

**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 Compounding Quality and Compliance**

**Division of Compounding II**

Effective Date: May 13, 2024

**1. Division of Compounding II (DCDFFB).**

- A. Develops and implements compliance strategies, programs and policies for protecting the public health that minimize exposure to unsafe, ineffective, and poor-quality compounded drug products.
- B. Engages in strategic, risk-based compliance and regulatory activities to minimize consumer exposure to unsafe, ineffective, and poor-quality compounded drug products.
- C. Coordinates the response to incidents associated with compounded drugs that threaten patient safety.
- D. Oversees the development of risk-based surveillance, follow-up or for-cause inspection assignments, and other related inquiries and assignments.
- E. Oversees technical support for judicial actions related to compounded drugs.

**2. Compounding Branch 4 (DCDFFB2).**

- A. Recommends, directs and/or coordinates case development, compliance strategies, and regulatory actions, including enforcement relating to compounded drug products.
- B. In collaboration with the Food and Drug Administration's (FDA) inspections and investigations program, directs inspectorate inspections and investigations, develops inspectional strategies and plans, and addresses

incidents associated with compounded drug products. Manages and coordinates operation of the compounding program.

- C. Initiates actions in response to incidents associated with compounded drugs that threaten patient safety.
- D. Develops risk-based surveillance, follow-up or for-cause inspection assignments, and other related inquiries and assignments.
- E. Provides technical support for judicial actions related to compounded drugs.

**3. Compounding Branch 5 (DCDFFB3).**

- A. Recommends, directs and/or coordinates case development, compliance strategies, and regulatory actions, including enforcement relating to compounded drug products.
- B. In collaboration with FDA's inspections and investigations program, directs inspectorate inspections and investigations, develops inspectional strategies and plans, and addresses incidents associated with compounded drug products. Manages and coordinates operation of the compounding program.
- C. Initiates actions in response to incidents associated with compounded drugs that threaten patient safety.
- D. Develops risk-based surveillance, follow-up or for-cause inspection assignments, and other related inquiries and assignments.
- E. Provides technical support for judicial actions related to compounded drugs.

**4. Compounding Branch 6 (DCDFFB4).**

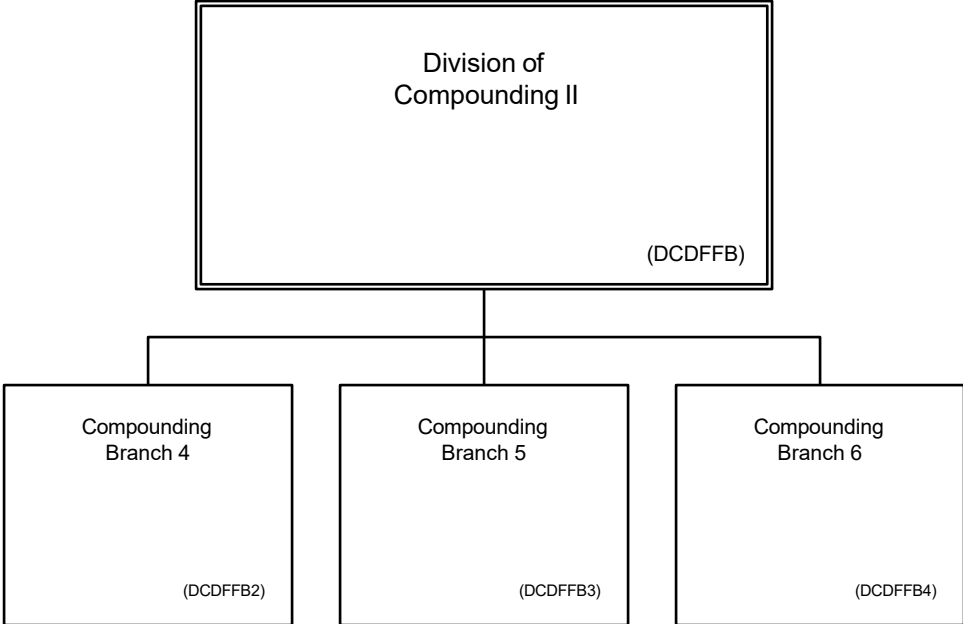
- A. Recommends, directs and/or coordinates case development, compliance strategies, and regulatory actions, including enforcement relating to compounded drug products.
- B. In collaboration with FDA's inspections and investigations program, directs inspectorate inspections and investigations, develops inspectional strategies and plans, and addresses incidents associated with compounded drug products. Manages and coordinates operation of the compounding programs.
- C. Initiates actions in response to incidents associated with compounded drugs that threaten patient safety.
- D. Develops risk-based surveillance, follow-up or for-cause inspection assignments, and other related inquiries and assignments.

E. Provides technical support for judicial actions related to compounded drugs.

**5. Authority and Effective Date.**

The functional statements for the Division of Compounding II were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Compliance  
Office of Compounding Quality and Compliance  
Division of Compounding II**



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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 Compounding Quality and Compliance, Division of Compounding II organization structure depicting all the organizational structures reporting to the Director:

Division of Compounding II (DCDFFB)  
Compounding Branch 4 (DCDFFB2)  
Compounding Branch 5 (DCDFFB3)  
Compounding Branch 6 (DCDFFB4)