

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

Effective Date: May 13, 2024

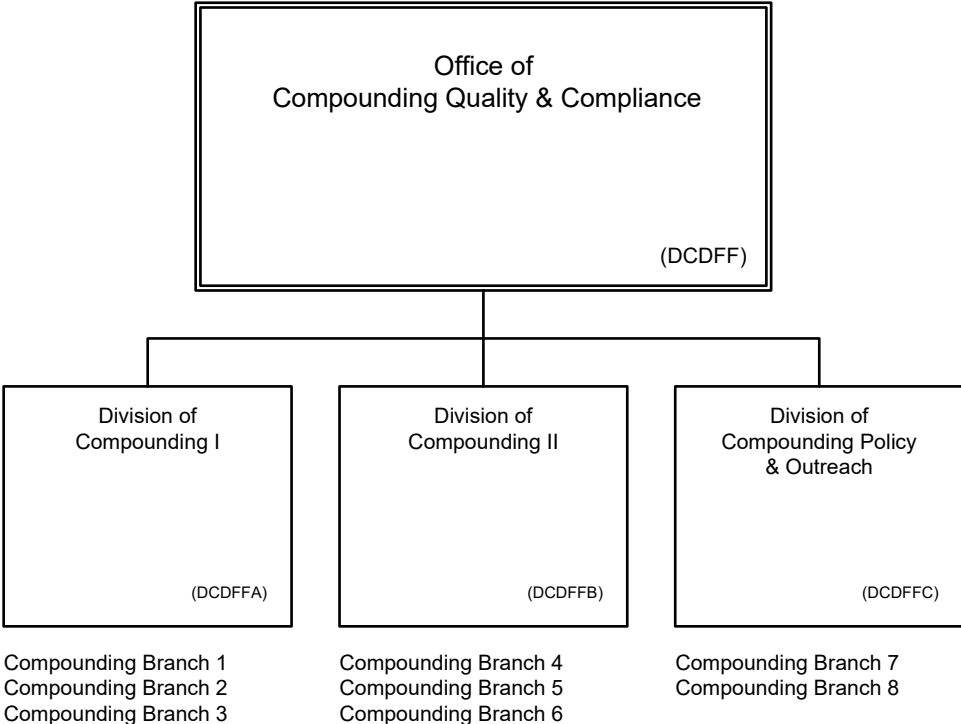
1. Office of Compounding Quality and Compliance (DCDFF).

- 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 while preserving access to lawfully-marketed compounded drugs for parties who have a medical need for them.
- B. Conducts stakeholder outreach and communication on human drug compounding issues, including guidance, regulations, and policies to promote voluntary compliance with pertinent laws and regulations.
- C. Provides oversight of human drug compounding by strengthening the scientific framework, bolstering existing and new regulatory and inspectional initiatives, and expanding policy development to support the needs of the compounding program.
- D. Establishes, develops, and oversees the Compounding Quality Center of Excellence designed to bolster the outsourcing facility sector and to enhance the quality of compounded drug products.
- E. Serves as Food and Drug Administration’s (FDA) focal point for human drug compounding issues, policies, and oversight.
- F. Provides overarching coordination between the Office of Compounding Quality and Compliance staff and FDA’s inspections and investigations program staff related to inspections.

2. Authority and Effective Date.

The functional statements for the Office of Compounding Quality and Compliance 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 organization structure depicting all the organizational structures reporting to the Director:

Division of Compounding I (DCDFFA)
Division of Compounding II (DCDFFB)
Division of Compounding Policy and Outreach (DCDFFC)

These organizations report to the Division of Compounding I (DCDFFA):

Compounding Branch 1
Compounding Branch 2
Compounding Branch 3

These organizations report to the Division of Compounding II (DCDFFB):

Compounding Branch 4
Compounding Branch 5
Compounding Branch 6

These organizations report to the Division of Compounding Policy and Outreach (DCDFFC):

Compounding Branch 7
Compounding Branch 8