

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: December 14, 2018

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

- A. Manages the review within Office of Generic Drugs (OGD) of those petitions on which OGD is requested to provide consult; manages the review of Abbreviated New Drug Applications (ANDA) Suitability Petitions.
- B. Functions as liaison and supports the work of the Office of Chief Counsel and CDER's Office of Regulatory Policy with respect to generic drug matters.
- C. Coordinates all work with respect to Hatch-Waxman matters in OGD, including but not limited to the review of approval and tentative approval letters when there is a paragraph IV certification, forfeitures, and 180-day exclusivity.

2. Authority and Effective Date.

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

Staff Manual Guide 1293.11
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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 & Regulatory Support organizational structures depicting all the organizational structures reporting to the Director:

Division of Legal & Regulatory Support (DCDMCA)