

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 NEW DRUG PRODUCTS I

Effective Date: September 26, 2014

1. DIVISION OF NEW DRUG PRODUCTS I (DKKNVBC).

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

2. NEW DRUG PRODUCTS BRANCH I (DKKNVBC1).

- A. Participates in team-based, cross-office collaborative evaluation and assessment of drug product information supporting industry meeting packages, NDAs, INDs, in conjunction with the associated clinical divisions.
- B. Makes risk-informed recommendations on these submissions.

3. NEW DRUG PRODUCTS BRANCH II (DKKNVBC2).

- A. Participates in team-based, cross-office collaborative evaluation and assessment of drug product information supporting industry meeting packages, NDAs, INDs, in conjunction with the associated clinical divisions.
- B. Makes risk-informed recommendations on these submissions.

4. NEW DRUG PRODUCTS BRANCH III (DKKNVBC3).

- A. Participates in team-based, cross-office collaborative evaluation and assessment of drug product information supporting industry meeting packages, NDAs, INDs, in conjunction with the associated clinical divisions.

B. Makes risk-informed recommendations on these submissions.

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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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 Products I organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVBC:

- New Drug Products Branch I – DKKNVBC1
- New Drug Products Branch II – DKKNVBC2
- New Drug Products Branch III – DKKNVBC3