

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Regulatory Science

Office of Medical Products, Tobacco and Specialty Laboratory Operations

Effective: December 14, 2018

1. Office of Medical Products, Tobacco and Specialty Laboratory Operations (DCIFB).

- A. Advises the Office of Regulatory Science (ORS) on scientific issues related to medical products, tobacco, drugs, electronic product radiation, medical devices, pharmaceuticals, radiopharmaceuticals, radionuclides in food, biological and microbiological safety of radiopharmaceuticals, and forensic chemistry.
- B. Provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning the Food and Drug Administration (FDA) regulated products, including their evaluation, quality, safety and effectiveness.
- C. Fosters development and use of innovative technologies to meet public health needs.
- D. Advises the Office of Regulatory Science concerning the management of the Office of Regulatory Affairs (ORA) field scientific resources (including national experts) to assure their coordinated, efficient, and effective use.

2. Medical Products and Tobacco Scientific Staff (DCIFB1).

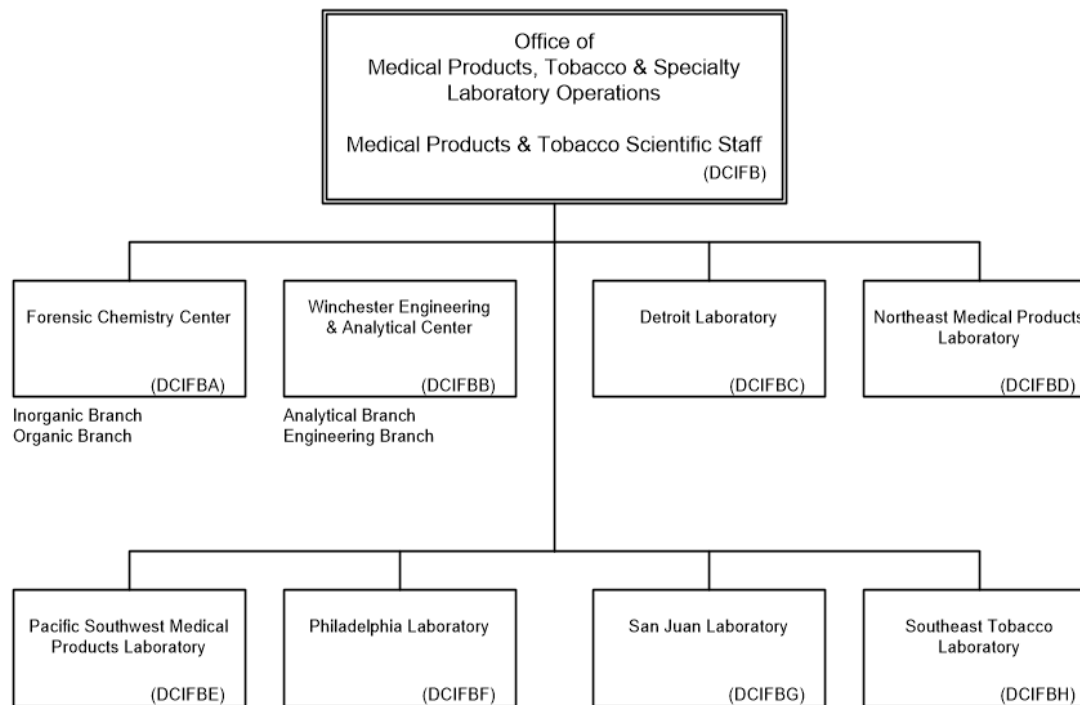
- A. Works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources relative to medical products, tobacco, forensic chemistry, and radiochemistry.

- B. Provides and coordinates day to day subject matter expertise and technical support and service to ORA laboratories relative to medical products and tobacco.
- C. Coordinates with ORS/Office of Research Coordination and Evaluation (ORCE) to identify and execute applied research based on data gaps, product risk, emerging public health issues.
- D. Serves as subject matter experts in the development of new or modified scientific and analytical compliance policies and regulatory procedures relevant to medical products and tobacco.
- E. Coordinates with ORA's Human Resource Development program and ORS/Office of Research Coordination and Evaluation to develop and implement training programs relative to medical products, tobacco, forensic chemistry, and radiochemistry based analytical methods.
- F. Leads in the development, implementation and maintenance of relevant laboratory accreditation standards and oversight programs.
- G. Represents ORA on internal and external working groups, committees, taskforces etc. in area of program and product responsibility.

3. Authority and Effective Date.

The functional statements for the Office of Medical Products, Tobacco and Specialty Laboratory Operations were approved by the Secretary for Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Regulatory Science
Office of Medical Products, Tobacco and Specialty Laboratory Operations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Science, Office of Medical Products, Tobacco and Specialty Laboratory Operations organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Medical Products, Tobacco and Specialty Laboratory Operations (DCIFB):

Medical Products & Tobacco Scientific Staff

Forensic Chemistry Center (DCIFBA)

Winchester Engineering & Analytical Center (DCIFBB)

Detroit Laboratory (DCIFBC)

Northeast Medical Products Laboratory (DCIFBD)

Pacific Southwest Medical Products Laboratory (DCIFBE)

Philadelphia Laboratory (DCIFBF)

San Juan Laboratory (DCIFBG)

Southeast Tobacco Laboratory (DCIFBH)

These organizations report to the Forensic Chemistry Center (DCIFBA):

Inorganic Branch

Organic Branch

These organizations report to the Winchester Engineering & Analytical Center (DCIFBB):

Analytical Branch

Engineering Branch