

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

Effective Date: September 25, 2019

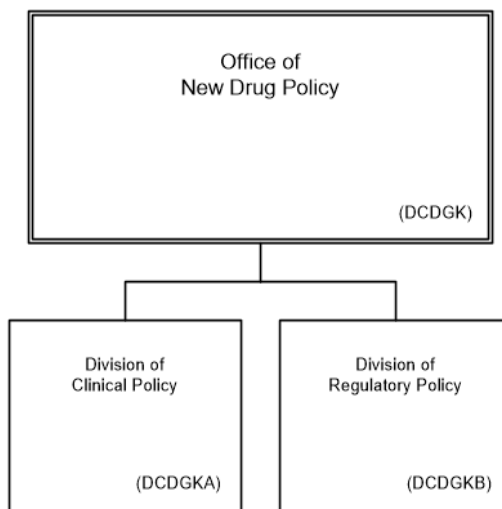
1. Office of New Drug Policy (DCDGK).

- A. Coordinates the development, drafting, publication, and implementation of policy within the Office of New Drugs (OND); conducts other functions with respect to the review of Investigational new drug applications (INDs), new drug applications (NDAs), and Center for Drug Evaluation and Research (CDER) regulated biological license applications (BLAs) and other administrative matters affecting the new drug program.
- B. Coordinates the policy initiatives developed by OND and other offices within CDER/Food and Drug Administration, and coordinates these and other policy matters with other relevant Food and Drug Administration offices.
- C. Ensures consistent application of the statute, regulations, policies and regulatory actions in assessing INDs, NDAs, and CDER-regulated BLAs.

2. Authority and Effective Date.

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

**Department of Health and Human Services
Food and Drug Administration
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Office of New Drug Policy**



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

Office of New Drug Policy (DCDGK).

These organizations report to the Office of New Drug Policy:
Division of Clinical Policy (DCDGKA)
Division of Regulatory Policy (DCDGKB)