

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 Clinical Policy

Effective Date: September 25, 2019

1. Division of Clinical Policy (DCDGKA).

- A. Monitors, coordinates the development of, and ensures consistent implementation of Office of New Drug (OND) policy with respect to clinical aspects of the regulation of Investigational New Drugs (INDs), New Drug Applications (NDAs) and Center for Drug Evaluation and Research (CDER) – regulated Biological License Applications (BLAs).
- B. Monitors, coordinates the development of, and ensures consistent implementation of, OND policy with respect to labeling of INDs, NDAs and CDER-Regulated BLAs.
- C. Supports all areas of drug product safety within OND through research and the development of methods, policies, and procedures that promote a consistent approach to evaluation and management of drug safety issues.
- D. Functions as liaison and supports the work of CDER’s Office of Medical Policy and other CDER offices with respect to clinical, labeling, and safety issues affecting OND-regulated products.

2. Authority and Effective Date.

The functional statements for the Division of Clinical 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
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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 Clinical Policy organization structure depicting all the organizational structures reporting to the Director.

Division of Clinical Policy (DCDGKA).