

**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 Labeling, Registration, and Unapproved Drugs**

Effective Date: October 9, 2020

**1. Division of Labeling, Registration, and Unapproved Drugs (DCDFBC).**

- A. Develops and implements compliance strategies, programs and policies to ensure that drugs marketed in the United States meet applicable 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. Coordinates communications with stakeholders, Congress and Federal partners regarding regulation of over-the-counter drug products and drug registration and listing requirements.
- D. 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.
- E. Manages drug registration and listing database and associated policy issues.

**2. Over-the-Counter Drugs Branch (DCDFBC1).**

- A. Directs, recommends and conducts Center for Drug Evaluation and Research (CDER) risk-based surveillance activities relating to unapproved over-the-counter 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 non-compliant over-the-counter 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 to help ensure the safety and efficacy of over-the-counter (OTC) drug products.
- D. Reviews and develops legislative proposals, implementing regulations, policy and guidance documents, and outreach activities relating to OTC drug products.
- E. Conducts stakeholder outreach and communication on over-the-counter drug product issues, including threats to public health, new regulations, requirements, and policies to promote voluntary compliance.

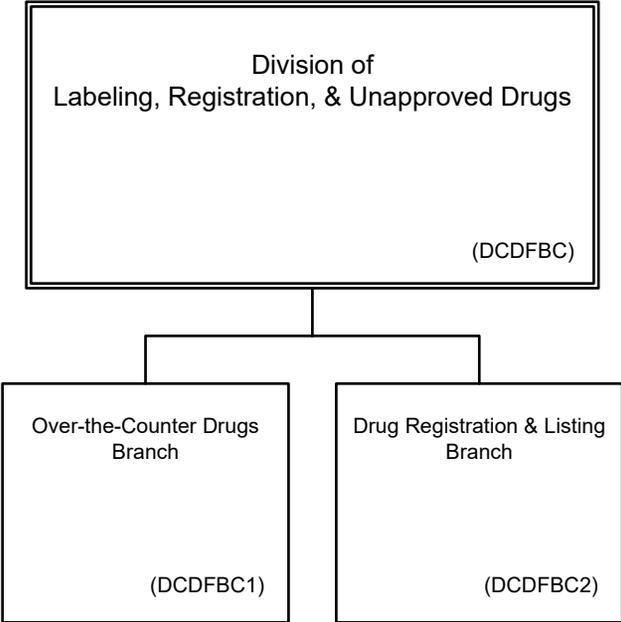
**3. Drug Registration and Listing Branch (DCDFBC2).**

- A. Serve as Food and Drug Administration (FDA) lead for management of drug registration and listing database and associated policy issues.
- B. Assists industry regarding submission of establishment registration and drug product listing data through the management of the electronic drug registration and listing helpdesk.
- C. Publishes the National Drug Code Directory of all finished drug products available in the United States.
- D. Publishes the Drug Establishment Current Registration Site list of all currently registered drug establishments.
- E. Provides drug registration and/or listing support to FDA surveillance programs and other Government Agencies.
- F. Assesses and implements regulatory actions concerning violations of drug registration and listing requirements and facility obligations under the Generic Drug User Fee Amendments of 2012.

**4. Authority and Effective Date.**

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

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

Division of Labeling, Registration, and Unapproved Drugs (DCDFBC).  
Over the Counter Drugs Branch (DCDFBC1).  
Drug Registration and Listing Branch (DCDFBC2).