

SMG 1260.2

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

Effective Date: December 14, 2018

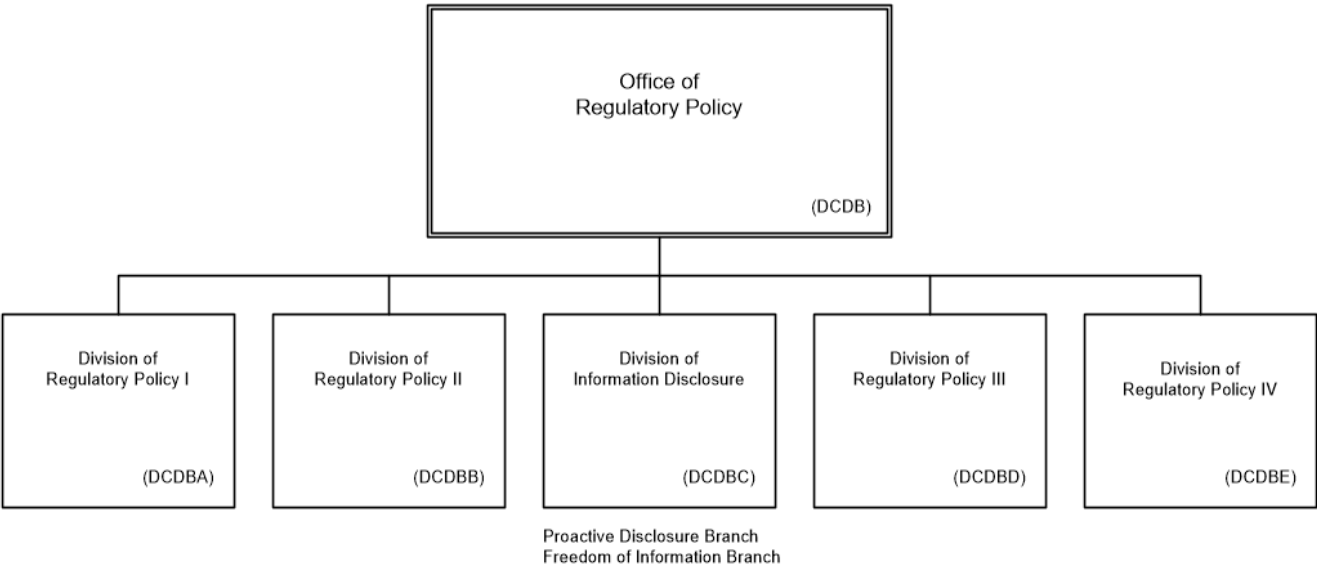
1. Office of Regulatory Policy (DCDB).

- A. Provides Center oversight and leadership in the development of regulations, policies, procedures and guidance's that affect the drug approval process, and in the development of new legislation.
- B. Provides Center oversight and leadership in the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and Food and Drug Administration's public disclosure regulations.

2. Authority and Effective Date.

The functional statements for the Office of Regulatory Policy 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
Center for Drug Evaluation and Research
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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Regulatory Policy (DCCB).

These organizations report to the Office of Regulatory Policy:

Division of Regulatory Policy I (DCCBA)

Division of Regulatory Policy II (DCCBB)

Division of Information Disclosure Policy (DCCBC)

Division of Regulatory Policy III (DCCBD)

Division of Regulatory Policy IV (DCCBE)

These organizations report to the Division of Information Disclosure Policy

Proactive Disclosure Branch

Freedom of Information Branch