SMG 1293.1a

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 Generic Drug Policy

Effective Date: December 14, 2018

1. Office of Generic Drug Policy (DCDMC).

A. Coordinates the development of policy within the Office of Generic Drugs (OGD); conducts other functions with respect to the review of Abbreviated New Drug Applications (ANDA) and other administrative matters affecting generic drugs.

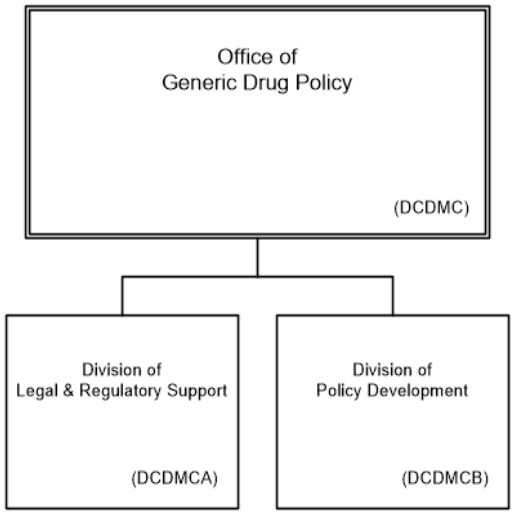
B. Coordinates the policy initiatives developed by OGD and other offices within Center for Drug Evaluation and Research (CDER)/Food and Drug Administration.

C. Ensures consistent policies in assessing ANDAs in the context of active citizen's petitions, and communication with Office of New Drugs and other relevant offices in CDER.

2. Authority and Effective Date.

The functional statements for the Office of Generic Drug Policy 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 Generic Drug Policy



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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 Generic Drug Policy organizational structures depicting all the organizational structures reporting to the Director:

Office of Generic Drug Policy (DCDMC)

These organizations report to the Office of Generic Drug Policy:
Division of Legal & Regulatory Support (DCDMCA)
Division of Policy Development (DCDMCB)

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