

**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 Food and Feed Laboratory Operations**

**Denver Laboratory**

Effective Date: December 14, 2018

**1. Denver Laboratory (DCIFCB).**

- A. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates domestic and import analytical laboratory work plans and schedules with district offices being serviced.
- B. Conducts laboratory analysis of samples to:
  - 1. Assess each sample's compliance with applicable laws and regulations enforced by the Food and Drug Administration (FDA);
  - 2. Determines the extent to which findings provide evidence of violative conditions and practices; and
  - 3. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- C. Provides evidence regarding analytical findings as requested.
- D. Conducts research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- E. Conducts reviews of data provided from contract, state, and private laboratories in support of Office of Regulatory Affairs (ORA's) regulatory mission

- F. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to products regulated by the FDA.
- G. Serves as a resource in scientific knowledge and provides expert-advice and training regarding laboratory techniques and technological developments to other Federal agencies, State and local agencies, foreign counterpart agencies, and industry.
- H. Provides assistance to the food and feed programs, as requested, in the conduct of complex inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.
- I. Conducts studies and surveys of issues, operations and procedures, and evaluations to measure program effectiveness and accomplishments against the field work plan objectives.
- J. Serves as national resource for analyses requiring complex mass spectroscopic and other instrumental analyses.
- K. Serves as a national resource for microbiological analyses requiring serological identification of pathogenic microorganisms.
- L. Develops analytical methods for drug residues in animal feeds for food and in animal tissue.
- M. Conducts and/or participates in the validation of analytical methods for drug residues in animal tissue and in animal feeds for food.
- N. Conducts research on the analytical chemistry of drugs in animal feeds for food in support of FDA regulatory programs.
- O. Develops and maintains the capability to utilize new analytical procedures and conducts complex analyses for animal drug residues.
- P. Assists in the preparation and revision of compliance programs for the Center for Veterinary Medicine and for the Center for Food Safety and Applied Nutrition.
- Q. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- R. Implements an effective internal quality assurance program.
- S. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.

T. Maintains working liaison with other Federal offices-providing support services to the FDA.

## **2. Chemistry Branch (DCIFCB1).**

- A. Performs laboratory analyses and examination of samples collected to assess each sample's compliance with laws and regulations enforced by the FDA; and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Maintains an effective internal quality assurance program (17025 accredited).
- C. Conducts research and participate in collaborative studies to develop and refine methodology used in the analysis of food samples and to explore new techniques and systems of analysis.
- D. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies; to State, local and foreign counterpart agencies, academia, and industry.
- E. Provides court testimony regarding analytical findings as requested.
- F. Plans, schedules, and controls Branch operations; and formulates, implements, and coordinates workplans for district offices served.
- G. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food, feed, and cosmetic products.
- H. Maintains liaison with scientists and scientific institutions, with interest pertinent to laboratory activities.
- I. Conducts research in a variety of aspects regarding food samples.

## **3. Microbiology Branch (DCIFCB2).**

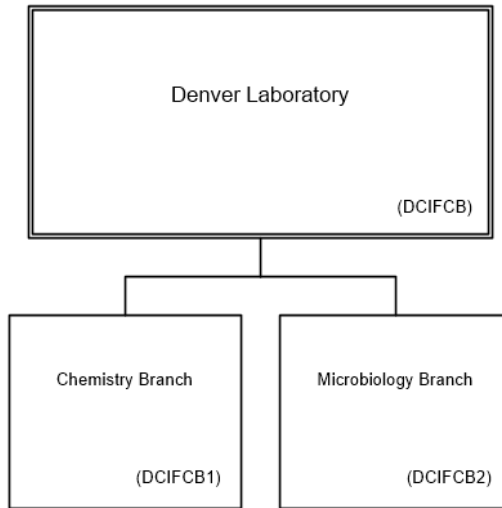
- A. Performs microbiological analyses of samples for district offices, as assigned by the National Sample Distributor or as directed by assignments, in order to assess each sample's compliance with applicable laws and regulations enforced by the FDA and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.

- B. Conducts research and participate in collaborative studies to develop and refine methodology used in the analysis of microbiological samples and to explore new techniques and systems of analysis.
- C. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, to State, local, and foreign counterpart agencies, academia, and industry.
- D. Provides court testimony regarding analytical findings, as requested.
- E. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in microbiologically contaminated products.
- F. Maintains liaison with scientists and scientific institutions with interest pertinent to their respective scientific specialties.
- G. Maintains an effective internal quality assurance program (17025 accredited).
- H. Plans, schedules, and manages Branch operations; and formulates, implements, and coordinates workplans with district offices served.
- I. Conducts research in a variety of aspects regarding microbiological concerns.

### **3. Authority and Effective Date.**

The functional statements for this Denver Laboratory were approved by the Secretary for Health and Human Services and effective December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Office of Regulatory Science  
Office of Food and Feed Laboratory Operations  
Denver Laboratory**



Staff Manual Guide 1121.932  
Organizations and Functions  
Effective Date: December 14, 2018

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

These organizations report to the Denver Laboratory (DCIFCB):

Chemistry Branch (DCIFCB1)

Microbiology Branch (DCIFCB2)