

**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 II**

Effective Date: September 26, 2014

**1. DIVISION OF NEW DRUG PRODUCTS II (DKKNVBD).**

- 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 IV (DKKNVBD1).**

- 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 V (DKKNVBD2).**

- 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 VI (DKKNVBD3).**

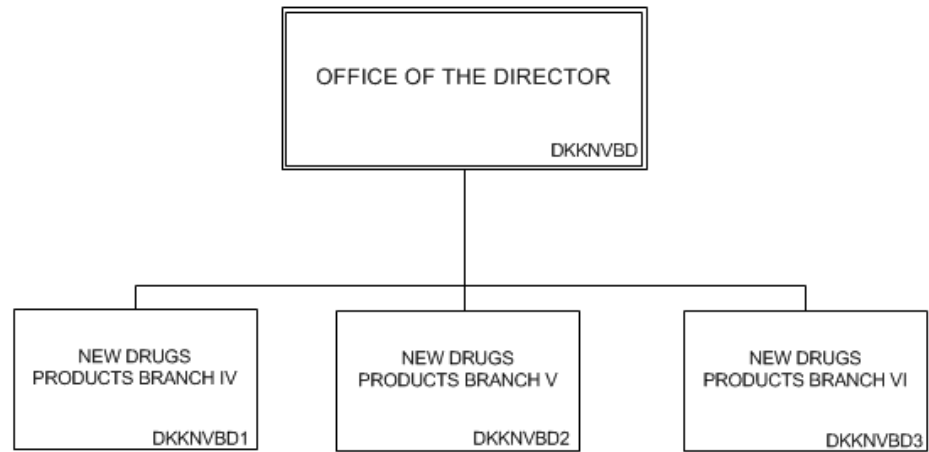
- A. Participates in team-based, cross-office collaborative evaluation and assessment of drug product information supporting industry meeting packages, NDAs, INDs, in conjunction with the associated clinical divisions.

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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**DIVISION OF NEW DRUG PRODUCTS II**



STAFF MANUAL GUIDE 1280.34  
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 II organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVBD:

- New Drug Products Branch IV – DKKNVBD1
- New Drug Products Branch V – DKKNVBD2
- New Drug Products Branch VI – DKKNVBD3