

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administrations**

**Center for Drug Evaluation and Research**

**Office of Pharmaceutical Quality**

**Office of Testing & Research**

**Division of Pharmaceutical Analysis**

Effective Date: September 25, 2019

**1. Division of Pharmaceutical Analysis (DCDLFB).**

- A. Evaluates, develops, and implements new technologies for characterizing chemical and biological properties of materials for pharmaceutical quality and bioequivalence purposes.
- B. Determines the suitability of analytical methods to support quality assessment and standard development of pharmaceutical ingredients and products.
- C. Conducts surveillance and laboratory testing of pharmaceutical ingredients and products to evaluate their quality in response to public health emergencies.

**2. Pharmaceutical Analysis Branch 1 (DCDLFB1).**

- A. Implements technologies, methods, and procedures for rapid evaluation of drug ingredient and product quality.
- B. Conducts research on new rapid screening technologies to improve quality surveillance of pharmaceutical products.
- C. Provides analytical support to Food and Drug Administration (FDA) to address public health emergencies.
- D. Provides subject matter experts and hands-on laboratory training to FDA staff to support review, inspection, and policy functions.

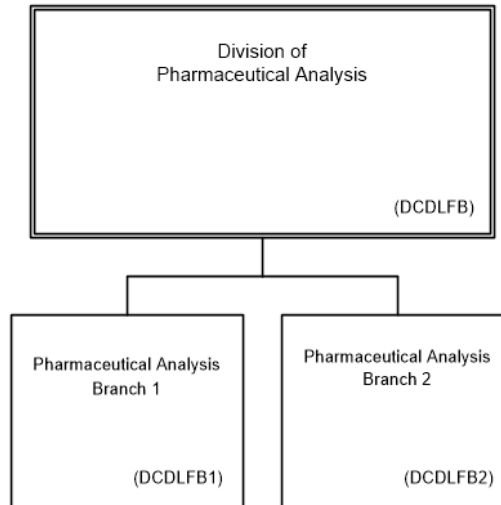
### **3. Pharmaceutical Analysis Branch 2 (DCDLFB2).**

- A. Evaluates analytical methods submitted with drug applications to determine their suitability for regulatory and quality control purposes.
- B. Develops improved testing methods, including compendial methods, to evaluate product quality.
- C. Identifies and researches gaps in existing methods and procedures for assuring drug ingredient and product quality.
- D. Provides subject matter experts and hands-on laboratory training to FDA staff to support review, inspection and policy functions.

### **4. Authority and Effective Date.**

The functional statements for the Division of Pharmaceutical Analysis were approved by the Secretary of Health and Human Services on September 25, 2019.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Pharmaceutical Quality  
Office of Testing and Research  
Division of Pharmaceutical Analysis**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Testing and Research, Division of Pharmaceutical Analysis organizational structures depicting all the organizational structures reporting to the Director.

Division of Pharmaceutical Analysis (DCDLFB).

These organizations report to the Division of Pharmaceutical Analysis:

Pharmaceutical Analysis Branch 1 (DCDLFB1)

Pharmaceutical Analysis Branch 2 (DCDLFB2)