

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 Science

Office of Lifecycle Drug Products

Effective Date: September 25, 2019

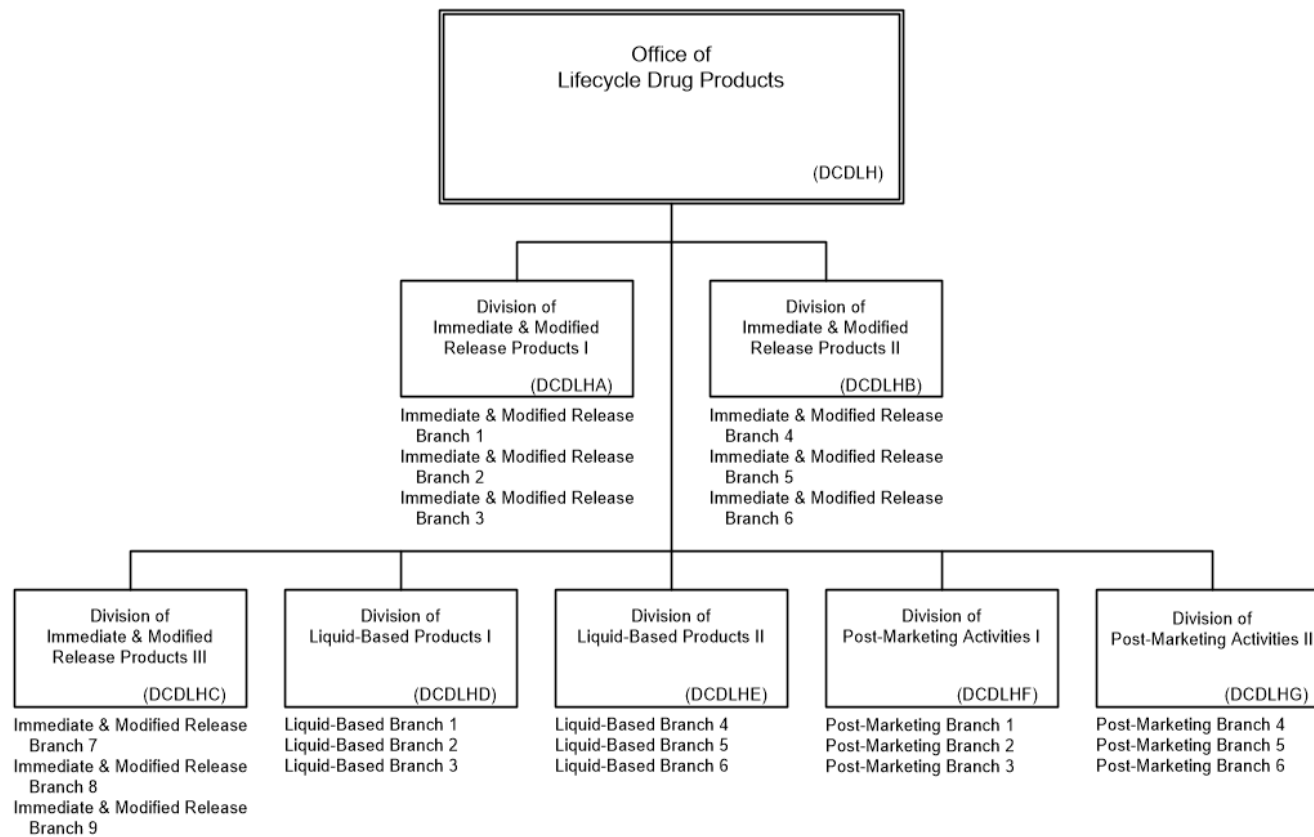
1. Office of Lifecycle Drugs Products (DCDLH).

- A. Evaluates and assesses product quality aspects of Abbreviated New Drug Applications (ANDA) and making risk-informed recommendations on the approvability of such products to appropriate stakeholders (e.g., Office of Generic Drugs (OGD), other offices within Office of Pharmaceutical Quality (OPQ), industry, etc.).
- B. Performs team-based reviews that include cross-office collaboration and participation in inspection where necessary. The output of this office will be a determination that a given ANDA is likely to produce a suitable generic equivalent to a reference listed drug product.
- C. Serves as a Liaison to OGD and is responsible for the following components of ANDA related to product quality: formulation/product design, identifying potential failure modes, risk assessment, quality standards, clinically relevant specifications, including those related to biopharmaceuticals, product characterization, method validation, control strategy relating to product attributes, container/closure system, stability, and post-approval change management.
- D. Evaluates and assesses post-marketing activities for both the approved brand and generic drug products to ensure that, over time, the generic version adequately mirrors the innovator drug product as lifecycle changes are made in either the brand or generic products.
- E. Participates in coordination with other OPQ components, as needed, in scientific investigations to evaluate and access any drug product quality problems that arise.

2. Authority and Effective Date.

The functional statements for the Office of Lifecycle Drug Products 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 Lifecycle Drug Products**



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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 Lifecycle Drug Products organizational structures depicting all the organizational structures reporting to the Director.

Office of Lifecycle Drug Products (DCDLH).

These organizations report to the Office of Lifecycle Drug Products:

Division of Immediate & Modified Release Products I (DCDLHA)

Division of Immediate & Modified Release Products II (DCDLHB)

Division of Immediate Modified Release Products III (DCDLHC)

Division of Liquid-Based Products I (DCDLHD)

Division of Liquid-Based Products II (DCDLHE)

Division of Post-Marketing Activities I (DCDLHF)

Division of Post-Marketing Activities II (DCDLHG)

These organizations report to the Division of Immediate & Modified Release Products I:

Immediate & Modified Release Branch 1

Immediate & Modified Release Branch 2

Immediate & Modified Release Branch 3

These organizations report to the Division of Immediate & Modified Release Products II:

Immediate & Modified Release Branch 4

Immediate & Modified Release Branch 5

Immediate & Modified Release Branch 6

These organizations report to the Division of Immediate & Modified Release Products III:

Immediate & Modified Release Branch 7

Immediate & Modified Release Branch 8

Immediate & Modified Release Branch 9

These organizations report to the Division of Liquid-Based Products I:

Liquid-Based Branch 1

Liquid-Based Branch 2

Liquid-Based Branch 3

These organizations report to the Division of Liquid-Based Products II:

Liquid-Based Branch 4

Liquid-Based Branch 5

Liquid-Based Branch 6

These organizations report to the Division of Post-Marketing Activities I:

Post-Marketing Branch 1

Post-Marketing Branch 2

Post-Marketing Branch 3

These organizations report to the Division of Post-Marketing Activities II:

Post-Marketing Branch 4

Post-Marketing Branch 5

Post-Marketing Branch 6

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