

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

National Forensic Chemistry Center

Effective Date: May 13, 2024

1. National Forensic Chemistry Center (DCPKA).

- A. Serves as the Food and Drug Administration's (FDA) national forensic laboratory resource for method development, analyses and research associated with criminal, regulatory, and counter-terrorism investigations.
- B. Provides rapid response and specialized analytical services in forensic chemistry and molecular/microbiology for activities related to product tampering, counterfeiting, counter terrorism, adulteration/contamination, and product composition. Provides rapid response and analytical problem solving in support of public health emergencies, and FDA forensic investigations.
- C. Works directly with FDA's Office of Criminal Investigations (OCI) to provide expert technical support and analyses of evidence associated with criminal investigations.
- D. Maintains liaisons with national and international scientists and scientific bodies; other federal, state, and local government officials; and industry personnel having interests pertinent to center activities regarding forensic investigations.
- E. Develops procedures to establish profiles of adulterants and deleterious substances in foods, feeds, medical products, pharmaceuticals, tobacco and other regulated products.
- F. Advises the Office of the Chief Scientist (OCS) on new and emerging problems and trends, future program needs and priorities, manpower, equipment, financial needs, and long-range planning.

- G. Conducts collaborative research and develops screening methods to identify unapproved food additives, active pharmaceutical ingredients, and chemical analogs.
- H. Develops and transfers analytical procedures to other FDA laboratories and develops and transfers tests that can be used by the FDA agents/investigators to identify counterfeit and potentially adulterated products.
- I. Responds to requests for analytical assistance from FDA units working on other types of investigations such as counterfeit drugs, illegal steroids, chemical contamination, etc.
- J. Develops joint research projects with universities, industry, and other federal, state, and international government agencies and provides training in analytical approaches used in forensic problem solving.
- K. Assists with on-site investigations requiring specialized expertise and experience in forensic investigations and maintains state-of-the-art expertise in forensic investigations.
- L. Manages and evaluates program activities, continuously measures achievements, and advises OCS of strategy needed to reach objectives or of the need to adjust objectives.
- M. Manages and implements an accredited quality program that fulfills the requirements of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2017.

2. Inorganic Branch (DCPKA1).

- A. Works as part of a forensic chemistry (FC) team to plan, schedule, and manage branch analytical operations and formulate, implement, and coordinate laboratory work with FDA components being supported.
- B. Serves as a resource in scientific knowledge and provides expert advice, testimony, and training regarding forensic techniques and technological developments to scientific bodies and institutions, other federal, state, and local agencies, foreign counterpart agencies, industries, and courts.
- C. Conducts in-depth method development to identify suspected adulterants and toxic contaminants in foods, pharmaceuticals, animal feeds, medical devices, tobacco, and other regulated products.
- D. Maintains a Quality System to assure reliability of analytical results.

3. Organic Branch (DCPKA2).

- A. Works as part of an FC team to plan, schedule, and manage branch analytical operations and formulate, implement, and coordinate laboratory work with FDA components being supported.
- B. Serves as a resource in scientific knowledge and provides expert advice, testimony, and training regarding forensic techniques and technological developments to scientific bodies and institutions, other federal, state, and local agencies, foreign counterpart agencies, industries, and courts. Specialized fields of testing include but are not limited to gas and liquid chromatographies with mass spectrometric detection, image analysis, infrared and Raman spectroscopies, capillary electrophoresis, scanning electron microscopy with energy dispersive x-ray analysis, immunoassay based testing, gel electrophoresis and matrix assisted laser desorption ionization mass spectrometry for protein characterization, polymerase chain reactions for detection/speciation of deoxyribonucleic (DNA), whole genome sequencing (WGS), microbiological and molecular biological practices for use in Biosafety level (BSL)-2 and BSL-3 laboratories.
- C. Conducts in-depth method development to identify suspected adulterants and toxic contaminants in foods, pharmaceuticals, animal feeds, medical devices, tobacco, and other regulated products.
- D. Maintains a Quality System to assure reliability of analytical results.

4. Satellite Laboratory Branch (DCPKA3).

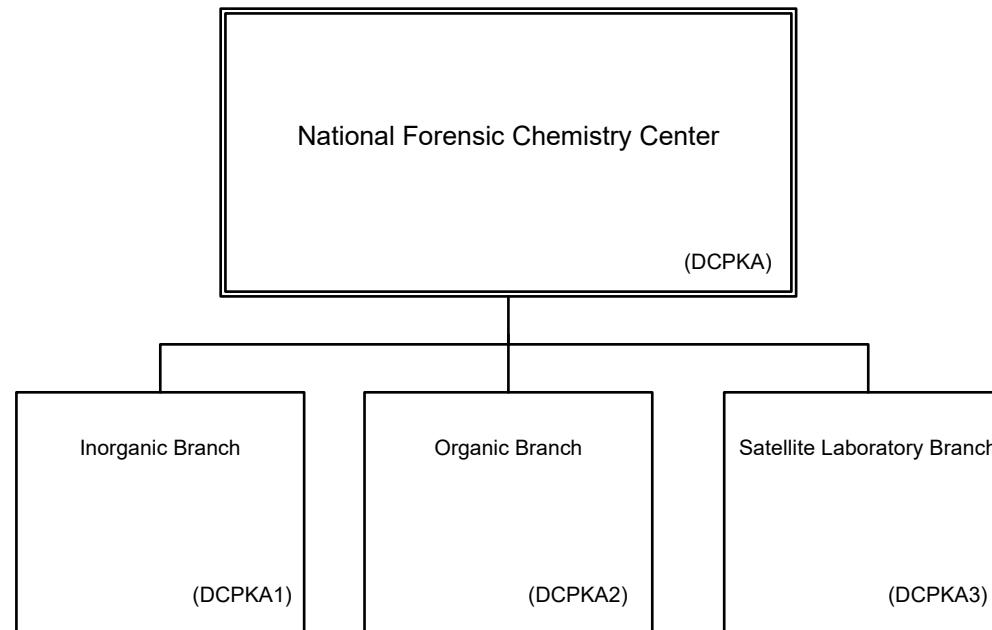
- A. Manages a laboratory branch that consists of multiple satellite laboratories located at selected points of regulated product entry across the nation.
- B. Works as part of an FC team to plan, schedule, and manage branch analytical operations and formulate, implement, and coordinate laboratory work with FDA Centers and Offices being supported.
- C. Coordinates partnerships and program activities with the OCS, FDA's Imports program, OCI, FDA Centers, United States Customs and Border Protection (CBP), and United States Drug Enforcement Administration, including shared laboratory activities, blitzes, and operations.
- D. Serves as a resource in scientific knowledge and provides expert advice, testimony, and training regarding forensic techniques and technological developments to scientific bodies and institutions, other federal, state, and local agencies, foreign counterpart agencies, industries, and courts.
- E. Conducts in-depth method development to identify suspected adulterants and toxic contaminants in foods, pharmaceuticals, medical devices, tobacco, and other regulated products.

- F. Designs satellite laboratories at selected international mail facilities and points of product entry and ensures the laboratories meet safety protocols.
- G. Evaluates and selects emerging deployable handheld and portable technologies and provides training in support of regulatory and criminal investigations; maintains a reach-back system for reviewing and evaluating data generated by agents and investigators using these technologies.

5. Authority and Effective Date.

The functional statements for the National Forensics Chemistry Center 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
Food and Drug Administration
Office of the Chief Scientist
Office of Specialty Laboratories and Enforcement Support
National Forensic Chemistry Center**



Staff Manual Guide 1119A.91
Organizations and Functions
Effective Date: May 13, 2024

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, National Forensic Chemistry Center organization structure depicting all the organizational structures reporting to the Director:

Inorganic Branch (DCPKA1)

Organic Branch (DCPKA2)

Satellite Laboratory Branch (DCPKA3)