

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 Policy and Outreach

Effective Date: May 13, 2024

1. Division of Compounding Policy and Outreach (DCDFFC).

- A. Oversees the development and implementation of compliance strategies, programs, and policies for protecting the public health that minimize exposure to unsafe, ineffective, and poor-quality compounded drug products.
- B. Oversees the development and implementation of the Compounding Quality Center of Excellence program.
- C. Directs the review and development of legislative proposals, implementing regulations, policy and guidance documents related to human drug compounding.
- D. Directs collaboration with regulatory partners to promote voluntary compliance.
- E. Coordinates stakeholder outreach, education, and communication on human drug compounding guidance, requirements, and policies to promote voluntary compliance.

2. Compounding Branch 7 (DCDFFC3).

- 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.

- B. Develops and implements the Compounding Quality Center of Excellence.
- C. Reviews and develops legislative proposals, implementing regulations, policy and guidance documents related to human drug compounding.
- D. Collaborates with regulatory partners to promote voluntary compliance.
- E. Conducts stakeholder outreach, education, and communication on human drug compounding guidance, requirements, and policies to promote voluntary compliance.

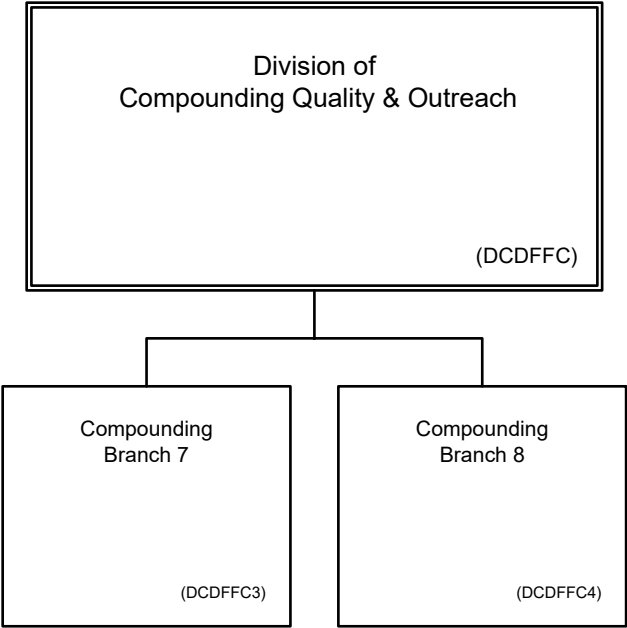
3. Compounding Branch 8 (DCDFFC4).

- A. Reviews and develops policies and outreach activities, and prepares for advisory committee meeting related to compounding, including developing regulations, and guidance and policy documents to implement the compounding provisions of the Drug Quality and Security Act.
- B. Develops and implements the Compounding Quality Center of Excellence program.
- C. Reviews and develops legislative proposals, implementing regulations, policy and guidance documents related to human drug compounding.
- D. Collaborates with regulatory partners to promote voluntary compliance.
- E. Conducts stakeholder outreach, education, and communication on human drug compounding guidance, requirements, and policies to promote voluntary compliance.

4. Authority and Effective Date.

The functional statements for the Division of Compounding Policy and Outreach 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
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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 Policy and Outreach organization structure depicting all the organizational structures reporting to the Director:

Compounding Branch 7 (DCDFFC3)
Compounding Branch 8 (DCDFFC4)