SMG 1280.32

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

DIVISION OF NEW DRUG API

Effective Date: September 26, 2014

1. DIVISION OF NEW DRUG API (DKKNVBB).

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 to ensure consistent review policies are applied to API information supporting INDs, NDAs, and Abbreviated New Drug Applications (ANDAs).

2. NEW DRUG BRANCH I (DKKNVBB1).

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 stakeholders Office of New Drugs (OND), other offices within OPQ.

C. Provides support, when requested by Division of Life Cycle API, for industry meeting packages and ANDAs Generic Drug User Fee Act (GDUFA) goals.

3. NEW DRUG BRANCH II (DKKNVBB2).

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.

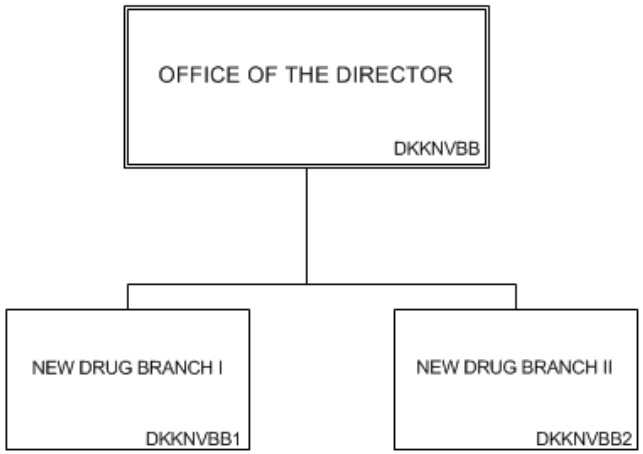
B. Utilizes risk based approach to assess the API related CMC information convey risk-informed recommendations on the approvability of API, and communicate API-specific residual risk identified in the pre-marketing area to appropriate stakeholders (OND, other offices within OPQ).

C. Provides support, when requested by Division of Life Cycle API, for industry meeting packages and ANDAs GDUFA goals.

4. 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.

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 NEW DRUG API



STAFF MANUAL GUIDE 1280.32
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 New Drug API organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVBB:

- New Drug Branch I – DKKNVBB1
- New Drug Branch II – DKKNVBB2