

**SMG 1262.3**

**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**

Effective Date: December 14, 2018

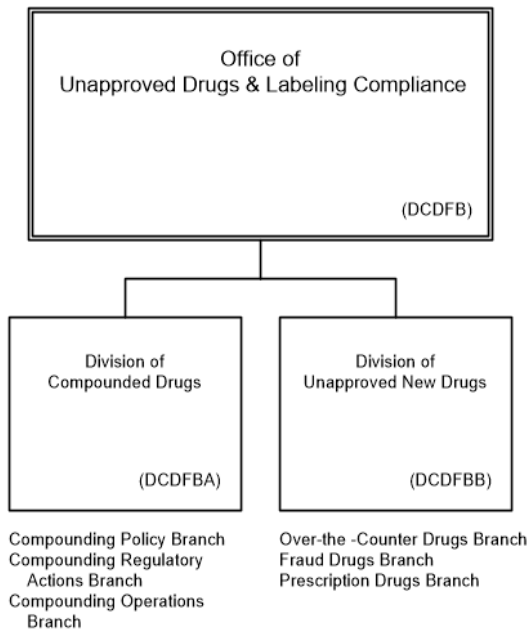
**1. Office of Unapproved Drugs and Labeling Compliance (DCDFB).**

A. Develops and implements policies and compliance strategies for protecting the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic Act.

**2. 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.

**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 Unapproved Drugs and Labeling Compliance organization structure depicting all the organizational structures reporting to the Director.

Office of Unapproved Drugs and Labeling Compliance (DCDFB)

These organizations report to the Office of Unapproved Drugs and Labeling Compliance:

Division of Compounded Drugs (DCDFBA)

Division of Unapproved New Drugs (DCDFBB)

These organizations report to the Division of Compounded Drugs:

Compounding Policy Branch

Compounding Regulatory Actions Branch

Compounding Operations Branch