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: October 9, 2020

1. Office of Regulatory Operations (DCDMD).

A. Reviews Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generics drugs including complex products for regulatory filing and labeling acceptability and the overall management of generic drug applications.

B. Performs the required regulatory filing for ANDA acceptability.

C. Reviews all labeling for the ANDA to ensure labeling consistency with the Referenced Listed Drug.

D. Performs project management of the ANDA reviews.

E. Manages the Generic Drug User Fee Amendments Controlled Correspondence program from triaging to tracking and reporting.

F. Makes the final decision on the approval of generic drug applications and several key post-approval change types.

2. Authority and Effective Date.

The functional statements for the Office of Regulatory Operations were approved by the Commissioner of Food and Drugs on September 8, 2020, and effective on October 9, 2020.

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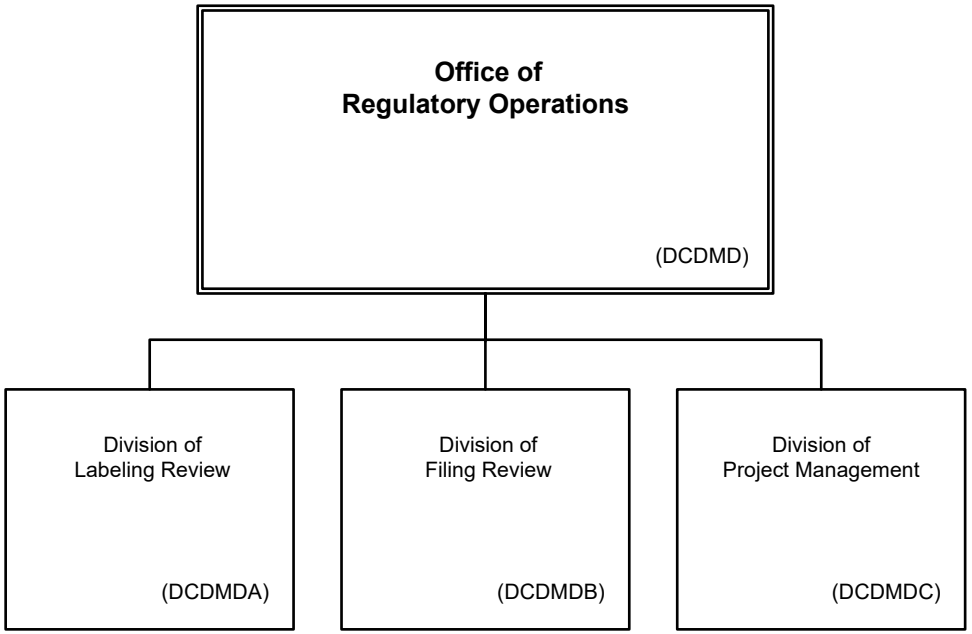

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Regulatory Operations, organization structure depicting all the organizational structures reporting to the Director:

Office of Regulatory Operations (DCDMD)

Division of Labeling Review (DCDMDA)

Division of Filing Review (DCDMDB)

Division of Project Management (DCDMDC)