SMG 1280.52

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Pharmaceutical Manufacturing Assessment

Division of Pharmaceutical Manufacturing II

Effective Date**:** September 25, 2019

1. Division of Pharmaceutical Manufacturing II (DCDLDB).

A. Oversees the scientific review and quality evaluation of pharmaceutical manufacturing including process and facilities for Investigational New Drug applications (IND), New Drug applications (NDA), Abbreviated New Drug applications (ANDA) as well as Drug Master Files (DMF), supplemental NDA and supplemental ANDA assigned to division.

B. Advises Center for Drug Evaluation and Research and other Centers on scientific and regulatory issues associated with manufacturing assessment, and on inspectional and facilities activities related to pre-approval and post-approval inspections.

2. Pharmaceutical Manufacturing Branch 4 (DCDLDB1).

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

B. Assesses the suitability of microbiological data in IND, NDA, ANDA, DMF and supplemental NDA and ANDA for products with a lower risk of microbial contamination (e.g., non-sterile solid oral products).

C. Assesses the manufacturing processes and facilities, through evaluation of facility and inspection related documentation.

D. Participates on inspections for NDA, ANDA, and supplements, as merited.

E. Uses risk-based approaches and communicates review and inspection issues with application team members.

F. Provides clear science, and risk-based recommendations during assessment related activities.

3. Pharmaceutical Manufacturing Branch 5 (DCDLDB2).

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

B. Assesses the suitability of microbiological data in IND, NDA, ANDA, DMF, and supplemental NDA and ANDA for products with a lower risk of microbial contamination (e.g., non-sterile solid oral products).

C. Assesses the manufacturing processes and facilities, through evaluation of facility and inspection related documentation.

D. Participates on inspections for NDA, ANDA and supplements, as merited.

E. Uses risk-based approaches and communicates review and inspection issues with application team members.

F. Provides clear science and risk-based recommendations during assessment related activities.

4. Pharmaceutical Manufacturing Branch 6 (DCDLDB3).

A. Assesses manufacturing process data in IND, NDA, ANDA, DMF and supplemental NDA and ANDA.

B. Assesses the suitability of microbiological data in IND, NDA, ANDA, DMF, and supplemental NDA and ANDA for products with a lower risk of microbial contamination (e.g., non-sterile solid oral products).

C. Assesses the manufacturing processes and facilities, through evaluation of facility and inspection related documentation.

D. Participates on inspections for NDA, ANDA and supplements, as merited.

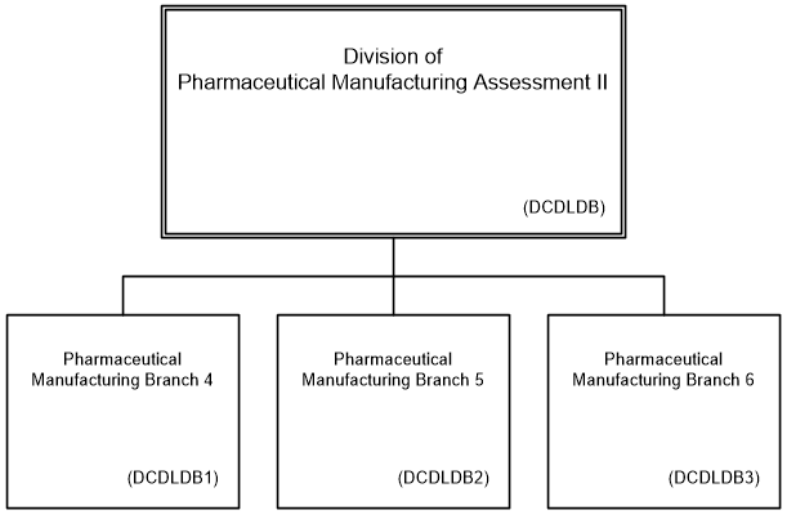
E. Uses a risk-based approaches and communicates review and inspection issues with application team members.

F. Provides clear science and risk-based recommendations during assessment related activities.

5. Authority and Effective Date.

The functional statements for the Division of Pharmaceutical Manufacturing II were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
Office of Pharmaceutical Manufacturing Assessment
Division of Pharmaceutical Manufacturing Assessment II



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Pharmaceutical Manufacturing Assessment, Division of Pharmaceutical Manufacturing Assessment II organizational structures depicting all the organizational structures reporting to the Director.

Division of Pharmaceutical Manufacturing Assessment II (DCDLDB).

These organizations report to the Division of Process Assessment II:

Pharmaceutical Manufacturing Branch 4 (DCDLDB1)

Pharmaceutical Manufacturing Branch 5 (DCDLDB2)

Pharmaceutical Manufacturing Branch 6 (DCDLDB3)

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