SMG 1262.61

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 IMPORTS, EXPORTS AND RECALLS

Effective Date: September 26, 2014

1. DIVISION OF IMPORTS, EXPORTS AND RECALLS (DKKNDFA).

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 (OC) and the Center for Drug Evaluation and Research (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 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 (DKKNDFA1).

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 (OMQ), and misbranding violations from the Office of Unapproved Drugs and Labeling Compliance (OUDLC).

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 (DKKNDFA2).

A. Serves as Food and Drug Administation (FDA) 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 the Office of Regulatory Affairs (ORA) 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 this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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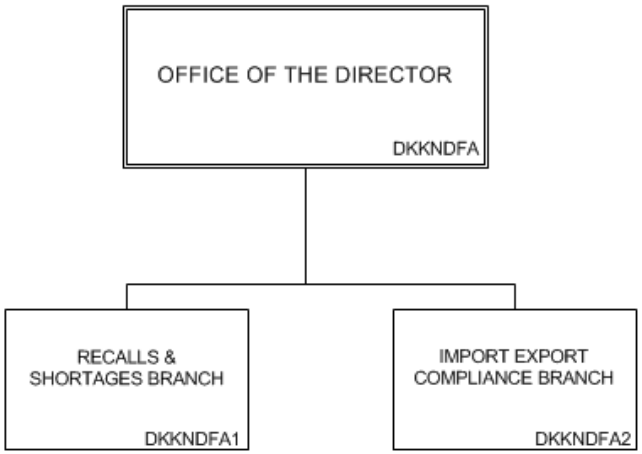

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Compliance, Office of Drug Security, Integrity, and Response, Division of Imports, Exports and Recalls organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNDFA:

- Import Export Compliance Branch – DKKNDFA1

- Recalls & Shortages Branch – DKKNDFA2