

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 New Drugs

Office of New Drug Policy

Division of Regulatory Policy

Effective Date: September 25, 2019

1. Division of Regulatory Policy (DCDGKB).

- A. Develops guidance's, Manual of Policies and Procedures, and other statements of policy with respect to Investigational New Drugs (INDs), New Drug Applications (NDAs) and Center for Drug Evaluation and Research (CDER) regulated Biological License Applications (BLAs).
- B. Functions as liaison and supports the work of the Office of Chief Counsel and Policy offices within CDER with respect to regulatory policies and actions involving INDs, NDAs and CDER- regulated BLAs.
- C. Advises other offices within Office of New Drugs (OND) regarding consistent application of regulatory policies and actions in assessing INDs, NDAs, and CDER- regulated BLAs.
- D. Coordinates work with respect to Hatch-Waxman matters in OND, including with respect to the review and approval of 505(b)(2) NDAs.

2. Authority and Effective Date.

The functional statements for the Division of Regulatory Policy were approved by the Secretary of Health and Human Services on September 25, 2019.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs
Office of New Drug Policy
Division of Regulatory Policy**

Division of
Regulatory Policy

(DCDGKB)

Staff Manual Guide 1263.142
Organizations and Functions
Effective Date: September 25, 2019

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of New Drug Policy, Division of Regulatory Policy organization structure depicting all the organizational structures reporting to the Director.

Division of Regulatory Policy (DCDGKB).