SMG 1280.41

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administrations

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Policy for Pharmaceutical Quality

Division of Regulations, Guidance & Standards

Effective Date: September 25, 2019

1. Division of Regulations, Guidance & Standards (DCDLCA).

A. Leads and coordinates development of new regulations and guidance regarding the submission of investigational new drug applications and marketing applications, and to promote consistent production of high-quality drug components and drug products and conformance with pharmaceutical quality policies, like the Current Good Manufacturing Practices regulations, by regulated industry.

B. Evaluates, routinely and collaboratively, existing regulations and guidance to determine whether they meet their intended objectives. Revises the existing documents and/or training/outreach for documents, as applicable.

C. Analyzes and provides recommendations on policy relating to novel, controversial, or precedent-setting issues related to pharmaceutical quality.

D. Leads the development of responses to quality-related issues in Citizen Petitions through collaboration with other Office of Pharmaceutical Quality (OPQ) sub-offices and Center for Drug Evaluation and Research (CDER), Office of Regulatory Policy.

2. Policy Development & Evaluation Branch 1 (DCDLCA1).

A. Leads and coordinates development of new regulations and guidance related to pharmaceutical quality information submitted in applications with input from subject matter experts across OPQ, CDER, and, as appropriate, Office of

Regulatory Affairs (ORA) and other Centers/Offices throughout the Food and Drug Administration (FDA).

B. Assesses, routinely, existing regulations and guidance's to determine whether revisions are needed to improve effectiveness or implementation, reflect the most recently available scientific information, or incorporate information learned from application assessment or establishment inspections.

C. Leads and coordinates efforts to revise existing regulations and guidance, as applicable, with input from subject matter experts across OPQ, CDER, and, as appropriate, ORA and other Centers/Offices throughout the FDA.

D. Coordinates product quality outreach to and communications from external stakeholders and actively solicits feedback from internal stakeholders to ensure consistent interpretation and application of external-facing pharmaceutical quality policies and programs.

E. Coordinates the review and clearance of non-OPQ-led regulations and guidance on behalf of OPQ.

3. Policy Development & Evaluation Branch 2 (DCDLCA2).

A. Leads and coordinates development of new regulations and guidance related to pharmaceutical quality requirements that are also assessed during inspection of manufacturing establishments, including non-application drug manufacturers, with input from subject matter experts across OPQ, CDER, and, as appropriate, ORA and other Centers/Offices throughout the FDA.

B. Assesses, routinely, existing regulations and guidance to determine whether revisions are needed to improve effectiveness or implementation, reflect the most recently available scientific information, or incorporate information from application assessment/or establishment inspections.

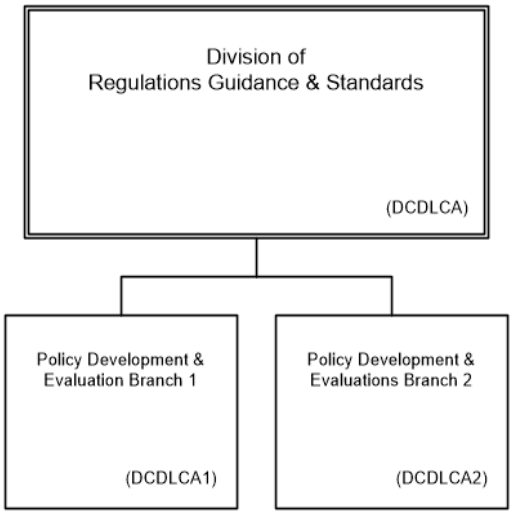
C. Leads and coordinates efforts to revise existing regulations and guidance, as applicable, with input from subject matter experts across OPQ, CDER, and, as appropriate, ORA and other Centers/Offices throughout the FDA.

D. Coordinates product quality outreach to and communications from external stakeholders and actively solicits feedback from internal stakeholders to ensure consistent interpretation and application of external-facing pharmaceutical quality policies and programs.

5. Authority and Effective Date.

The functional statements for the Division of Regulations, Guidance & Standards were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Policy For Pharmaceutical Quality
Division of Regulation Guidance & Standards



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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 Regulations Guidance & Standards organizational structures depicting all the organizational structures reporting to the Director.

Division of Regulations Guidance & Standards (DCDLCA).

These organizations report to the Division of Regulations Guidance & Standards:

Policy Development & Evaluation Branch 1 (DCDLCA1)

Policy Development & Evaluation Branch 2 (DCDLCA2)

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