SMG 1293.13

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Generic Drugs

Office of Generic Drug Policy

Division of Orange Book Publication and Regulatory Assessment

Effective Date: October 9, 2020

1. Division of Orange Book Publication and Regulatory Assessment (DCDMCC).

A. Publishes and maintains the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) and ensures timely and accurate information is included in the Orange Book regarding all new drug approvals and therapeutic equivalence evaluations for multi-source products, as required by section 505(j) of the Federal Food, Drug, and Cosmetic Act.

B. Makes recommendations on and coordinates the resolution of policy issues related to the patent and exclusivity, substitutability, and drug product information that appear in the Orange Book.

C. Evaluates and provides advice on and responses to regulatory submissions and external stakeholder inquiries to the Food and Drug Administration on general and application-specific issues, including citizen petitions and controlled correspondence related to designation of additional reference listed drugs and reference standards.

D. Represents the Office of Generic Drugs in drug shortage matters.

E. Supports the development of policy deliverables related to the Orange Book, including regulations, guidance, manuals, and other statements of policy.

F. Provides education and assistance to external stakeholders on patent listings, transfers of ownership, and other issues impacting the information published in the Orange Book through regular external presentations.

2. Authority and Effective Date.

The functional statements for the Division of Orange Book Publication and Regulatory Assessment 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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(DCDMCC)

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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 Orange Book Publication and Regulatory Assessment, organization structure depicting all the organizational structures reporting to the Director:

Division of Orange Book Publication and Regulatory Assessment (DCDMCC)