

**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 Complex Drug Analysis**

Effective Date: September 25, 2019

**1. Division of Complex Drug Analysis (DCDLFC).**

- A. Provides state of the art analytical support for characterizing complex drug substances, products and dosage forms.
- B. Develops and disseminates new technologies and methods for characterizing complex drug substances, products, and dosage forms for the purposes of equivalence or similarity analysis and product testing.
- C. Conducts laboratory testing of complex drug substances, products and dosage forms to evaluate product quality in response to public health emergencies.
- D. Provides subject matter experts and hands-on laboratory training to Food and Drug Administration (FDA) staff to support review, inspection, and policy functions.

**2. Complex Drug Analysis Branch 1 (DCDLFC1).**

- A. Characterizes drug substances and products with complex composition including biological molecules and complex mixtures.
- B. Applies state-of-the-art analytical technologies and uses new technologies as needed for the structural and performance evaluation of complex drug substances and products.
- C. Develops advanced analytical procedures for assay and purity of complex drug substances and products.

D. Provides subject matter experts and hands-on laboratory training to FDA staff to support review, inspection and policy functions.

**3. Complex Drug Analysis Branch 2 (DCDLFC2).**

A. Evaluates the performance and reliability of complex dosage forms or drug delivery systems including transdermal, inhalation and nasal systems.

B. Measures the impact of device properties and environmental factors on product performance and failure modes for complex dosage forms or drug delivery systems.

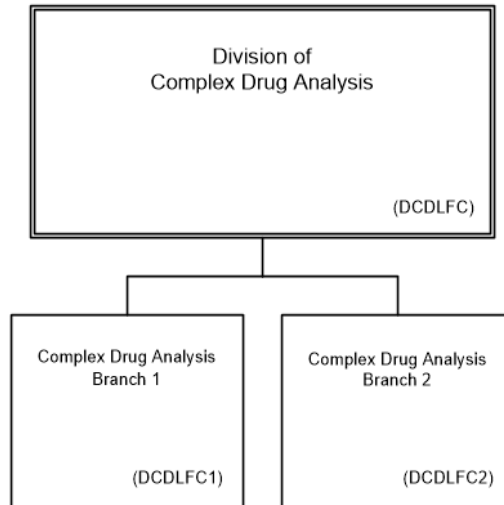
C. Implements improved analytical methodologies to better predict the *in vivo* performance.

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 Complex Drug 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  
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Office of Testing and Research  
Division of Complex Drug 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 Complex Drug Analysis organizational structures depicting all the organizational structures reporting to the Director.

Division of Complex Drug Analysis (DCDLFC).

These organizations report to the Division of Pharmaceutical Analysis:

Complex Drug Analysis Branch 1 (DCDLFC1)

Complex Drug Analysis Branch 2 (DCDLFC2)