SMG 1280.54

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 MICROBIOLOGY ASSESSMENT

Effective Date: September 26, 2014

1. DIVISION OF MICROBIOLOGY ASSESSMENT (DKKNVDD).

A. Oversees the scientific review and quality evaluation of the manufacturing process and facilities for Investigational New Drugs (IND), New Drug applications (NDA), Abbreviated New Drug applications (ANDA), Biologic License Applications (BLA) and supplemental New Drug applications (NDA), Abbreviated New Drug applications (ANDA), Biologic License Applications (BLA) assigned to Division.

B. Advises Center for Drug Evaluation and Research (CDER) and other Centers on applied microbiological issues relating to product quality and drug manufacturing.

2. MICROBIOLOGY ASSESSMENT BRANCH I (DKKNVDD1).

A. Assesses the suitability of microbiological data in IND, NDA, ANDA, and BLA and supplemental NDA and ANDA, typically for products intended to be sterile or at a higher risk of microbial contamination.

B. Assesses the suitability of process manufacturing data in IND, NDA, and ANDA, and supplemental NDA and ANDA for lower risk manufacturing processes.

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. MICROBIOLOGY ASSESSMENT BRANCH II (DKKNVDD2).

A. Assesses the suitability of microbiological data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs, typically for products intended to be sterile or at a higher risk of microbial contamination.

B. Assesses the suitability of process manufacturing data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs for lower risk manufacturing processes.

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 NDAs, ANDAs 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. MICROBIOLOGY ASSESSMENT BRANCH III (DKKNVDD3).

A. Assesses the suitability of microbiological data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs, typically for products intended to be sterile or at a higher risk of microbial contamination.

B. Assesses the suitability of process manufacturing data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs for lower risk manufacturing processes.

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 NDAs, ANDAs and supplements, as merited.

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

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

5. MICROBIOLOGY ASSESSMENT BRANCH IV (DKKNVDD4).

A. Assesses the suitability of microbiological data for BLAs and supplements.

B. Assesses other CMC data relevant to facilities, manufacturing controls, product packaging integrity, cross-contamination prevention, microbiology product quality and sterility assurance.

C. Leads or participates in, as appropriate, inspections of establishments manufacturing biological products.

D. Using a risk-based approach, communicates issues with review and inspection related application team members.

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

6. 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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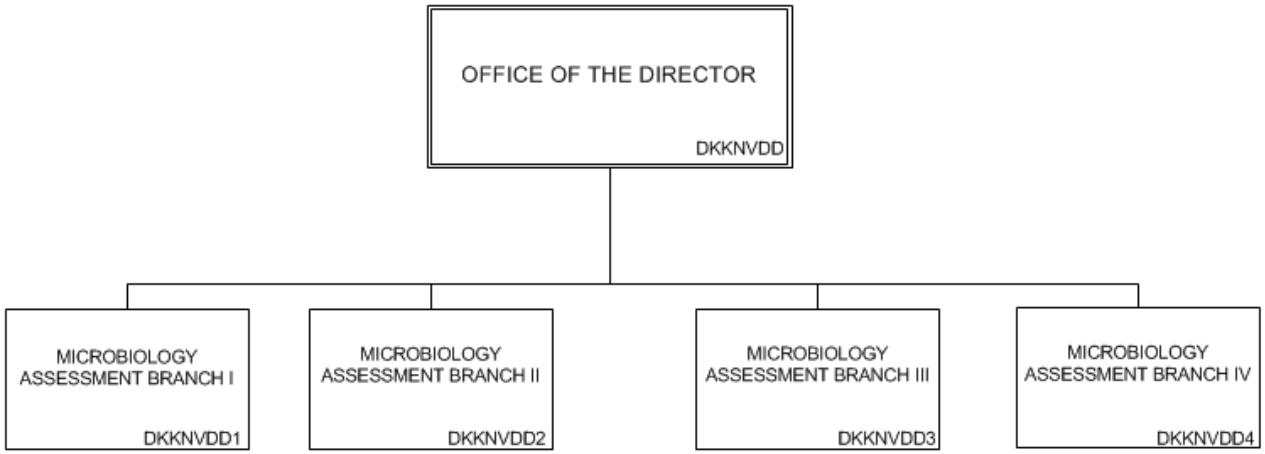

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ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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 Microbiology Assessment organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVDD:

- Microbiology Assessment Branch I – DKKNVDD1
- Microbiology Assessment Branch II – DKKNVDD2
- Microbiology Assessment Branch III – DKKNVDD3
- Microbiology Assessment Branch IV – DKKNVDD4