

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: October 9, 2020

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

- A. Coordinates evaluation and classification of drug recalls and provides the Center for Drug Evaluation and Research (CDER) coordination with field organizations 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 CDER 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. Imports Compliance Branch (DCDFDA3).

- A. Serves as the Food and Drug Administration (FDA) focal point for all operational, compliance, and policy issues related to the import of drugs.
- B. Serves as CDER's focal point for import operations, surveillance, sampling, and work planning.

- C. Consults and provides guidance to the field on import programs and operations for drugs.
- D. Assists in ensuring consistent and strategic import activities and compliance programs.
- E. Provides assistance and guidance to the field and consults on import issues and problems related to specific products offered for import.
- F. Coordinates with the FDA inspection organizations on policies and programs related to import operations.
- G. Request drug firm or drug product shipping history using the Inquiring Office Shipping History Request Form.

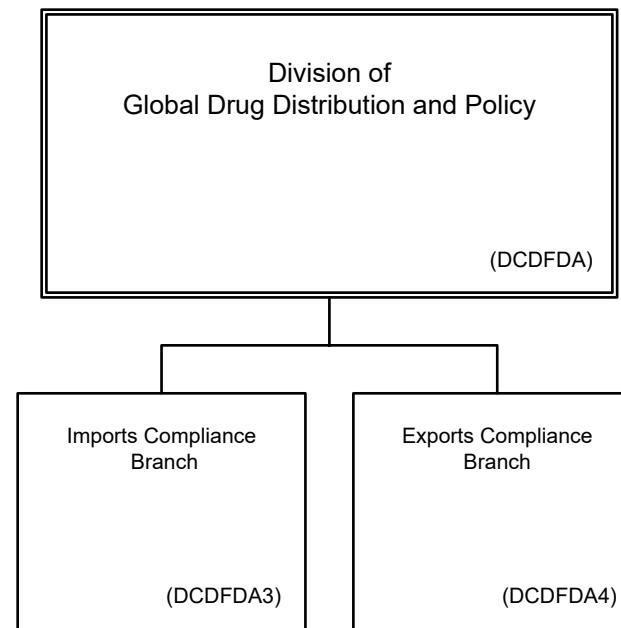
3. Exports Compliance Branch (DCDFDA4).

- A. Serves as FDA's focal point for all operational and compliance issues related to the export of drugs.
- B. Reviews requests for and issues, export certificates, when appropriate.
- C. Develops and provides guidance on drug export policies and procedures.
- D. Provides guidance to the export and international community on the exports program for drugs.
- E. Collaborates with other Center Exports Programs to align on common strategic and compliance activities for exported commodities.
- F. Manages the Exports Compliance Program for CDER.

4. Authority and Effective Date.

The functional statements for the Division of Global Drug Distribution and Policy 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 Drug Security, Integrity, and Response
Division of Global Drug Distribution and Policy**



Staff Manual Guide 1262.61
Organizations and Functions
Effective Date: October 9, 2020

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 organization structure depicting all the organizational structures reporting to the Director:

Division of Global Drug Distribution and Policy (DCDFDA)
Imports Compliance Branch (DCDFDA3)
Exports Compliance Branch (DCDFDA4)