SMG 1294.1a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drugs Evaluation and Research

Office of Generic Drugs

Office of Regulatory Operations

Effective Date: December 14, 2018

1. Office of Regulatory Operations (DCDMD).

A. Reviews Abbreviated New Drug Applications (ANDA); regulatory filing; labeling review process and the overall Quality Management Systems in generic drugs.

B. Performs the required regulatory filing for ANDA acceptability.

C. Reviews all labeling for the ANDA to ensure labeling consistency with the RLD.

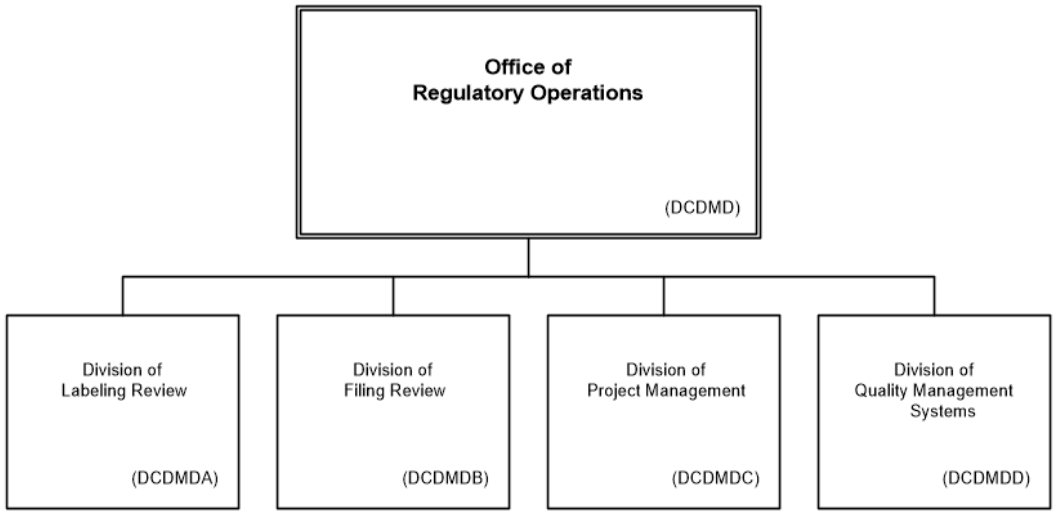
D. Performs project management of the ANDA reviews.

E. Ensures that quality management system for ANDA process is followed.

2. Authority and Effective Date.

The functional statements for the Office Regulatory Operations were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Office of Regulatory Operations



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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 Generic Drugs, Office of Regulatory Operations organizational structures depicting all the organizational structures reporting to the Director:

Office of Regulatory Operations (DCDMD)

These organizations report to the Office of Regulatory Operations:
Division of Labeling Review (DCDMDA)
Division of Filing Review (DCDMDB)
Division of Project Management (DCDMDC)
Division of Quality Management Systems (DCDMDD)

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