

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 Drug Security, Integrity, and Response

Division of Global Drug Distribution and Policy

Effective Date: December 14, 2018

1. Division of Global Drug Distribution and Policy (DCDFDA).

- A. Coordinates evaluation and classification of drug recalls and provides Center coordination with field Offices for implementation of recalls, and monitors resolution, and coordinates expert input into related compliance issues.
- B. Serves as the coordinator between the Office of Compliance and the Center for Drug Evaluation and Research Drug Shortage Staff to help avert drug shortages of medically necessary drugs.
- C. Reduces consumer exposure to unsafe, ineffective, and poor quality imported drugs, by developing risk-based policies, assuring compliance with applicable legal requirements and by providing guidance for drug import operations.
- D. Ensures quality exported drugs by providing guidance and consults on export policies and procedures.

2. Recalls and Shortages Branch (DCDFDA1).

- A. Coordinates potential recalls and prompt follow-up activities by including all relevant Agency units, including field Offices.
- B. Obtains technical evaluations on adulteration issues from Office of Manufacturing Quality, and misbranding violations from the Office of Unapproved Drugs and Labeling Compliance.

- C. Convenes committee of experts to create consensus on classification of significant drug recalls, and assures endorsements of involved organizational units.
- D. Provides risk communication on pending or completed recalls to internal and external stakeholders.
- E. Reviews and develops legislative proposals and implementing regulations, policy and guidance documents, enforcement strategies, and outreach activities related to drug recalls.

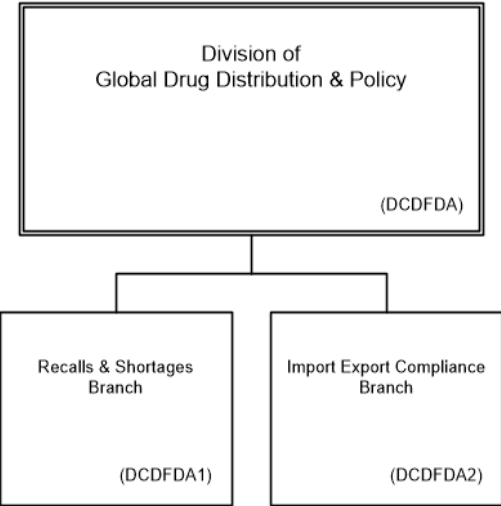
3. Import Export Compliance Branch (DCDFDA2).

- A. Serves as Food and Drug Administration's focal point for all operational compliance issues related to imported and exported drugs.
- B. Consults and provides guidance to the field on import programs and operations for drugs. Assists in ensuring consistent and strategic import activities and compliance programs.
- C. Provides assistance and guidance to the field and consults on import issues and problems related to specific products offered for import.
- D. Coordinates with Office of Regulatory Affairs on policies and programs related to import operations.
- E. Reviews requests for and issues, when appropriate, export certificates.
- F. Develops and provides guidance on export policies and procedures.

4. Authority and Effective Date.

The functional statements for the Division of Global Drug Distribution and Policy were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Drug Security Integrity and Response
Division of Global Drug Distribution and Policy**



Staff Manual Guide 1262.61
Organizations and Functions
Effective Date: December 14, 2018

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 Drug Security Integrity and Response, Division of Global Drug Distribution and Policy organizational structures depicting all the organizational structures reporting to the Director:

Division of Global Drug Distribution and Policy (DCDFDA)

These organizations report to the Division of Global Drug Distribution and Policy:

Recall and Shortages Branch (DCDFDA1)

Import Export Compliance Branch (DCDFDA2)