**SMG 1262.45**

# 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 MANUFACTURING QUALITY

## DIVISION OF DRUG QUALITY I

Effective Date: September 26, 2014

### 1. DIVISION OF DRUG QUALITY I (DKKNDAE).

A. Leads the Agency's team-based evaluation and assessment of potential compliance and enforcement actions for both application and non-application drugs; provides specialized expertise in drug compounding.

B. Oversees early coordination on compliance inspections and frontloading of cases, and provides guidance and assistance during inspections or investigations relating to deficient manufacturing quality and quality systems.

C. Oversees and monitors remedial actions and metrics for firms which pose significant risk to public health with the aim of achieving sustainable quality.

D. Provides technical support for judicial actions related to application and non-application products.

### 2. GLOBAL COMPLIANCE BRANCH I (DKKNDAE1).

A. Reviews recommendations for potential administrative and judicial actions based on adulteration charges under the Act to ensure consistency and adherence to Agency policy.

B. Provide enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability.

C. Participates with other Agency Offices, Divisions, and districts on compliance issues and in regulatory meetings to ensure consistency of interpretation of Good Manufacturing Practices (GMPs).

D. Provides risk-based expertise in the preparation of “directed” or “for-cause” assignments, and other related inquiries and assignments.

E. Provides expertise to address significant manufacturing problems or quality defects.

F. Collaborates with international regulatory partners to develop and execute compliance programs and actions related to manufacturing quality.

## 3. GLOBAL COMPLIANCE BRANCH II (DKKNDAE2).

A. Reviews recommendations for potential administrative and judicial actions based on adulteration charges under the Act to ensure consistency and adherence to agency policy.

B. Provide enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability.

C. Participates with other Agency Offices, Divisions, and districts on compliance issues and in regulatory meetings to ensure consistency of interpretation of GMPs.

D. Provides risk-based expertise in the preparation of “directed” or “for-cause” assignments, and other related inquiries and assignments.

E. Provides expertise to address significant manufacturing problems or quality defects.

F. Collaborates with international regulatory partners to develop and execute compliance programs and actions related to manufacturing quality.

## 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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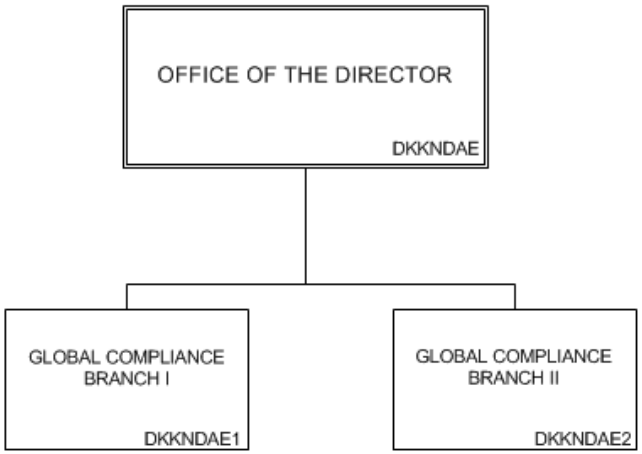
# **DIVISION OF DRUG QUALITY I**



STAFF MANUAL GUIDE 1262.45
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, Office of Manufacturing Quality, Division of Drug Quality I organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNDE:

- Global Compliance Branch I – DKKNDE1

- Global Compliance Branch II – DKKNDE2