SMG 1280.51

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 Pharmaceutical Quality

Office of Pharmaceutical Manufacturing Assessment

Division of Pharmaceutical Manufacturing Assessment I

Effective Date: October 10, 2023

1. Division of Pharmaceutical Manufacturing Assessment I (DCDLDA).

A. Conducts science and risk-based assessment of pharmaceutical manufacturing, including processes, facilities, microbial controls, and sterility assurance for Investigational New Drug Applications (INDs); Biologic License Applications (BLAs); New Drug Applications (NDAs); Abbreviated New Drug Applications (ANDAs); supplemental NDAs, ANDAs, BLAs; Drug Master Files (DMF), and other quality-related regulatory submissions throughout the product lifecycle.

B. Conveys recommendations on pharmaceutical manufacturing-specific risks identified throughout the product lifecycle (including post-approval change management) to appropriate stakeholders within the Office of Pharmaceutical Quality (OPQ), the Center for Drug Evaluation and Research (CDER), the Food and Drug Administration (FDA), and industry.

C. Serves as a liaison and resource to OPQ, CDER, and FDA organizations and external entities on aspects of pharmaceutical manufacturing, inspection, and product quality.

D. Leads and/or participates in inspections for BLAs, NDAs, ANDAs, and their supplements using science and risk-based approaches to support pharmaceutical manufacturing assessment of regulatory submissions.

E. Participates in coordination with other organizations in OPQ, CDER, and the FDA in scientific investigations as needed to evaluate and assess any drug

product quality problems that arise from pharmaceutical manufacturing processes, facilities, and microbiology quality aspects for compliance with applicable standards.

F. Provides subject matter expertise in the development of policies, guidance, procedures, surveillance, and research supporting the evaluation of product quality, pharmaceutical manufacturing, and inspection for CDER regulated products.

2. Authority and Effective Date.

The functional statements for the Division of Pharmaceutical Manufacturing Assessment I were approved by the Secretary of Health and Human Services on August 10, 2023, and effective on October 10, 2023.

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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 Pharmaceutical Quality, Office of Pharmaceutical Manufacturing Assessment, Division of Pharmaceutical Manufacturing Assessment I organization structure depicting all the organizational structures reporting to the Director:

Division of Pharmaceutical Manufacturing Assessment I (DCDLDA)