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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: December 14, 2018

1. Division of Policy Development (DCDMCB).

A. Develops guidance's, Manual of Policy and Procedures (MaPPs), and other statements of policy with respect to generic drugs.

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, represents OGD in drug shortage matters, and provides coordination with external organizations on international issues regarding generic drugs.

D. Publishes and maintains the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book); coordinates the resolution of policy issues related to what goes into the Orange Book, including but not limited to 3- and 5-year exclusivity, Therapeutic Equivalence codes, dosage forms, patent listing and patent usage codes

2. Authority and Effective Date.

The functional statements for the Division of Policy Development were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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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 organizational structures depicting all the organizational structures reporting to the Director:

Division of Policy Development (DCDMCB)

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