

**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 New Drug Products II**

Effective Date: September 25, 2019

**1. Division of New Drug Products II (DCDLBD).**

- A. Participates in team-based, cross-office collaborative evaluation and assessment of drug product information supporting industry meeting packages, New Drug Applications (NDAs), Investigational New Drug Applications (INDs), and makes risk-informed recommendations on adequacy of such submissions.

**2. New Drug Products Branch 3 (DCDLBD1).**

- A. Participates in team-based, cross-office collaborative evaluation and assessment of drug product information supporting industry meeting packages, NDAs, INDs, in conjunction with the associated clinical divisions.
- B. Makes risk-informed recommendations on these submissions.

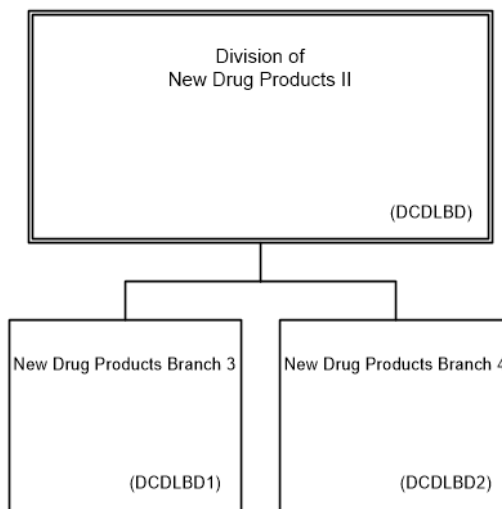
**3. New Drug Products Branch 4 (DCDLBD2).**

- A. Participates in team-based, cross-office collaborative evaluation and assessment of drug product information supporting industry meeting packages, NDAs, INDs, in conjunction with the associated clinical divisions.
- B. Makes risk-informed recommendations on these submissions.

**4. Authority and Effective Date.**

The functional statements for the Division of New Drug Products II was approved by the Secretary of the Health and Human Services on September 25, 2019.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
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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 New Drug Products II organizational structures depicting all the organizational structures reporting to the Director.

Division of New Drug Products II (DCDLBD).

These organizations report to the Division of New Drug Products II:

New Drug Products Branch 4 (DCDLBD1)

New Drug Products Branch 5 (DCDLBD2)