

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Compliance

Office of Unapproved Drugs and Labeling Compliance

Division of Compounded Drugs

Effective Date: December 14, 2018

1. Division of Compounded Drugs (DCDFBA).

- A. Develops and implements compliance strategies, programs and policies for protecting the public health that minimize exposure to unsafe compounded drug products.
- B. Engages in strategic, risk-based, compliance and regulatory activities to minimize consumer exposure to unsafe compounded drug products.

2. Compounding Policy Branch (DCDFBA1).

- A. Reviews and develops policies and outreach activities and prepares for advisory committee meetings related to compounding, including developing regulations, and guidance and policy documents to implement the compounding provisions of the Drug Quality and Security Act.

3. Compounding Regulatory Actions Branch (DCDFBA2).

- A. Recommends, directs and/or coordinates case development, compliance strategies, and regulatory actions, including enforcement relating to compounded drug products.

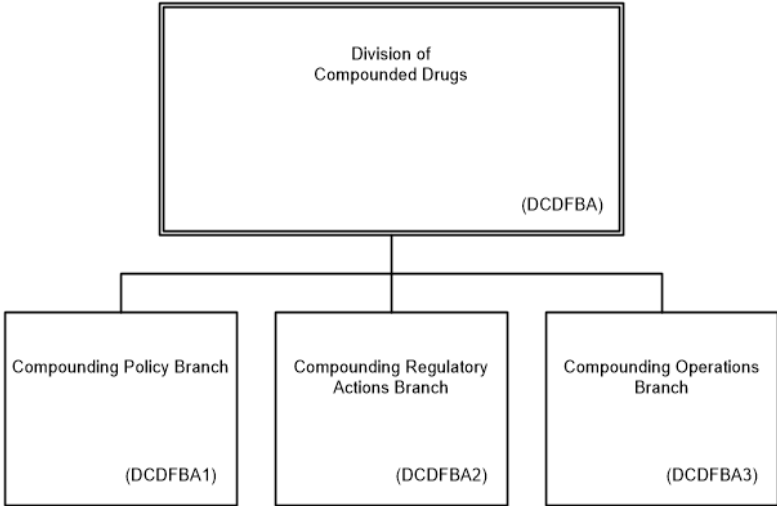
4. Compounding Operations Branch (DCDFBA3).

- A. Directs field inspections and investigations, develops inspectional strategies and plans, and addresses incidents associated with compounded drug products. Manages and coordinates operation of the compounding program.

5. Authority and Effective Date.

The functional statements for the Office of Unapproved Drugs and Labeling Compliance were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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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 Compliance, Office of Unapproved Drugs and Labeling Compliance, Division of Compounded Drugs organization structure depicting all the organizational structures reporting to the Director.

Division of Compounded Drugs (DCDFBA)

These organizations report to the Division of Compounded Drugs:

Compounding Policy Branch (DCDFBA1)

Compounding Regulatory Actions Branch (DCDFBA2)

Compounding Operations Branch (DCDFBA3)