SMG 1280.31

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 New Drug Products

Division of Life Cycle API

Effective Date: September 25, 2019

1. Division of Life Cycle API (DCDLBA).

A. Participates in team-based, cross-office collaborative evaluation and assessment of API information supporting new Abbreviated New Drug Applications (ANDAs), New Drug Applications (NDAs) and ANDA supplements, and makes risk-informed recommendations on adequacy to support such submissions.

B. Serves as a liaison to other Offices within Office of Pharmaceutical (OPQ) and will work collaboratively to conduct review of applications and will participate in inspections as needed.

C. Works collaboratively with the Division of New Drug API to ensure consistent review policies are applied to API information supporting Investigational New Drug Applications (INDs), NDAs, and ANDAs.

2. Life Cycle Branch 1 (DCDLBA1).

A. Performs assessment of API information included in ANDA submissions directly or by reference to a Type II Drug Master File (DMF) to meet Generic Drug User Fee Act (GDUFA) goals.

B. Performs assessment of API information included in supplemental NDA and ANDA submissions directly or by reference to a Type II DMF.

C. Performs GDUFA Completeness Assessments for Type II DMFs.

D. Provides support for industry meeting packages for ANDAs.

E. Provides industry meeting package support, when requested by the Division of New Drug API, to meet Prescription Drug User Fee Act (PDUFA) goals associated with NDA and IND submissions.

3. Life Cycle Branch 2 (DCDLBA2).

A. Performs assessment of API information included in ANDA submissions directly or by reference to a Type II DMF to meet GDUFA goals.

B. Performs assessment of API information included in supplemental NDA and ANDA submissions directly or by reference to a Type II DMF.

C. Performs GDUFA Completeness Assessments for Type II DMFs.

D. Provides support for industry meeting packages for ANDAs.

E. Provides industry meeting package support, when requested by the Division of New Drug API, to meet PDUFA goals associated with NDA and IND submissions.

4. Life Cycle Branch 3 (DCDLBA3).

A. Performs assessment of API information included in ANDA submissions directly or by reference to a Type II DMF to meet GDUFA goals.

B. Performs assessment of API information included in supplemental NDA and ANDA submissions directly or by reference to a Type II DMF.

C. Performs GDUFA Completeness Assessments for Type II DMFs.

D. Provides support for industry meeting packages for ANDAs.

E. Provides industry meeting package support, when requested by the Division of New Drug API, to meet PDUFA goals associated with NDA and IND submissions.

5. Authority and Effective Date.

The functional statements for the Division of Life Cycle API 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
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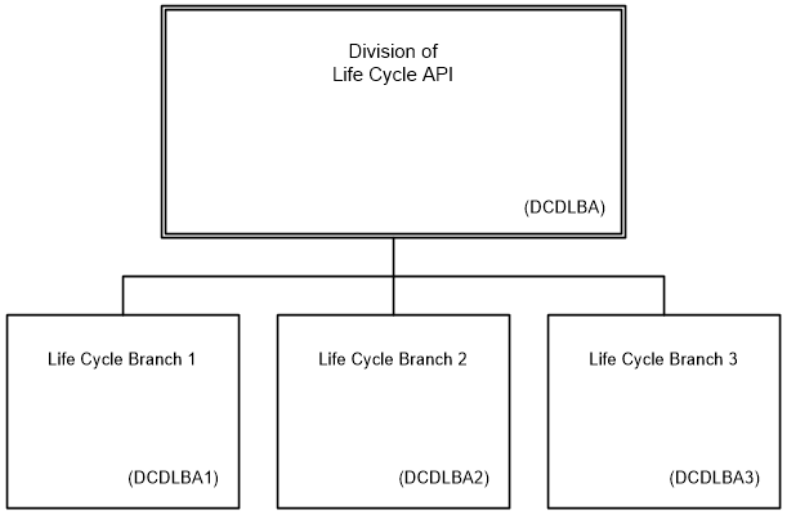

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of New Drug Products, Division of Life Cycle API organizational structures depicting all the organizational structures reporting to the Director.

Division of Life Cycle API (DCDLBA).

These organizations report to the Division of Life Cycle API:

Life Cycle Branch 1 (DCDLBA1)

Life Cycle Branch 2 (DCDLBA2)

Life Cycle Branch 3 (DCDLBA3)

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