SMG 1262.45

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 Manufacturing Quality

Division of Drug Quality I

Effective Date: December 14, 2018

1. Division of Drug Quality I (DCDFAA).

A. Leads the Food and Drug Administration'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 1 (DCDFAA1).

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

C. Collaborates with other Food and Drug Administration's 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 2 (DCDFAA2).

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

C. Participates with other Food and Drug Administration's 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.

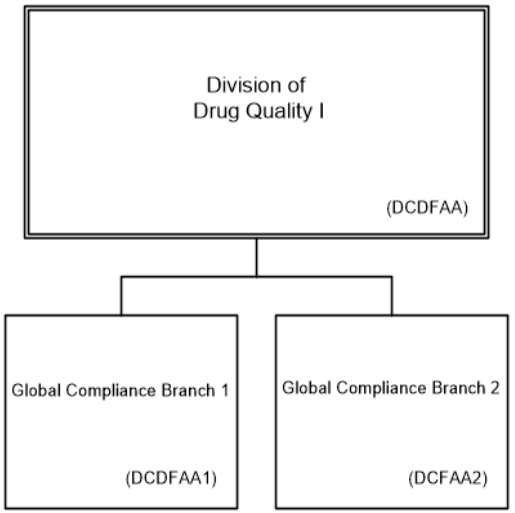
E. E. Provides expertise to address significant manufacturing problems or quality defects.

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 the Division of Drug Quality I were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Manufacturing Quality
Division of Drug Quality I



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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 Manufacturing Quality, Division of Drug Quality I organization structure depicting all the organizational structures reporting to the Director.

Division of Drug Quality I (DCDFAA)

These organizations report to the Division of Drug Quality I:

Global Compliance Branch 1 (DCDFAA1)

Global Compliance Branch 2 (DCDFAA2)

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