SMG 1280.31

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF PHARMACEUTICAL QUALITY

OFFICE OF NEW DRUG PRODUCTS

DIVISION OF LIFE CYCLE API

Effective Date: September 26, 2014

1. DIVISION OF LIFE CYCLE API (DKKNVBA).

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 I (DKKNVBA1).

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 support, when requested by Division of New Drug API, for industry meeting packages, NDAs and INDs to meet Prescription Drug User Fee Act (PDUFA) goals.

3. LIFE CYCLE BRANCH II (DKKNVBA2).

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 support, when requested by Division of New Drug API, for industry meeting packages, NDAs and INDs to meet PDUFA goals.

4. LIFE CYCLE BRANCH III (DKKNVBA3).

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 support, when requested by Division of New Drug API, for industry meeting packages, NDAs and INDs to meet PDUFA goals.

5. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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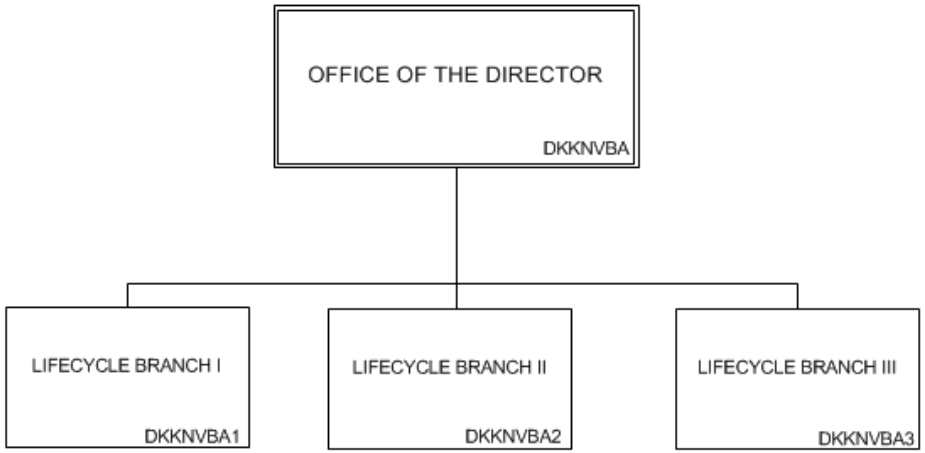
DIVISION OF LIFECYCLE API



STAFF MANUAL GUIDE 1280.31
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of New Drug Products, Division of Lifecycle API organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVBA:

- Life Cycle Branch I – DKKNVBA1
- Life Cycle Branch II – DKKNVBA2
- Life Cycle Branch III – DKKNVBA3