

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Regulatory Policy

Division of Regulatory Policy I

Effective Date: December 14, 2018

1. Division of Regulatory Policy I (DCDBA).

- A. Initiates, develops, and reviews regulations, policies, procedures and guidance's that affect the regulation of drugs under the Federal Food, Drug, and Cosmetic Act.
- B. Serves as the Center's focal point on regulatory issues providing advice and assistance on such matters as scope, applicability and meaning of the Federal Food, Drug, and Cosmetic Act other laws, regulations, and policies.

2. Authority and Effective Date.

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

**Department of Health and Human Services
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(DCDBA)

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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 Regulatory Policy, Division of Regulatory Policy I organization structure depicting all the organizational structures reporting to the Director:

Division of Regulatory Policy I (DCCBA).