SMG 1280.96a

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 I

Effective Date: September 25, 2019

1. Division of Post-Marketing Activities I (DCDLHF).

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.

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

2. Post-Marketing Branch 1 (DCDLHF1).

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 Office of Generic Drugs (OGD) regarding supplements for generic drug applications as needed.

D. Provides scientific and technical support to Center for Drug Evaluation and Research (CDER) in such areas as drug shortage alleviation, drug product recalls, and communications with industry.

3. Post-Marketing Branch 2 (DCDLHF2).

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 3 (DCDLHF3).

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.

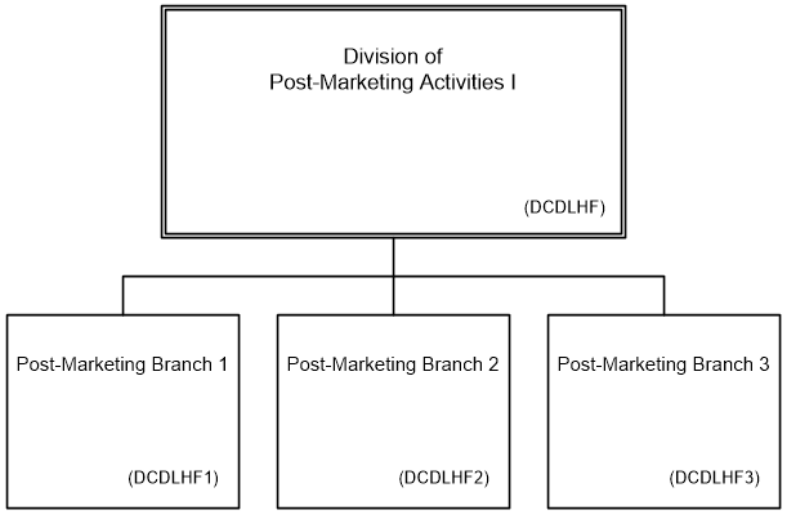
C. Collaborates with the OGD regarding supplements for generic drug applications as needed.

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 I 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 I



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

Division of Post-Marketing Activities I (DCDLHF).

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

Post-Marketing Branch 1 (DCDLHF1)

Post-Marketing Branch 2 (DCDLHF2)

Post-Marketing Branch 3 (DCDLHF3)

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