SMG 1293.12

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

Division of Policy Development

Effective Date: October 9, 2020

1. Division of Policy Development (DCDMCB).

A. Develops regulations, guidances, Manuals of Policy and Procedures, and other statements of policy with respect to generic drugs to implement section 505(j) of the Federal Food, Drug, and Cosmetic Act.

B. Coordinates with Center for Drug Evaluation and Research (CDER) with respect to drug/device combinations and develops Office of Generic Drugs (OGD) policy with respect to these products; monitors and coordinates the development of OGD policy with respect to emerging therapies.

C. Manages generic drug withdrawals and provides coordination with external organizations on national and international issues regarding generic drugs.

D. Ensures consistency across CDER policies and procedures affecting regulation of generic drug products, including through the development and implementation of policy solutions to address lifecycle management matters.

E. Collaborates across the Food and Drug Administration (FDA) to ensure timely implementation and fulfillment of FDA's commitments pursuant to the Generic Drug User Fee Amendments.

2. Authority and Effective Date.

The functional statements for the Division of Policy Development 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
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Center for Drug Evaluation and Research
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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, Division of Policy Development, organization structure depicting all the organizational structures reporting to the Director:

Division of Policy Development (DCDMCB)