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 New Drugs

Effective Date: December 14, 2018

1. Division of Unapproved New Drugs (DCDFBB).

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

B. Engages in strategic, risk-based, compliance and regulatory activities to minimize consumer exposure to unsafe or ineffective drug products that do not meet labeling and approval requirements.

2. Over-the-Counter Drugs Branch (DCDFBB1).

A. Directs field inspections and investigations, and recommends, directs and/or coordinates case development, compliance strategies, and regulatory actions relating to unapproved over-the-counter drug products.

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

3. Fraud Drugs Branch (DCDFBB2).

A. Directs field inspections and investigations, and recommends, directs and/or coordinates case development, compliance strategies, and regulatory actions relating to unapproved fraudulent and homeopathic drug products.

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

4. Prescription Drugs Branch (DCDFBB3).

A. Directs field inspections and investigations and recommends, directs and/or coordinates case development, compliance strategies, and regulatory actions relating to unapproved prescription drug products.

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

5. Authority and Effective Date.

The functional statements for the Division Unapproved New Drugs were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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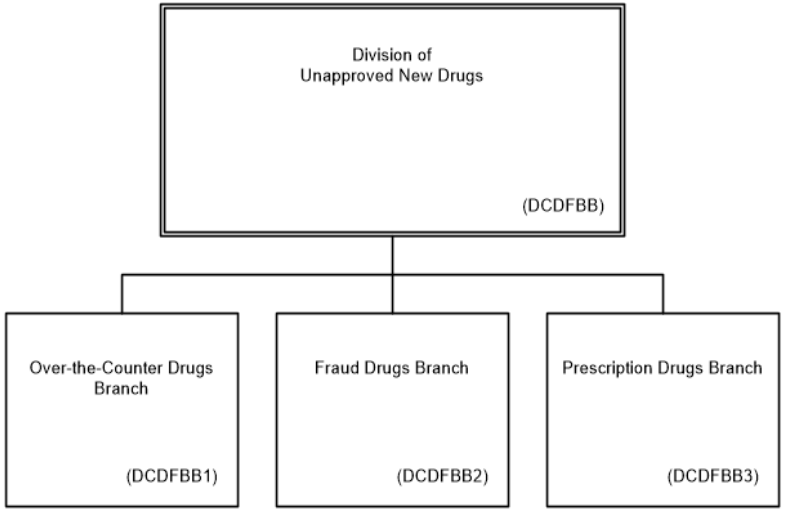

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Unapproved Drugs and Labeling Compliance, Division of Unapproved New Drugs organization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

Division of Unapproved New Drugs (DCDFBB)

These organizations report to the Division of Compounded Drugs:

Over-the-Counter Drugs Branch (DCDFBB1)

Fraud Drugs Branch (DCDFBB2)

Prescription Drugs Branch (DCDFBB3)

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