

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 PROCESS AND FACILITIES

DIVISION OF PROCESS ASSESSMENT II

Effective Date: September 26, 2014

1. DIVISION OF PROCESS ASSESSMENT II (DKKNVDB).

- A. Oversees the scientific review and evaluation of Investigational New Drug applications (IND) New Drug applications (NDA), Abbreviated New Drug applications (ANDA) and supplemental New Drug applications (NDA), and Abbreviated New Drug applications (ANDA) assigned to division, including immediate and modified release dosage forms including tablets, capsules, and inhalation, transdermal and implantable drug-device products.
- B. Advises the Center for Drug Evaluation and Research (CDER) and Office of Pharmaceutical Quality (OPQ) on scientific and regulatory issues associated with manufacturing of modified release dosage forms, and inhalation, transdermal and implantable drug-device products.

2. PROCESS ASSESSMENT BRANCH IV (DKKNVDB1).

- A. Assesses the suitability of manufacturing process data in IND, NDA, and ANDA and supplemental NDA and ANDA.
- B. Assesses the suitability of microbiological data in IND, NDA, and ANDA and supplemental NDA and ANDA for products with a lower risk of microbial contamination.
- C. Assesses the acceptability of manufacturing facilities for lower risk facilities, through evaluation of facility and pre-approval inspection related documentation.
- D. Participates in or leads pre-approval inspections for NDA, ANDA and supplements, as merited.

E. Uses risk-based approach, communicates issues with review and inspection related application team members.

F. Provides clear risk-based recommendation on assessment related activities.

3. PROCESS ASSESSMENT BRANCH V (DKKNVDB2).

A. Assesses the suitability of manufacturing process data in IND, NDA, and ANDA and supplemental NDA, and ANDA.

B. Assesses the suitability of microbiological data in IND, NDA, and ANDA and supplemental NDAs and ANDAs for products with a lower risk of microbial contamination.

C. Assesses the acceptability of manufacturing facilities for lower risk facilities, through evaluation of facility and pre-approval inspection related documentation.

D. Participates in or leads pre-approval inspections for NDA, ANDA and supplements, as merited.

E. Uses risk-based approach, communicates issues with review and inspection related application team members.

F. Provides clear risk-based recommendation on assessment related activities.

4. PROCESS ASSESSMENT BRANCH VI (DKKNVDB3).

A. Assesses the suitability of manufacturing process data in IND, NDA, ANDA and supplemental NDA and ANDA.

B. Assesses the suitability of microbiological data in IND, NDA, ANDA and supplemental NDA and ANDA for products with a lower risk of microbial contamination.

C. Assesses the acceptability of manufacturing facilities for lower risk facilities, through evaluation of facility and pre-approval inspection related documentation.

D. Participates in or leads pre-approval inspections for NDA, ANDA, and supplements, as merited.

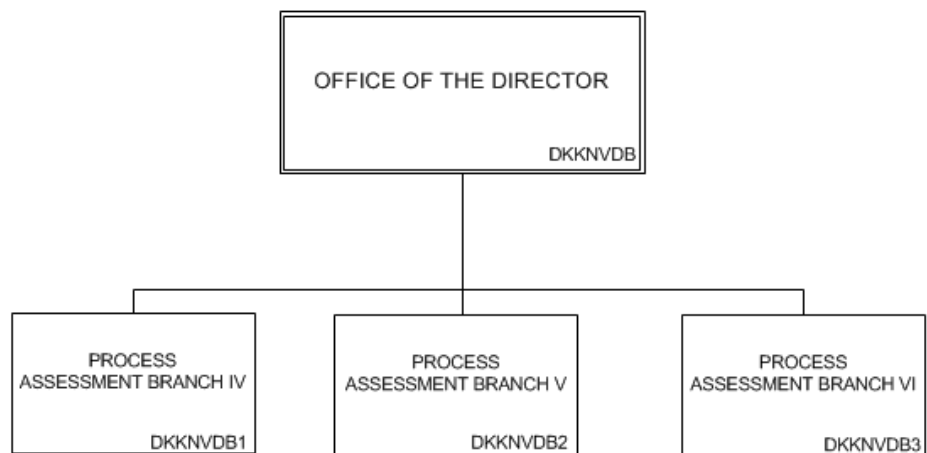
E. Uses risk-based approach, communicates issues with review and inspection related application team members.

F. Provides clear risk-based recommendation on assessment related activities.

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 Process and Facilities, Division of Process Assessment II organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVDB:

- Process Assessment Branch IV – DKKNVDB1
- Process Assessment Branch V – DKKNVDB2
- Process Assessment Branch VI - DKKNVDB3