SMG 1262.62

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 Supply Chain Integrity

Effective Date: October 9, 2020

1. Division of Supply Chain Integrity (DCDFDB).

A. Serves as the Food and Drug Administration (FDA) focal point for drug supply chain integrity and security issues and policies including counterfeiting, diversion, intentional adulteration, theft, and other supply chain threats; fostering good distribution practices; and developing and implementing standards for tracking and tracing of prescription drugs in the U.S.

B. Develops and implements compliance strategies, programs and policies to improve the safety and security of the nation's drug supply and ensure that all drugs in distribution and offered for import meet applicable statutory and regulatory requirements.

C. Engages in and supports strategic, risk-based, enforcement activities to minimize consumer exposure to unsafe, ineffective, and poor quality drugs.

D. Develops educational programs to promote compliance with applicable laws and regulations that pertain to drug integrity and security.

E. Coordinates response to incidents that threaten the safety and quality of the nation's drug supply involving counterfeits, unapproved drugs, and manufacturing quality issues, and collaborates closely with other Agency resources to resolve these public health threats.

2. Incidents, Recalls, and Shortages Branch (DCDFDB3).

A. Coordinates potential drug product recalls and prompt follow-up activities by including all relevant Agency units, including field Offices. Reviews firms recall strategies and classifies initiated drug product recalls.

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 ensures endorsements of involved organizational units.

D. Provides risk communications on pending or completed recalls to internal and external stakeholders.

E. Provides central coordination in the Office of Compliance for obtaining and evaluating Health Hazard Evaluations.

F. Reviews and develops legislative proposals and implementing regulations, policy and guidance documents, enforcement strategies, and outreach activities related to drug recalls.

G. Functions as the point of contact for and supports the Drug Shortage Staff (DSS) by coordinating all CDER OC program actions for management of a drug shortage.

H. Receives, evaluates, and disseminates Rapid Alert Notifications (RANs) to various components within the Office of Compliance or other FDA components, as necessary.

I. Coordinates response to incidents that threaten the safety and quality of the nation’s drug supply involving counterfeits, unapproved drugs, and manufacturing quality issues, and collaborates closely with other Agency resources to resolve these public health threats.

3. Supply Chain Security Branch (DCDFDB4).

A. Provides strategic policy direction, planning, and data-driven analytics for the Center for Drug Evaluation and Research (CDER) that addresses drug security and supply chain issues more effectively and efficiently.

B. Serves as CDER's focal point for the development, coordination, oversight, and implementation of compliance strategies, regulations, guidance and other policy documents to ensure the safety and security of the nation's drug supply.

C. Coordinates response to incidents such as counterfeit and unapproved drugs, drug manufacturing quality issues, and drug cargo thefts.

D. Conducts risk-based drug supply chain surveillance activities and initiates appropriate regulatory actions against violative firms.

E. Conducts stakeholder outreach and communication on drug security and supply chain issues, including threats to the supply chain, new regulations, requirements, and policies to promote voluntary compliance.

4. Authority and Effective Date.

The functional statements for the Division of Supply Chain Integrity were approved by the Commissioner of Food and Drugs on September 8, 2020, and effective on October 9, 2020.

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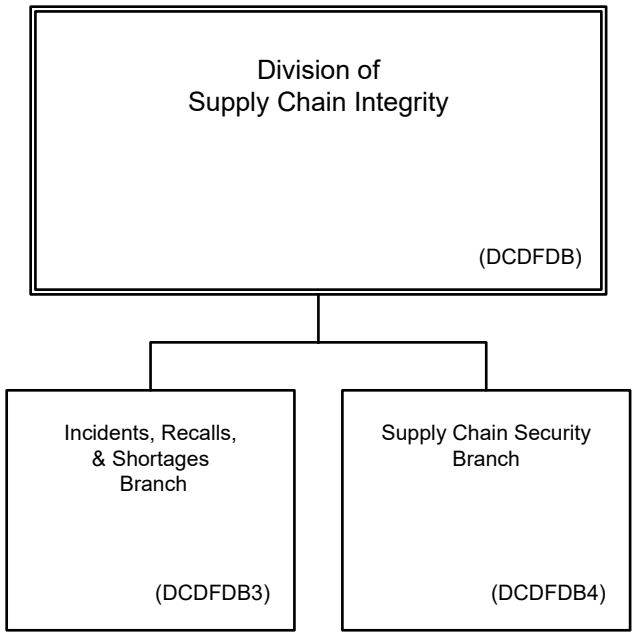

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Drug Security Integrity and Response, Division of Supply Chain Integrity organization structure depicting all the organizational structures reporting to the Director:

Division of Supply Chain Integrity (DCDFDB)
Incidents, Recalls, and Shortages Branch (DCDFDB3)
Supply Chain Security Branch (DCDFDB4)