

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF COMPLIANCE

OFFICE OF DRUG SECURITY, INTEGRITY, AND RESPONSE

DIVISION OF SUPPLY CHAIN INTEGRITY

Effective Date: September 26, 2014

1. DIVISION OF SUPPLY CHAIN INTEGRITY (DKKNDFB).

- 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 United States (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 FDA drug import policies with the Office of Regulatory Affairs (ORA), including the development and institution of joint initiatives with other Federal Agencies and Foreign Governments.
- F. 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. SUPPLY CHAIN STRATEGY AND POLICY BRANCH (DKKNDFB1).

- A. Provides strategic policy direction, planning, and data-driven analysis for CDER to more effectively and efficiently address drug security and supply chain issues.
- B. Serves as CDER's focal point for the development, coordination, oversight, and processing of regulations, guidance and other policy documents related to supply chain integrity, import and export policy, recalls, drug importation, and internet pharmacies.

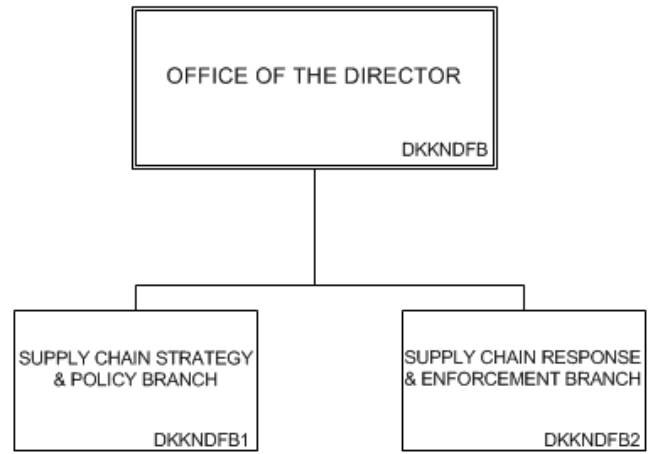
3. SUPPLY CHAIN RESPONSE AND ENFORCEMENT BRANCH (DKKNDFB2).

- A. Serves as FDA focal point at the Center for Drug Evaluation and Research (CDER) for drug supply chain integrity breaches.
- B. Coordinate response to confirmed incidents involving counterfeits, unapproved drugs, manufacturing quality issues, and cargo thefts.
- C. Conducts drug supply chain surveillance activities and initiates appropriate regulatory actions against violative firms.
- D. Conducts industry outreach and communication on drug security and supply chain issues.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, 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.

OFFICE OF THE DIRECTOR – DKKNDFB:

- Supply Chain Strategy & Policy Branch – DKKNDFB1
- Supply Chain Response & Enforcement Branch – DKKNDFB2