

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 New Drug Products

Division of Biopharmaceutics

Effective Date: September 25, 2019

1. Division of Biopharmaceutics (DCDLBF).

- 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 1 (DCDLBF1).

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

3. Biopharmaceutics Branch 2 (DCDLBF2).

- A. Evaluates biopharmaceutics-related information to support assessment of INDs as needed.
- B. Evaluates biopharmaceutics-related information to support quality recommendations for NDAs, ANDAs, sNDAs and sANDAs as needed

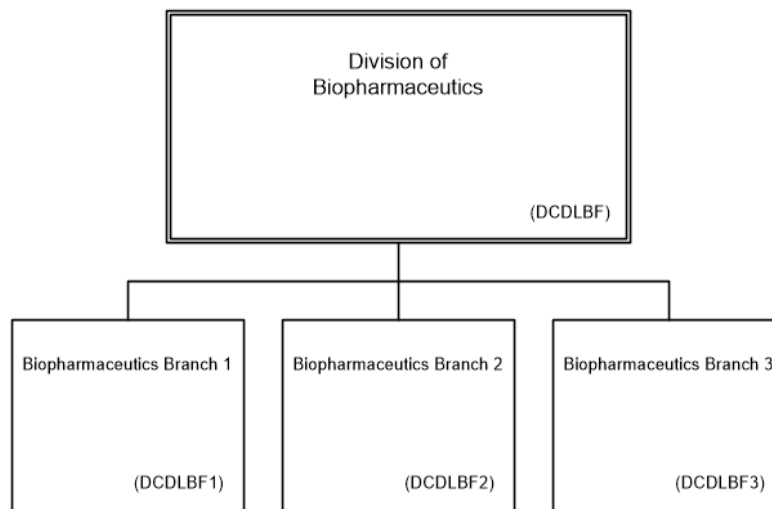
4. Biopharmaceutics Branch 3 (DCDLBF3).

- A. Evaluates biopharmaceutics-related information to support assessment of INDs as needed.
- B. Evaluates biopharmaceutics-related information to support quality recommendations for NDAs, ANDAs, sNDAs and sANDAs as needed.

5. Authority and Effective Date.

The functional statements for the Division of Biopharmaceutics were approved by the Secretary of the Department 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 New Drug Products
Division of Biopharmaceutics**



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Organizations and Functions
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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 New Drug Products, Division of Biopharmaceutics organizational structures depicting all the organizational structures reporting to the Director.

Division of Biopharmaceutics (DCDLBF).

These organizations report to the Division of Biopharmaceutics (DCDLBF):

Biopharmaceutics Branch 1 (DCDLBF1)

Biopharmaceutics Branch 2 (DCDLBF2)

Biopharmaceutics Branch 3 (DCDLBF3)