SMG 1262.1

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

Effective Date: September 26, 2014

1. OFFICE OF COMPLIANCE (DKKND).

A. Plans, develops, and directs compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply.

B. Proactively advises the Center Director and other Agency officials on Food and Drug Administration's (FDA's) regulatory and enforcement responsibilities and possible risks associated with human drugs.

C. Strategically implements programs and projects to identify, assess, and prioritize the public health significance and patient risk associated with drug quality and safety concerns presented throughout the drug lifecycle.

D. Leads and oversees the development of human drug enforcement and compliance policy and standards.

E. Develops and guides compliance strategies and enforcement actions, and ensures uniform interpretation of standards.

F. Oversees the planning and development of compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply.

G. Executes high-level decisions, monitors performance, and directs strategies and operations of component offices to ensure compliance and enforcement decisions and policies are patient-focused and risk-based.

H. Designs and develops internal procedures and processes to support work quality, and oversight of implementation, monitoring, and continual improvement of the quality system.

2. PROGRAM MANAGEMENT AND ANALYSIS STAFF (DKKND1).

A. Provides leadership, guidance and support services to the Office of Compliance on all aspects of administrative, budget, contracts and provides service and support on human resource, personnel operations services and recruitment activities.

3. AUTHORITY AND EFFECTIVE DATE.

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

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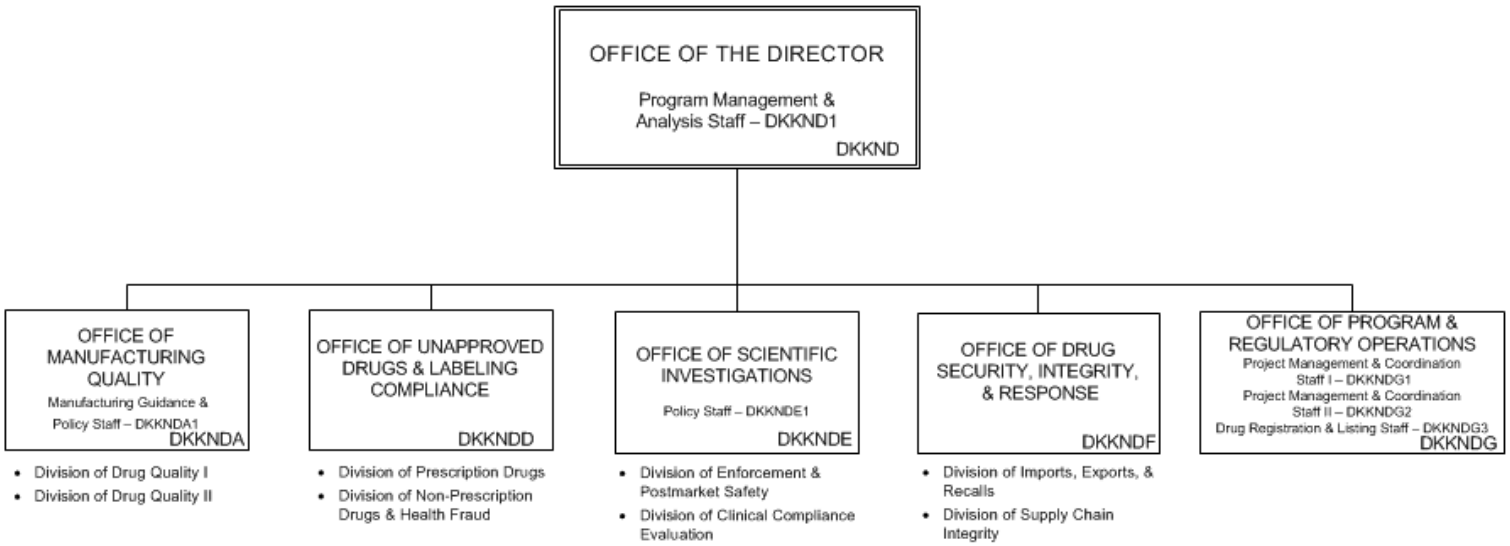

STAFF MANUAL GUIDE 1262.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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

OFFICE OF THE DIRECTOR – DKKND:

- Program Management and Analysis Staff- DKKND1

- OFFICE OF MANUFACTURING QUALITY – DKKNDA
  - Manufacturing Guidance & Policy Staff – DKKNDA1
  - Division of Drug Quality I - DKKNDAE
  - Division of Drug Quality II - DKKNDAF
- OFFICE OF UNAPPROVED DRUGS & LABELING COMPLIANCE – DKKNDD
  - Division of Prescription Drugs - DKKNDDA
  - Division of Non-Prescription Drugs & Health Fraud - DKKNDDB
- OFFICE OF SCIENTIFIC INVESTIGATIONS – DKKNDE
  - Policy Staff – DKKNDE1
  - Division of Enforcement & Postmarket Safety - DKKNDED
  - Division of Clinical Compliance Evaluation - DKKNDEF
- OFFICE OF DRUG SECURITY, INTEGRITY, & RESPONSE – DKKNDF
  - Division of Imports, Exports, & Recalls - DKKNDFA
  - Division of Supply Chain Integrity - DKKNDFB
- OFFICE OF PROGRAM AND REGULATORY OPERATIONS – DKKNDG
  - Project Management & Coordination Staff I – DKKNDG1
  - Project Management & Coordination Staff II – DKKNDG2
  - Drug Registration & Listing Staff – DKKNDG3