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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 III

Effective Date: May 13, 2024

1. Division of Drug Quality III (DCDFAD).

A. Develops and implements compliance and enforcement strategies and programs, that minimize patient exposure to unsafe, ineffective, and poor-quality drug products.

B. Reviews recommendations or initiates regulatory or judicial actions, based on the Food and Drug Administration's (FDA) evidence collected from various sources based on adulteration charges under the Food and Drug & Cosmetic (FD&C) Act, to ensure consistency and adherence to FDA policy for both application and non-application drugs. Advises the Center on Current Good Manufacturing Practices (CGMP) issues related to inspections, and compliance matters related to drug adulteration provisions.

C. Provides oversight and direction on the evaluation and assessment of potential compliance, enforcement, and discretionary actions for both application and non-application drugs.

D. Oversees the scientific assessment and evaluation of compliance inspections and inspectional findings. Provides guidance and assistance throughout the inspection process on investigations related to deficient drug manufacturing quality and quality systems.

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

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

G. Participates with other FDA Offices, Divisions, and districts on compliance issues and in regulatory meetings to ensure consistency of interpretation of CGMPs.

H. Provides risk-based expertise in the preparation of directed or for-cause inspection or sample collection assignments, significant manufacturing problems or quality defects, and other related inquiries and assignments.

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

2. Authority and Effective Date.

The functional statements for the Division of Drug Quality III were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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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 III organization structure depicting all the organizational structures reporting to the Director: