filed by the U. S. Attorney through the conclusion of the case in the courts. Some files include correspondence with witnesses whom the agency sought to recruit for the trials.

Sometimes FDA had an observer at trials who would correspond with headquarters about the progress of the proceedings, conversations overheard, and occasionally the results of "tailing" a suspicious defense witness outside the courtroom. Complete transcripts of trials sometimes are in the case file. However, one should be aware that the courts themselves might be a better source for transcripts and supporting documentation, especially for cases accepted on appeal by the Supreme Court. The above-mentioned *Notices of Judgment* are an important tool to be used in conjunction with the case files, since these summarize—often in considerable detail—the same legal proceedings documented in the case file. They also include the key numbers identifying the location of the case jackets. Thus, the researcher should consult the published notice first before examining the case file.

AF Files and Decimal Files

The so-called AF files reveal much about FDA's interaction with the regulated industry. These include correspondence between the agency and companies, as well as inspection reports on the firm. Used together with the case files, the researcher can derive a full appreciation for the enforcement of food and drug laws. One can trace the story of a violative item beginning with FDA's initial inspection of a company, to seizure of the product in question, to final resolution of the affair in the courts.

The agency's decimal files include the widest ranging topics of all the collections. These files, which represent the totality of the agency's concerns, are arranged by subject; each subject is given a discrete number between 000 and 999. The system, which is indexed alphabetically by subject and by number, has been updated constantly through time. For example, this system assigns food softeners the number 489.1, radio advertising for cosmetics is 580.71, complaints from businesses about enforcement methods is 691 whereas consumer complaints about the laxness of enforcement procedures is 609.3, counterfeit drugs are 500.24, exporting of medical devices is covered in 570.66, regulations for pesticides in foods is 051.12 (FDA regulations in general are covered under 051), and so on.

A drug reviewer pores over the many volumes of a new drug application

New Drug Applications

New drug applications (NDAs) began in 1938 when manufacturers were mandated under the Food, Drug, and

Cosmetic Act to prove the safety of their drugs before FDA could approve the product for marketing. Companies submitted chemical, pharmacological, and clinical evidence to the agency to establish safety and—following the 1962 drug amendments—efficacy of their pharmaceuticals. The volume of each NDA has grown over the years to meet the changing laws and regulations, such that the earliest NDAs are merely a fraction of what manufacturers submit today. At present the total number of NDAs is about 20,000. This group of records documents, more than any other single collection anywhere, the evidence for the revolution in drug therapy in this century.

Most of each NDA is confidential because of the commercial information required; in addition, there are privacy act concerns that prevent release of most of the NDA. However, there is still substantial so-called approvability correspondence that is releasable, and since the 1970s the FDA has issued a summary basis of approval (SBA) for each NDA, which distills the voluminous data and conclusions in the application (for other product approval documents, see Dockets Management Branch Files below, or consult the relevant Center). The History Office is working with a distinguished committee of outside and internal experts on drug information and the history of pharmacology to conduct a systematic examination of the NDAs. This effort will identify historically significant NDAs that will be permanently preserved in the National Archives, as well as randomly selected NDAs to capture changes in drug evaluation methodology over time.

President Kennedy awards Dr. Frances Kelsey the highest recognition possible for civilian service in the federal government in 1962 for her efforts in keeping thalidomide out of general distribution in the United States.

Dockets Management Branch Files

Many files of the Dockets Management Branch of FDA overlap other record groups that have been discussed, but since this broad group of public records is under the jurisdiction of a single office, they will be cited here. Noteworthy holdings of this office include records from evidentiary hearings of the Administrative Law Judge; Hearing Clerk's records; summaries of approval for new animal drugs and new medical devices, including labelling and environmental impact statements; and papers pertaining to citizens' petitions. Of particular interest to researchers are the records of public comments on proposed rulemaking, i.e., responses to proposed regulations published in the *Federal Register*, and the minutes and transcripts of advisory committee meetings (with the exception of those portions of meetings that are closed to the public).

Audio-Visual Resources

Researchers should also be aware of the rich collections of non-textual documentation of FDA history. The National Archives has the most extensive collection of prints and photographs of or related to FDA. Record Group 88 has nearly 4,000 photographs before the 1938 act. Post-1938 photos number about three times that many. For example, pictures of FDA activities from 1962 to 1977, mostly from *FDA Papers* and *FDA Consumer*, total 61 boxes. Fortunately, there is a finding aid that identifies both subjects (for the first twenty-one boxes in this collection) and the location of pictures from individual issues of the two publications above (for the remaining forty boxes); the cumulative indices to *FDA Papers* and *FDA Consumer* can function as de facto subject guides to these forty boxes. In addition to the material at the National Archives, the Wiley Papers at the Library of Congress include ten boxes of prints and photographs.

The History Office has a sizeable collection of visuals in various media. The photographs and slides are organized by subject, covering a wide array of agency functions and relevant topics, as well as a number of group and individual portraits. The collection of videotapes also represent the agency in the broadest sense; these include discussions of key issues and events by agency executives, public service announcements, and programs designed to educate regulated industry. There are a number of 8-, 16-, and 35-mm films that have not yet been transferred to videotape. All of the historically significant films have been deposited in the film archives in the History of Medicine Division of the National Library of Medicine. The History Office is in the process of cataloguing the hundreds of films and audiotapes in this collection. In addition to this office's visuals, the Public Affairs Office maintains a collection of photos used in the *FDA Today* newsletter since that publication began in 1974.

This should sufficiently introduce the researcher to the published and unpublished resources on the history of the FDA. Many other sources exist, especially in the secondary literature on the agency; FDA History Office staff can assist in identifying additional works that are more directed toward a person's interests. The full-time staff here is small and our time reserved for historical research is not great.

Thus, we encourage those with an interest in the history of the FDA to apply this concern to generate narrative and interpretation of FDA's past. Regulatory history can be immensely beneficial to the discussion of public policy and, thus, immensely rewarding to the researcher.

THE FDA HISTORY OFFICE

EVOLUTION

The origins of the FDA History Office can be traced back to March 1968, when Commissioner James Goddard assigned Wallace Janssen, a Public Information Specialist and Special Assistant to the Assistant Commissioner for Education and Information, the responsibility of establishing an agency-wide Historian's Office. The office was located within the short-lived Science Information Facility, but Janssen reported directly to the Commissioner. Three months later Janssen engaged James Harvey Young, a distinguished scholar from Emory University and an authority on the history of food and drug control, as a Consultant on History. Also in 1968, Young received a grant from the National Library of Medicine to begin conducting oral histories with former FDA officials and others who were pertinent to his work in progress on the history of the FDA. The tapes and transcripts were deposited in the History of Medicine Division of the National Library of Medicine, part of the National Institutes of Health in Bethesda, Maryland (NLM).

Janssen continued as FDA Historian after 1975 as a reemployed annuitant, and in 1976 a Historian Staff was to be established in the Office of the Commissioner, the staff to include a full-time professional historian. However, a government hiring freeze aborted this effort, and this proposal was no longer pursued. The following year FDA gave Young a contract to permit him to pursue research for his history of the agency.

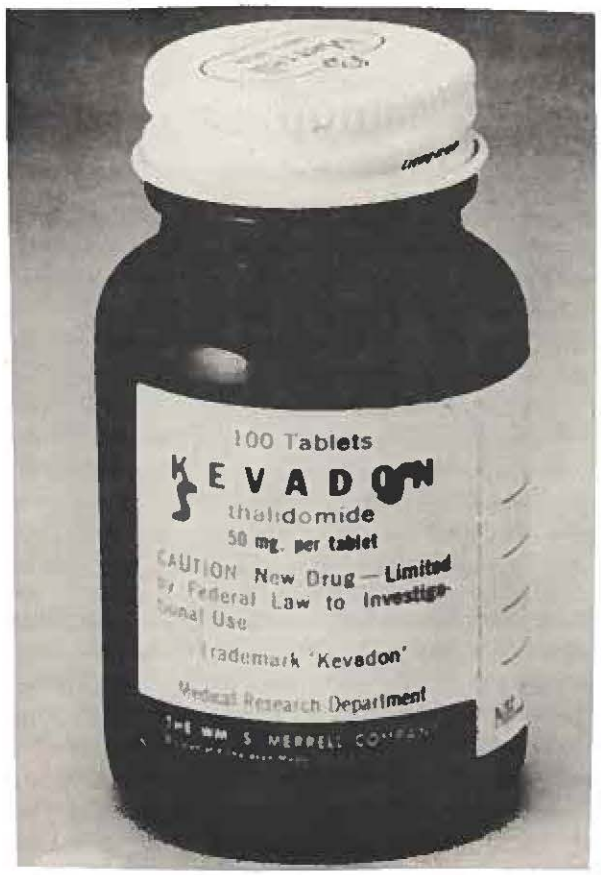
In 1977, long-time FDA employees Fred Lofsvold and Robert Porter wrote a memo to the Executive Director of Regional Operations pointing out their growing concerns about the lack of organized and sustained efforts to collect and preserve documents, exhibits, and other material documenting the history of the agency. None of the original inspectors appointed in 1907 was alive by that time, but several retired former employees from the 1920s and 1930s were still around. The recent deaths of two FDA retirees who "knew all kinds of things that were now lost to history" highlighted the need to institute a means to recover these memories before it was too late.

Lofsvold and Porter proposed that, in addition to seeking documentary information from these former employees, their recollections be collected and preserved as a supplement to the written record. Lofsvold and Porter recognized that these interviews would be a valuable resource in the recruiting and training of new employees, and a tool to engender the kind of esprit de corps they had experienced in the agency. Later that year, Commissioner Donald Kennedy signed a memo to all Food and Drug Administration field offices enlisting their help in identifying and collecting documents, photographs, and artifacts, and other documentary material dating from the earliest era of the agency's history.

Lofsvold and Porter met with Professor Young, who shared with them interviews on the history of food and drug control that he and his students had developed over the years. The former FDA employees soon schooled themselves in the techniques of oral history through one of the workshops offered by the Oral History Association, a national organization of oral historians. In addition, they contracted with the NLM to preserve the tapes and transcripts of these oral history interviews as they were completed.

As the volume of their task became greater, in 1986 Lofsvold and Porter recruited another long-time FDA employee, Ronald Ottes, who worked out of headquarters conducting interviews and editing transcripts. Following Porter and Lofsvold's retirement, Robert Tucker, another Rockville employee, arrived as the second oral historian in 1994. To date there are over 100 oral histories in the collection at NLM, accompanied by an updated cumulative index to virtually all the transcripts.

In 1984 the agency's history function—by this time housed in the Office of Legislative Affairs—was reinstituted formally as the FDA History Office and placed in the Office of Regulatory Affairs. The latter, a descendant of the early chemists and inspectors in the Bureau of Chemistry and a part of the FDA especially rich with career employees, was a likely part of the agency to foster the growth of the history program. The History Office



An investigational sample of thalidomide, which was shown to cause dramatic birth defects. It affected thousands of babies, mostly in Europe, in the late 1950s and early 1960s.

remained agency-wide in scope. Also, it assumed additional responsibilities, including the oral history project and the program to collect and preserve historically significant papers and objects (see Functions below).

The full-time professional staff was increased to fulfill the office's expanded mission. Suzanne White Junod (Ph.D., Emory University) was hired in 1984 as a one-year intern and given a permanent position the following year. She specializes in the history of food regulation. John Swann (Ph.D., University of Wisconsin) was hired in 1989. His specialty is the history of drug regulation. The appointment of Donna Hamilton (B.A., Messiah College) in 1994 as an entry-level historian rounded out the staff.

Under pressure from FDA in 1991, Procter & Gamble agreed to remove the word "fresh" from the labeling of its reconstituted orange juice.

FUNCTIONS

The mission of the FDA History Office is to increase knowledge of the history, mission, and activities of the FDA and its predecessor, the Bureau of Chemistry of the U. S. Department of Agriculture. The office provides perspective on current policy objectives and increases public understanding of FDA's purpose and function. In general, office activities concern research, documentation, consultation, and information.

Research includes but is not limited to the preparation of publishable articles, long-term projects designed to result in monographs, and staff papers in areas where the FDA Historian believes there is a need for research. This function informs all other activities the office pursues. Documentation refers to our role as preservers of the institutional memory of FDA. This includes but is not limited to the collection and preservation of paper records, oral histories, objects (although producing exhibits really is more a research enterprise), photographs, videotapes, and so on.

Consultation consists of broad assistance to and collaboration with our fellow FDA employees, historians, and other outsiders as national experts on the history of the regulation of foods, drugs, devices, biologics, and cosmetics. Information, usually narrow in scope, is provided on a frequent basis to a host of individuals representing many different institutions and organizations. These are divided roughly equally between FDA queries and those originating outside the agency. The following exemplifies some of the activities of the History Office:

Research:

- development of historical background on legislative initiatives
- creation of briefing documents on precedents to major organizational changes in the agency
- background papers on policy considerations
- scholarly articles and monographs on select areas of scientific and regulatory history

Documentation:

- oral history interviews to fill in gaps in the paper record (see below)
- collection, preservation, and exhibition of museum objects illustrating the history of the agency (see below)
- identification and preservation of historically significant records
- development of commemorations of significant agency events and milestones

Consultation:

- facilitation of scholarly studies of FDA history
- referee and review of articles, books, and grant applications in the general area of FDA history
- promotion of accurate and informed FDA history, including sponsorship of a lecture series for FDA employees and interaction with colleagues in other government agencies and professional organizations

Information:

- on-the-spot information to centers, offices, and all field offices
- historically-related freedom of information queries
- reference or guidance for industry, law firms, students, the media, foundations, historical societies, and anyone else with a question about the agency's past

THE ORAL HISTORY PROGRAM

As previously mentioned, this project has produced over one hundred cumulatively indexed interviews; transcripts are available at the NLM and Emory University. The former also has the interview tapes. Individuals interviewed represent a broad spectrum of the agency's activities. Included are oral histories with former FDA Commissioners, scientists, executive officers, early inspectors and analysts, pubic information and consumer information officers, and many others. The interviews of James Harvey Young and his

students, which are included in the cumulative index, include Morris Fishbein, former editor of the *Journal of the American Medical Association*, Robert Fischelis, former Secretary of the American Pharmaceutical Association, and Rexford Tugwell, Under Secretary of the Department of Agriculture during the New Deal.

The oral histories have had wide use within and outside of the agency. The interviews have served as the basis for briefing reports for virtually all centers and offices in the FDA. They are frequently consulted by historians and others interested in the development of FDA and its functions. In addition, they have been an important reference for new hire training of investigators, analysts, consumer affairs officers, and others.

The success of this program has been due largely to the involvement of experienced employees, people who have spent their entire careers in various program areas of the Food and Drug Administration. By applying their collective experience in the selection of those to be interviewed, these former employees have ensured that the oral histories reflect the depth and breadth of FDA's regulatory and scientific experience.

While professional historians on staff and outside the agency can and do provide some questions, the interviews have a special interest, accuracy, and flow because they take place between like-minded colleagues. No matter how uninhibited the interviewee may be, the success of an oral history—and thus the success of an oral history program—depends on the ability of the interviewer to push the session in the direction most likely to fill in the gaps in our understanding of FDA history.

THE MUSEUM COLLECTION

One of the first actions Lofsvold and Porter took, in conjunction with the oral history program, was to recruit submissions of significant artifacts from the field offices. These, along with a wide variety of objects representing self-contained individual collections and miscellaneous acquisitions gathered from unknown sources over the past decades, make up the museum collection of the FDA History Office. All the objects, which total about 1100 individual items, illustrate products the FDA regulates, and many document key enforcement cases in the history of the agency. In addition to these, the Smithsonian Institution, the St. Louis Science Center, and the Museum of Questionable Medical Devices in Minneapolis have a significant number of objects on loan from the FDA.

For example, the collection includes a box of Pillsbury Blueberry Pancake Mix, which the FDA seized in 1959 for misbranding. Contrary to the listed ingredients and the picture on the box, this product had no blueberries. The collection also includes bogus bust developers such as Lady Ample, seized in the 1960s, and misbranded and dangerous faux exercise devices, including different models of the Relaxacizor, against which FDA took action several times in the 1970s. Other notable items included in this collection are samples of Elixir Sulfanilamide and Kevadon (thalidomide), the culprits that killed or maimed many patients in this country and thereby revolutionized drug laws in 1938 and 1962, respectively, as well as Lash Lure, a synthetic aniline eyelash dye that blinded many women in the 1930s, before cosmetics came under regulation.

Lash Lure was one of the products FDA used to illustrate the many shortcomings of the 1906 Act.

The objects are organized under many categories and subcategories, determined by the agency's regulatory jurisdictions: pharmaceuticals (including labels, promotional matter, drug containers, and weight loss pharmaceuticals—the latter because of the volume of such objects), biologic agents, foods (including vitamins, labels, and promotional items), medical devices, cosmetics, veterinary feed and drugs, equipment used for inspections and for laboratory analyses (mostly chemical and microbiological), quack products (including devices, pharmaceuticals, foods, biologics, and cosmetics), pesticides, and colors. Finally, the collection includes ephemeral objects, including awards that employees or offices received and unusual company promotional items not included elsewhere, such as paper-weights, letter openers, and pill trays.

Historically, the exhibition of objects has had a prominent role at the FDA. For example, in the 1930s the agency collected Lash Lure and scores of other fraudulent and dangerous products for an exhibit—dubbed by a reporter the "American Chamber of Horrors"—that would demonstrate to Congress and the public the shortcomings of the 1906 Food and Drugs Act. In the late 1950s and early 1960s the agency organized a room of photos and objects to illustrate the hazards of quackery. An FDA Museum informed visitors in the 1970s about how the agency administered the 1906 and 1938 acts. Today the FDA History Office manages photo and artifact exhibits in several display cases in the Parklawn Building in Rockville and in the Federal Building 8 in the District of Columbia.

STAFF

Wallace Janssen:

In 1968 he was named the first Historian at FDA. Originally joined FDA in 1951 as Assistant to the Commissioner to head the agency's public information effort.

Suzanne White Junod:

Served a one-year temporary appointment in the FDA History Office in 1984, then joined the office as Historian in 1985. Received Ph. D. from Emory University (History) in 1994. Specializes in the history of food and food regulation.

Ronald Ottes:

Appointed to the Oral History Program in 1986. Originally hired by FDA as a Chemist in 1957, and retired in 1985 as Director of the Office of Regional Operations in the Office of Regulatory Affairs.

John Swann:

Hired as Historian in 1989. Received Ph. D. from the University of Wisconsin (Pharmacy and History of Science) in 1985. Specializes in the history of drugs and drug regulation.

Donna Hamilton:

Started as a Research Assistant with the FDA History Office in 1991. Received B. A. (History) from Messiah College in 1992. Hired into the Historian series in 1994.

Robert Tucker:

Appointed to the Oral History Program in 1994. Originally began as a Food and Drug Officer with FDA in 1962; retired from the Division of Federal State Relations in the Office of Regulatory Affairs in 1992.