

**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 BIOPHARMACEUTICS**

Effective Date: September 26, 2014

**1. DIVISION OF BIOPHARMACEUTICS (DKKNVBE).**

- A. Conducts evaluation and assessment of relevant biopharmaceutics information for Investigational New Drug Applications (INDs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), supplemental New Drug Applications (sNDAs), and supplemental Abbreviated New Drug Applications (sANDAs), and makes risk-informed recommendations on the approvability of such products to stakeholders.

**2. BIOPHARMACEUTICS BRANCH I (DKKNVBE1).**

- A. Evaluates biopharmaceutics-related information to support assessment of Investigational New Drug Applications (INDs) as needed.
- B. Evaluates biopharmaceutics-related information to support quality recommendations for New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), supplemental New Drug Applications (sNDAs) and supplemental Abbreviated New Drug Applications (sANDAs) as needed.

**3. BIOPHARMACEUTICS BRANCH II (DKKNVBE2).**

- A. Evaluates biopharmaceutics-related information to support assessment of Investigational New Drug Applications (INDs) as needed.
- B. Evaluates biopharmaceutics-related information to support quality recommendations for New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), supplemental New Drug Applications (sNDAs) and supplemental Abbreviated New Drug Applications (sANDAs) as needed.

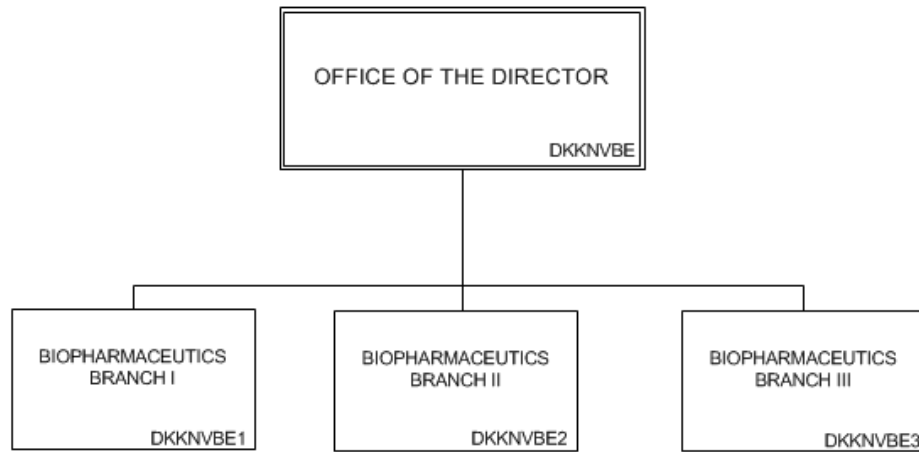
**4. BIOPHARMACEUTICS BRANCH III (DKKNVBE3).**

- A. Evaluates biopharmaceutics-related information to support assessment of Investigational New Drug Applications (INDs) as needed.
- B. Evaluates biopharmaceutics-related information to support quality recommendations for New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), supplemental New Drug Applications (sNDAs) and supplemental Abbreviated New Drug Applications (sANDAs) as needed.

**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.

FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATION AND RESEARCH  
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**DIVISION OF BIOPHARMACEUTICS**



STAFF MANUAL GUIDE 1280.35  
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 Biopharmaceutics organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVBE:

- Biopharmaceutics Branch I – DKKNVBE1
- Biopharmaceutics Branch II – DKKNVBE2
- Biopharmaceutics Branch III – DKKNVBE3