**SMG 1262.32**

**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**

**Division of Unapproved Drugs and Labeling**

Effective Date: October 9, 2020

**1. Division of Unapproved Drugs and Labeling (DCDFBB).**

A. Develops and implements compliance strategies, programs and policies to ensure that drugs marketed in the United States meet applicable approval and labeling 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 risk-based surveillance activities relating to unapproved prescription, homeopathic and fraudulent drug products and recommends field inspections and investigations.

D. Coordinates communications with stakeholders, Congress and Federal partners regarding unapproved prescription, homeopathic and fraudulent drug products.

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

**2. Fraud Drugs Branch (DCDFBB2).**

A. Directs, recommends and conducts Center for Drug Evaluation and Research (CDER) risk-based surveillance activities relating to homeopathic

and fraudulent drug products and recommends field inspections and investigations.

B. Directs and/or coordinates compliance strategies, case development and initiates appropriate regulatory and enforcement actions relating to homeopathic and fraudulent drug products and violative firms.

C. Serves as CDER's focal point for the development, coordination, oversight, and implementation of compliance strategies, regulations, guidance and other policy documents involving homeopathic and fraudulent drug products.

D. Reviews and develops legislative proposals, implementing regulations, policy and guidance documents, and outreach activities relating to homeopathic and fraudulent drug products.

E. Conducts stakeholder outreach and communication regarding homeopathic and fraudulent drug products, including threats to public health, new regulations, requirements, and policies to promote voluntary compliance.

**3. Prescription Drugs Branch (DCDFBB3).**

A. Directs, recommends and conducts CDER risk-based surveillance activities relating to unapproved prescription drug products, including labeling requirements, and recommends field inspections and investigations.

B. Directs and/or coordinates compliance strategies, case development and initiates appropriate regulatory and enforcement actions relating to unapproved prescription drug products and violative firms.

C. Serves as CDER's focal point for the development, coordination, oversight, and implementation of compliance strategies, regulations, guidance and other policy documents involving unapproved prescription drug products.

D. Reviews and develops legislative proposals, implementing regulations, policy and guidance documents, and outreach activities relating to unapproved prescription drug products.

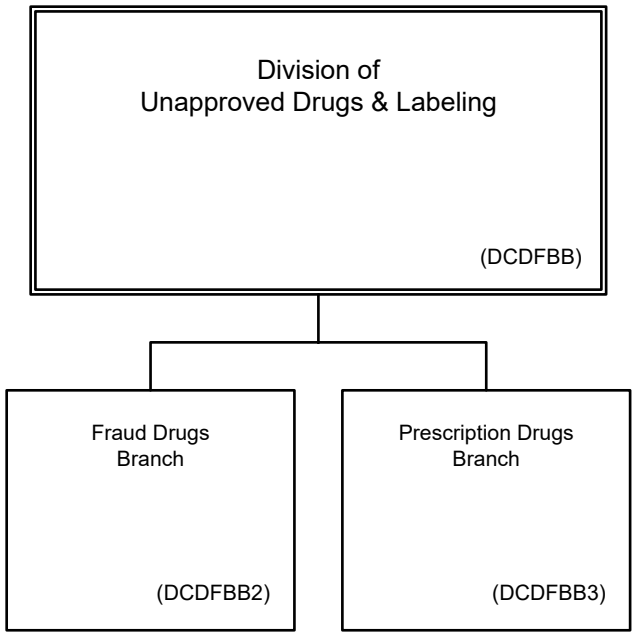
E. Conducts stakeholder outreach and communication regarding unapproved prescription drug products, including threats to public health, new regulations, requirements, and policies to promote voluntary compliance.

F. Conducts comprehensive labeling reviews and makes regulatory status determinations regarding compliance with the Food, Drug and Cosmetic Act.

**4. Authority and Effective Date.**

The functional statements for the Division of Unapproved Drugs and Labeling 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
# Food and Drug Administration
# Center for Drug Evaluation and Research
# Office of Compliance
# Office of Unapproved Drugs and Labeling Compliance
# Division of Unapproved Drugs and Labeling



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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, Division of Unapproved Drugs and Labeling organization structure depicting all the organizational structures reporting to the Director:

Division of Unapproved Drugs and Labeling (DCDFBB).
Fraud Drugs Branch (DCDFBB2).
Prescription Drugs Branch (DCDFBB3).