

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

Effective Date: September 25, 2019

1. Office of Testing & Research (DCDLF).

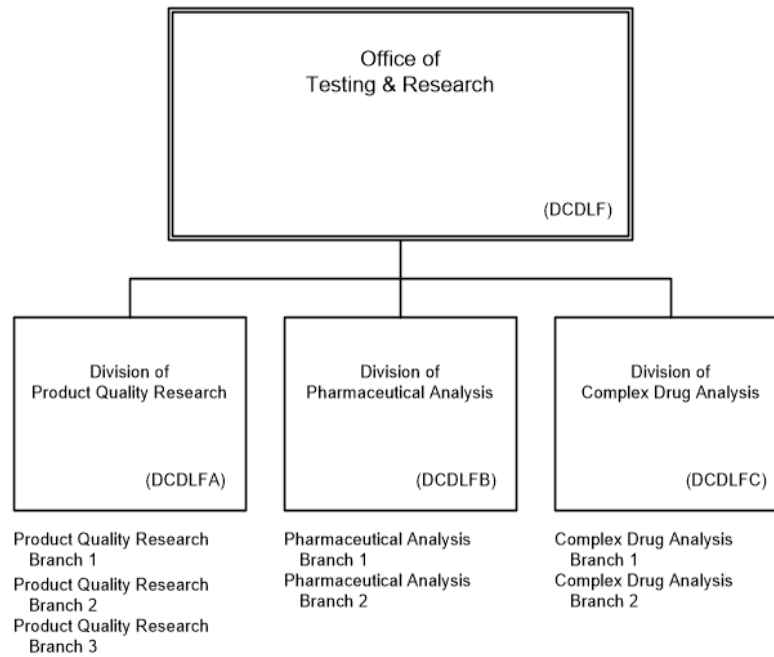
- A. Conducts laboratory research on manufacturing, formulation, and characterization of drugs that supports quality review, inspection, quality standard and policy development, education, and rapid response activities.
- B. Directs drug quality surveillance testing and laboratory-based investigational activities for the Center as needed for public health emergencies.
- C. Provides advice/consults, collaborative research opportunities, and scientific training for the Food and Drug Administration's (FDA) staff on pharmaceutical quality, pharmaceutical equivalence, and bioavailability/bioequivalence issues including manufacturing, formulation, analytical testing and modeling.
- D. Participates in an integrated quality assessment team in the Office of Pharmaceutical Quality in needed areas.
- E. Coordinates with other Agency components to educate the public on Center and Agency policy and activities.
- F. Participates in Center-level committees to coordinate research priorities with other Center for Drug Evaluation and Research (CDER) offices.
- G. Directs and coordinates with relevant FDA Offices to meet Generic User Fee Amendments science and research priorities and requirements.

- H. Supports a lifecycle approach to drug application approval by providing relevant expertise and laboratory data to aid quality assessment of supplements and abbreviated new drug applications.
- I. Coordinates extramural research through contracts or grants and administers extramural research activities for Office of Pharmaceutical Quality in needed areas.
- J. Works with relevant FDA offices to plan and direct CDER relevant Office of Regulatory Affairs laboratory activities.

2. Authority and Effective Date.

The functional statements for the Office of Testing & Research were approved by the Secretary of Health and Human Services, and effective 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**



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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 organizational structures depicting all the organizational structures reporting to the Director.

Office of Testing and Research (DCDLF).

These organizations report to the Office of Testing and Research:

Division of Product Quality (DCDLFA)

Division of Pharmaceutical Analysis (DCDLFB)

Division of Complex Drug Analysis (DCDLFC)

These organizations report to the Division of Product Quality:

Product Quality Branch 1

Product Quality Branch 2

Product Quality Branch 3

These organizations report to the Division of Pharmaceutical Analysis:

Pharmaceutical Analysis Branch 1

Pharmaceutical Analysis Branch 2

These organizations report to the Division of Complex Drug Analysis

Complex Drug Analysis Branch 1

Complex Drug Analysis Branch 2