

**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

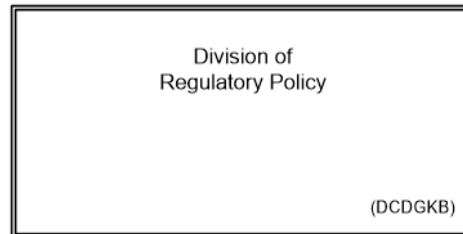
**1. Division of Regulatory Policy (DCDGKB).**

- 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  
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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 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).