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: October 9, 2020

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

A. Develops and implements compliance strategies, programs and policies to ensure that drugs marketed in the United States meet applicable approval, labeling, and listing requirements in accordance with the Federal Food, Drug and Cosmetic Act.

B. Engages in strategic, risk-based, compliance and regulatory activities to shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions.

C. Directs, recommends and conducts Food and Drug Administration (FDA) risk-based surveillance activities relating to over-the-counter, unapproved prescription, homeopathic and fraudulent drug products and recommends field inspections and investigations.

D. Coordinates communications with stakeholders, Congress and Federal partners regarding over-the-counter, unapproved prescription, homeopathic and fraudulent drug products as well as registration and listing requirements.

E. Reviews and develops legislative proposals, implementing regulations, policy and guidance documents, and outreach activities relating to over-the-counter, unapproved prescription, homeopathic and fraudulent drug products.

F. Develops and implements compliance programs and policies to promote the availability of comprehensive drug registration and listing information about the U.S. drug supply and entities involved in the supply chain.

G. Manages drug registration and listing database and serves as FDA-lead for associated policy issues.

2. Authority and Effective Date.

The functional statements for the Office of Unapproved Drugs and Labeling Compliance were approved by the Commissioner of Food and Drugs on September 8, 2020, and effective on October 9, 2020.

Department of Health and Human Services
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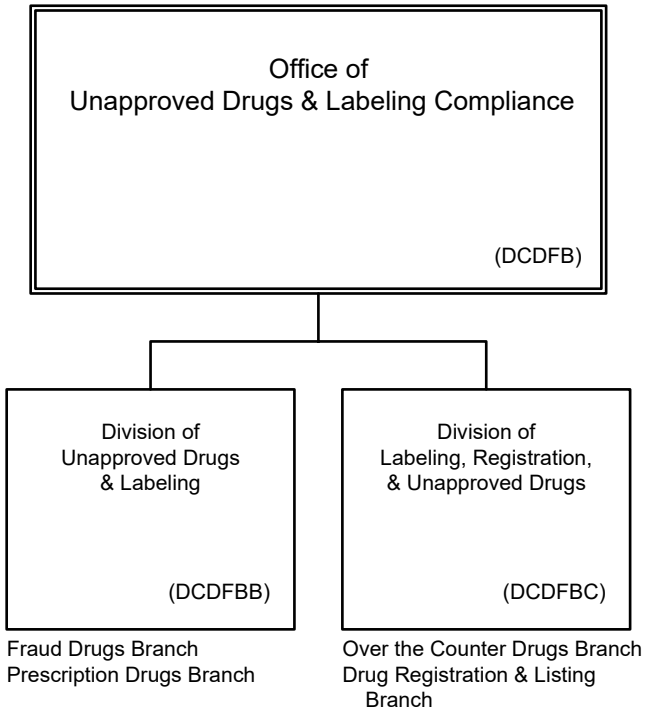

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Unapproved Drugs and Labeling Compliance organization structure depicting all the organizational structures reporting to the Director:

Office of Unapproved Drugs and Labeling Compliance (DCDFB).
Division of Unapproved Drugs and Labeling (DCDFBB)
Division of Labeling, Registration, and Unapproved Drugs (DCDFBC)

These organizations report to the Division of Unapproved Drugs and Labeling (DCDFBB).
Fraud Drugs Branch.
Prescription Drugs Branch.

These organizations report to the Division of Labeling, Registration, and Unapproved Drugs (DCDFBC).
Over the Counter Drugs Branch.
Drug Registration and Listing Branch.