SMG 1280.42

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 Policy for Pharmaceutical Quality

Division of Internal Policy and Communication

Effective Date: October 10, 2023

1. Division of Internal Policy and Communication (DCDLCB).

A. Leads and coordinates the development and lifecycle management of internal policy documents related to pharmaceutical quality for the Center for Drug Evaluation and Research (CDER) regulated products, such as policies related to submissions or applications and manufacturing establishments. This includes the management of Manuals of Policies and Procedures (MAPPs) and Compliance Programs, with input from subject matter experts across the Office of Pharmaceutical Quality (OPQ), CDER, and, as appropriate, the Food and Drug Administration (FDA) inspections and investigations organizational entity, and other FDA Centers and Offices. This also includes the coordination across OPQ, and, as appropriate FDA Centers and Offices on internal outreach and training on new and revised internal policy documents to ensure consistent interpretation and application of policies.

B. Evaluates, routinely and collaboratively, existing internal policies, standards, and programs to determine whether they meet their intended objectives and are followed by OPQ staff and business partners including other FDA organizations. This includes assessing CDER communications related to quality issues, such as integrated quality assessments and letters to sponsors/applicants, Form FDA 483s, and establishment inspection reports, for conformance to OPQ polices. Revises the existing documents and/or training/outreach for such documents, as applicable.

C. Analyzes and provides recommendations on policies relating to novel, controversial, or precedent-setting pharmaceutical quality issues, such as those identified through communications, submission or application assessment, or manufacturing establishment inspections and related information.

D. Leads the development of OPQ responses to controlled correspondence and other inquiries from external stakeholders, and coordinates product quality outreach to, and communications from, OPQ staff and business partners.

E. Coordinates the review and clearance of non-OPQ-led internal policy documents, including MAPPs, on behalf of OPQ.

2. Authority and Effective Date.

The functional statements for the Division of Internal Policy and Communication 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 Policy for Pharmaceutical Quality, Division of Internal Policies and Communication organization structure depicting all the organizational structures reporting to the Director:

Division of Internal Policies and Communication (DCDLCB)