A Chronology of Major Agency Reorganizations Affecting Field Operations*

1907
Establishment of the initial field laboratories in New York, Philadelphia, Boston, Chicago, New Orleans, and San Francisco. Facilities already existed at these sites, having been founded following the secretary of agriculture's authorization under an 1899 law to inspect imported foods. Many additional field laboratories soon followed. The laboratory directors in each office reported directly to Harvey Wiley, and the inspectors reported to Chief Inspector Walter Campbell in Washington.

An early meeting of Food & Drug Inspectors - circa 1912

1914
In an effort to increase efficiency in enforcement, the field is divided into three districts: Eastern (with headquarters in Washington), Central (Chicago), and Western (San Francisco). A single person is placed in charge of each district, bringing both the laboratory work and inspection activities under a single authority, and the district head reports to Washington.

1917
Establishment of distinct station districts within each principal district. One person is placed in charge of all laboratory and inspection work for each station. The field is now configured as:

- Eastern District, with headquarters now moved from Washington to New York (Boston, Buffalo, New York, Philadelphia, Savannah, Washington, and Puerto Rico)
- Central District (Chicago, Cincinnati, Minneapolis, St. Louis, New Orleans, and Kansas City (which no longer has a laboratory facility))
- Western District (Seattle, San Francisco, Denver, and Honolulu)

Additional inspection stations eventually were set up in the Central District (Detroit, Nashville, and Houston) and Western District (Los Angeles, Phoenix, and Portland, Oregon). Whether inspection stations reported to the head of the station or the head of the district was left to the discretion of the district chief.

1940

The predecessors of FDA had been a part of the Department of Agriculture since 1862, when Commissioner of Agriculture Isaac Newton appointed Charles Wetherill to serve as Chemist in the newly created department. In 1940 FDA was transferred through a presidential reorganization plan to the new Federal Security Agency that combined certain health, education, and welfare components of the government.

1948

A movement to centralize policy interpretation and direction results in the dissolution of the tripartite principal district system. The existing sixteen station districts now take on additional responsibilities and have direct communication with Washington. At headquarters, three divisions are created within the Office of the Commissioner in Washington to direct field activities:

James O. Clark

Allen E. Rayfield

1. The Division of Field Planning, to oversee general field operations and supervise the relationship between field programs and activities in the laboratory divisions at headquarters, which consisted of the Divisions of Cosmetics, Food, Medicine, Microbiology, Penicillin Control and Immunology, Pharmacology, and Vitamins. James O. Clarke, the former chief of the Central District, headed this division, the name of which was changed by the end of the year to the Division of Program Research.
2. The Division of Field Operations, responsible for the everyday functioning of the field offices to carry out plans developed by Director of Field Planning Clarke with the

approval of the Commissioner. Since the former chief of the Eastern district retired, Allan A. Rayfield, the Chief Inspector of the Eastern District, was named Director of Field Operations.

3. The Division of Litigation, which was charged with preparing court cases. John Harvey, the former head of the Western District, was the Director of Litigation. A year later the name of this division changed to the Division of Regulatory Management.

1953

Reorganization resulted in the abolition of the Federal Security Agency and the creation of the Department of Health, Education, and Welfare, with both FDA and the Public Health Service, both formerly part of FSA, becoming components of the new entity.

1956

Washington institutes a group of bureaus to reorganize efforts throughout the agency, in accord with the recommendations of the 1955 Report to the Secretary of Health, Education and Welfare of the Citizens Advisory Committee on the Food and Drug Administration. Pertinent to field activities, the Report stated that,

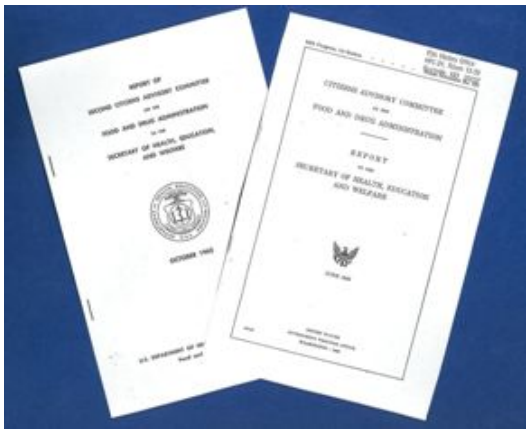
> "responsibility should be fixed at headquarters for the indoctrination and training of inspectors and chemists . . . Education, information, and interpretation activities should be a regularly planned part of field operations, coordinated policywise and programwise from a central point at headquarters . . . Action should be taken to develop more effective collaboration between FDA and other Federal, State, and local agencies in the field. . . . There should be better internal communication from Washington to the district offices so that field staffs will be fully informed of Washington thinking."

In addition to the Office of the Commissioner, which assumed responsibility for federal-state relations, regulation making, public relations, and other activities, FDA instituted five bureaus:

- The Bureau of Biological and Physical Sciences and the Bureau of Medicine included the functions of most of the old laboratory and technical divisions, such as antibiotics, cosmetics, foods, new drugs, and veterinary medicine.
- With respect to activities in the district offices, the Bureau of Enforcement, the Bureau of Program Planning and Appraisal, and the Bureau of Field Administration retained most of the functions formerly part of the Divisions of Regulatory Management, Program Research, and Field Operations.

1963

Like the previous changes, these organizational reforms stemmed largely from the counsel of an outside body.



The Report of the Second Citizens Advisory Committee of 1962 recommended a wide array of structural changes in FDA. More relevant to work in the field were such suggestions as:

> "A combination of all headquarters regulatory functions for coordination and improved administration . . . A major program of decentralization of decision making to the field offices . . . A reallocation of functions between headquarters and the field . . . A considerable strengthening of headquarters-field communications . . . There is an urgent need to upgrade personnel and to provide better training opportunities for headquarters and field staff."

While the Bureau of Medicine remained unchanged, the old Bureau of Biological and Physical Sciences was replaced by the Bureau of Scientific Research and the Bureau of Scientific Standards and Evaluation. The new Bureau of Education and Voluntary Compliance would focus on the educational functions of the agency, an emphasis of the 1962 Citizens Advisory Committee report. Most pertinent to the district offices was the Bureau of Regulatory Compliance, which combined the functions of the old Bureau of Field Administration and the Bureau of Enforcement.

1968

The functions of the Bureau of Regulatory Compliance and the Bureau of Education and Voluntary Compliance are combined in the Bureau of Compliance. In addition, ten Regional Food and Drug Directorships (RFDDs) are established to conform to the new field organization of HEW.

FDA becomes part of the Public Health Service in March. Later in the year, FDA is placed under the umbrella agency designed to coordinate environmental responsibilities in the government, the Consumer Protection and Environmental Health Service (CPEHS).

1969

FDA is removed from CPEHS (which is abolished the following year), again becoming part of the PHS and HEW framework in which the Commissioner answers to the Assistant Secretary for Health and Scientific Affairs.

Internally, FDA bureaus are developed according to product responsibilities with the formation of the Bureau of Drugs and the Bureau of Foods, Pesticides, and Product Safety; the Bureau of Veterinary Medicine had been in existence since 1965.

1971
Establishment of the Executive Director of Regional Operations (EDRO) at FDA headquarters to coordinate field activities through the ten RFDDs.

1978
Creation of position of Associate Commissioner of Regulatory Affairs, the head of the Office of Regulatory Affairs, part of the Office of the Commissioner.

1980
The Public Health Service and its constituent agencies, including FDA, become part of the new Department of Health and Human Services. The latter is derived from the removal of the education function from HEW in legislation a year earlier.

1984
EDRO is merged into the Office of Regulatory Affairs, with the following constituent offices: Office of Regulatory Resource Management, Office of Enforcement, and Office of Regional Operations.

1987
HHS approves agency proposal to consolidate regional offices from ten sites to six; regional offices in Boston, Denver, Kansas City, and Seattle are consolidated with the district offices in those cities. New regions (and regional offices) are: Northeast (New York), Mid-Atlantic (Philadelphia), Southeast (Atlanta), Midwest (Chicago), Southwest (Dallas), and Pacific (San Francisco).

1992
In the wake of congressional hearings in 1989 and 1990 on increasing criminal activities associated with FDA-regulated products, the agency creates the Office of Criminal Investigations

within ORA, organized into a headquarters office in Rockville, Maryland and six field offices (New York, Newark, New Jersey, Miami, Chicago, Kansas City, Kansas, and San Diego).

1997
The Mid-Atlantic and Midwest regions are consolidated into a single Central Region with regional offices in Philadelphia and Chicago.

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*This chronology is drawn from a variety of sources, including Michael Brannon, "Organizing and Reorganizing FDA," in Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law (Washington, D. C.: Food and Drug Law Institute, 1984), 135-173; Federal Food, Drug and Cosmetic Law: Administrative Reports, 1907-1949 (Chicago: Commerce Clearing House, 1951); Food and Drug Administration, Annual Reports, 1950-1974 (Washington: Government Printing Office, [1974]); Robert S. Roe, "Evolution of the Field Organization," Food Drug Cosmetic Law Journal 7 (1952): 773-782; Fred Lofsvold to Mount Warren, 13 December 1983, FDA History Office files; Food and Drug Review; the Federal Register; and selected transcripts from the FDA oral history program. Note that this chronology does not for the most part include individual laboratory or office closures or openings, as these would be too numerous to document in an overview of this nature.