

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 I

Effective Date: September 25, 2019

1. Division of New Drug Products I (DCDLBC).

- 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 1 (DCDLBC1).

- 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.

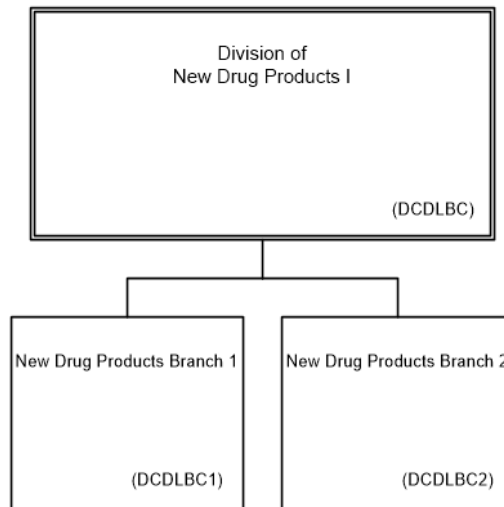
3. New Drug Products Branch 2 (DCDLBC2).

- 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 I 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
Office of Pharmaceutical Quality
Office of New Drug Products
Division of New Drug Products I**



Staff Manual Guide 1280.33
Organizations and Functions
Effective Date: September 25, 2019

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 I organizational structures depicting all the organizational structures reporting to the Director.

Division of New Drug Products I (DCDLBC).

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

New Drug Products Branch 1 (DCDLBC1)

New Drug Products Branch 2 (DCDLBC2)