

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of the Chief Scientist

Office of Specialty Laboratories and Enforcement Support

Effective Date: May 13, 2024

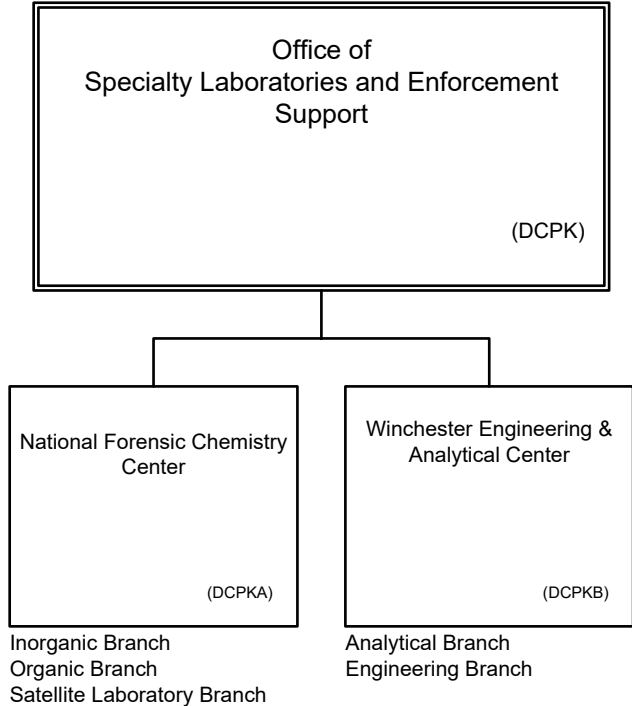
1. Office of Specialty Laboratories and Enforcement Support (DCPK).

- A. Advises the Office of the Chief Scientist (OCS) 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. Plans and conducts laboratory testing and fosters development and use of innovative technologies to meet current and emerging public health needs.
- D. Coordinates with FDA Centers and Offices on specialty laboratory scientific resources, including subject matter experts, to assure a cohesive, efficient, and effective approach to public health protection.
- E. Works with appropriate Centers and Offices to establish and execute strategic and tactical plans for the effective use of laboratory resources relative to medical products, forensic chemistry, radiochemistry, and tobacco.
- F. Provides administrative functions for laboratory operations, including budget execution, travel, and human resources, in coordination with OCS.

2. Authority and Effective Date.

The functional statements for the Office of Specialty Laboratories and Enforcement Support were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024.

**Department of Health and Human Services
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist, Office of Specialty Laboratories and Enforcement Support organizational structures reporting to the Director:

National Forensic Chemistry Center

Winchester Engineering and Analytical Center