SMG 1280.97

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

Division of Post-Marketing Activities II

Effective Date: September 25, 2019

1. Division of Post-Marketing Activities II (DCDLHG).

A. Manages the overall program responsibilities for the Division, primarily monitoring the lifecycle of both innovator and generic drugs through a team-based evaluation and assessment of supplements and annual reports using risk management practices.

B. Provides direction, clarification, and interpretation on policy and technical issues for the division.

C. Provides scientific and technical support in such areas as drug shortage alleviation, drug product recalls, and communications with industry.

2. Post-Marketing Branch 4 (DCDLHG1).

A. Monitors the lifecycle of both innovator and generic drugs through a team-based evaluation.

B. Assesses supplements and annual reports using risk management practices.

C. Collaborates with the OGD regarding supplements for generic drug applications as needed.

D. Provides scientific and technical support to CDER in such areas as drug shortage alleviation, drug product recalls, and communications with industry.

3. Post-Marketing Branch 5 (DCDLHG2).

A. Monitors the lifecycle of both innovator and generic drugs through a team-based evaluation.

B. Assesses supplements and annual reports using risk management practices.

C. Collaborates with the OGD regarding supplements for generic drug applications as needed.

D. Provides scientific and technical support to CDER in such areas as drug shortage alleviation, drug product recalls, and communications with industry.

4. Post-Marketing Branch 6 (DCDLHG3).

A. Monitors the lifecycle of both innovator and generic drugs through a team-based evaluation.

B. Assesses supplements and annual reports using risk management practices.

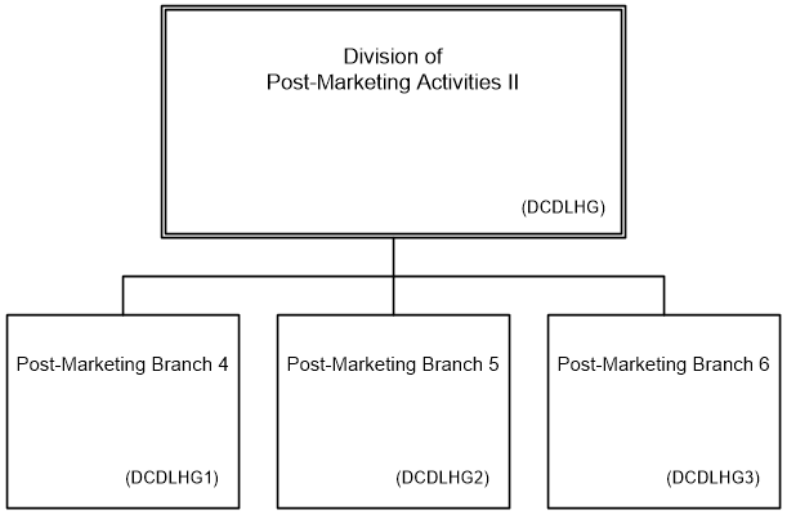
C. Collaborates with the OGD regarding supplements for generic drug applications as needed.

D. Provides scientific and technical support to CDER in such areas as drug shortage alleviation, drug product recalls, and communications with industry.

5. Authority and Effective Date.

The functional statements for the Division of Post-Marketing Activities 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 Lifecycle Drug Products
Division of Post-Marketing Activities 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 Lifecycle Drug Products, Division of Post-Marketing Activities II organizational structures depicting all the organizational structures reporting to the Director.

Division of Post-Marketing Activities II (DCDLHG).

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

Post-Marketing Branch 4 (DCDLHG1)

Post-Marketing Branch 5 (DCDLHG2)

Post-Marketing Branch 6 (DCDLHG3)

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