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 II

Effective Date: December 14, 2018

1. Division of Regulatory Policy II (DCDBB).

- 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 II were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Staff Manual Guide 1260.22 Organizations and Functions Effective Date: December 14, 2018

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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 II organization structure depicting all the organizational structures reporting to the Director:

Division of Regulatory Policy II (DCCBB).