

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 Legal and Regulatory Support

Effective Date: October 9, 2020

1. Division of Legal and Regulatory Support (DCDMCA).

- A. Advises the Office of Generic Drugs (OGD) regarding generic drug application-specific legal, regulatory, and policy issues in the course of Food and Drug Administration (FDA) implementation of section 505(j) of the Federal Food, Drug, and Cosmetic Act, and provides expertise on generic drug regulatory issues at both the Center and FDA level.
- B. Serves as liaison and supports the work of the Office of Chief Counsel and the Center's policies with respect to generic drug matters, including by managing the review of citizens petitions on which OGD is requested to provide a consult.
- C. Tracks and helps expedite review of public health priority submissions, including for first generics and drug shortages, to help achieve timely approval of generic drug products.
- D. Advises and makes decisions on patent and exclusivity matters for brand and generic drugs and determines timing of generic drug approvals, including through evaluation of whether 180-day patent challenge exclusivity or 180-day competitive generic therapy exclusivity has been forfeited.

2. Authority and Effective Date.

The functional statements for the Division of Legal and Regulatory Support 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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(DCDMCA)

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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 Legal and Regulatory Support, organization structure depicting all the organizational structures reporting to the Director:

Division of Legal and Regulatory Support (DCDMCA)