SMG 1280.32

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

Division of New Drug API

Effective Date: September 25, 2019

1. Division of New Drug API (DCDLBB).

A. Participates in team-based, cross-office collaborative evaluation and assessment of API information supporting industry meeting packages, New Drug Applications (NDAs), Investigational New Drug Applications (INDs), and makes risk-informed recommendations on adequacy to support such submissions.

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

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

2. New Drug Branch 1 (DCDLBB1).

A. Evaluates all API related information included in NDAs, INDs and meeting packages directly or by reference to a Type II Drug Master File (DMF) to meet Prescription Drug User Fee Act (PDUFA) goals.

B. Utilizes risk-based approach to assess the API related Chemistry, Manufacturing and Controls (CMC) information convey risk-informed recommendations on the approvability of API and communicate API-specific residual risk identified in the pre-marketing area to appropriate Office of New Drugs (OND) stakeholders and other offices within OPQ.

C. Provides industry meeting package support, when requested by the Division of Lifecycle API, to meet Generic Drug User Fee Act (GDUFA) goals associated with ANDA submissions.

3. New Drug Branch 2 (DCDLB2).

A. Evaluates all API related information included in NDAs, INDs and meeting packages directly or by reference to a Type II DMF to meet PDUFA goals.

B. Utilizes risk-based approach to assess the API related CMC information convey risk-informed recommendations on the approvability of API and communicate API-specific residual risk identified in the pre-marketing area to appropriate stakeholders (OND, other offices within OPQ).

C. Provides industry meeting package support, when requested by the Division of Lifecycle API, to meet GDUFA goals associated with ANDA submissions.

4. New Drug Branch 3 (DCDLBB3).

A. Evaluates all API related information included in NDAs, INDs and meeting packages directly or by reference to a Type II DMF to meet PDUFA goals.

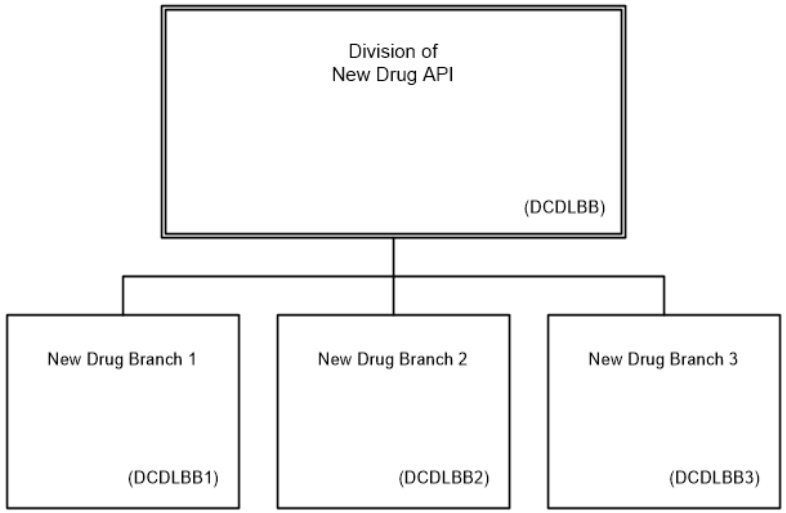
B. Utilizes risk-based approach to assess the API related CMC information convey risk-informed recommendations on the approvability of API and communicate API-specific residual risk identified in the pre-marketing area to appropriate stakeholders (OND, other offices within OPQ).

C. Provides industry meeting package support, when requested by the Division of Lifecycle API, to meet GDUFA goals associated with ANDA submissions.

5. Authority and Effective Date.

The functional statements for the Division of New Drug 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
Office of Pharmaceutical Quality
Office of New Drug Products
Division of New Drug API



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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 New Drug API organizational structures depicting all the organizational structures reporting to the Director.

Division of New Drug API (DCDLB).

These organizations report to the Division of New Drug API:

New Drug Branch 1 (DCDLBB1)

New Drug Branch 2 (DCDLBB2)

New Drug Branch 3 (DCDLBB3)

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