SMG 1280.91

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 Science

Office of Lifecycle Drug Products

Division of Immediate & Modified Release Products I

Effective Date: September 25, 2019

1. Division of Immediate & Modified Release Products I (DCDLHA).

A. Manages the overall program responsibilities for the Divison, primarily assessments and establishment of adequacy for the drug product sections of original Abbreviated New Drug Applications (ANDAs).

B. Provides direction, clarification, and interpretation on policy and technical issues for the division.

C. Monitors the lifecycle of both innovator and generic drugs.

2. Immediate & Modified Release Branch 1 (DCDLHA1).

A. Perform assessments for the drug product sections of original ANDAs and associated amendments using a risk-based approach to determine scientific adequacy and regulatory compliance.

B. Collaborate with other offices within the Office of Pharmaceutical Quality (OPQ) to prepare Integrated Quality Assessments and Executive Summaries for submission to the Office of Generic Drug (OGD) establishing the adequacy of ANDAs.

C. Monitors the lifecycle of both innovator and generic drugs through team-based assessments and collaboration with offices throughout the Center for Drug Evaluation and Research (CDER).

D. Serve as an information resource for other offices within OPQ and CDER regarding generic drug products for resolution of non-assessment functions such

as Controlled Correspondences, Application Reconsiderations, and Dispute Resolutions.

3. Immediate & Modified Release Branch 2 (DCDLHA2).

A. Perform assessments for the drug product sections of original ANDAs and associated amendments using a risk-based approach to determine scientific adequacy and regulatory compliance.

B. Collaborate with other offices within the OPQ to prepare Integrated Quality Assessments and Executive Summaries for submission to the OGD establishing the adequacy of ANDAs.

C. Monitors the lifecycle of both innovator and generic drugs through team-based assessments and collaboration with offices throughout the CDER.

D. Serve as an information resource for other offices within OPQ and CDER regarding generic drug products for resolution of non-assessment functions such as Controlled Correspondences, Application Reconsiderations, and Dispute Resolutions.

4. Immediate & Modified Release Branch 3 (DCDLHA3).

A. Perform assessments for the drug product sections of original ANDAs and associated amendments using a risk-based approach to determine scientific adequacy and regulatory compliance.

B. Collaborate with other offices within the OPQ to prepare Integrated Quality Assessments and Executive Summaries for submission to the OGD establishing the adequacy of ANDAs.

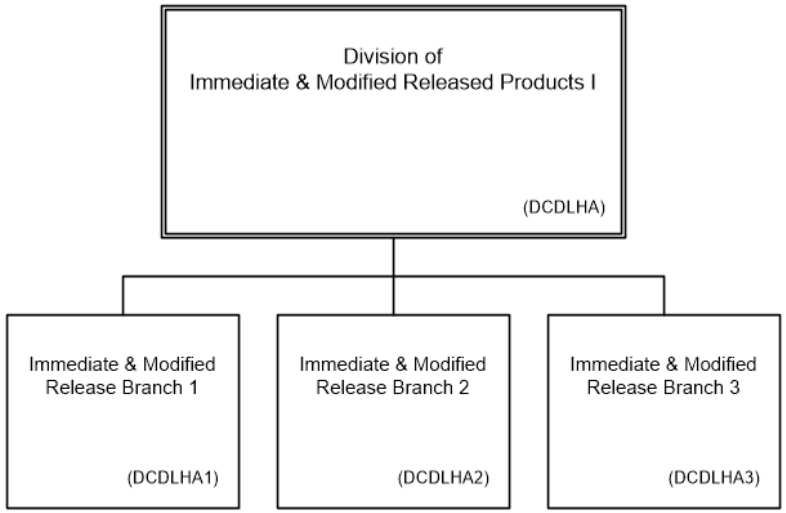
C. Monitors the lifecycle of both innovator and generic drugs through team-based assessments and collaboration with offices throughout the Drug Evaluation and Research (CDER).

D. Serve as an information resource for other offices within OPQ and CDER regarding generic drug products for resolution of non-assessment functions such as Controlled Correspondences, Application Reconsiderations, and Dispute Resolutions.

5. Authority and Effective Date.

The functional statements for the Division of Immediate and Modified Release Products I 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 Pharmaceutical Quality
Office of Lifecycle Drug Products
Division of Immediate & Modified Release Products 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 Pharmaceutical Quality, Office of Lifecycle Drug Products, Division of Immediate Release I organizational structures depicting all the organizational structures reporting to the Director.

Division of Immediate Release I (DCDLHA).

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