

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 Regulatory Operations

Effective Date: September 25, 2019

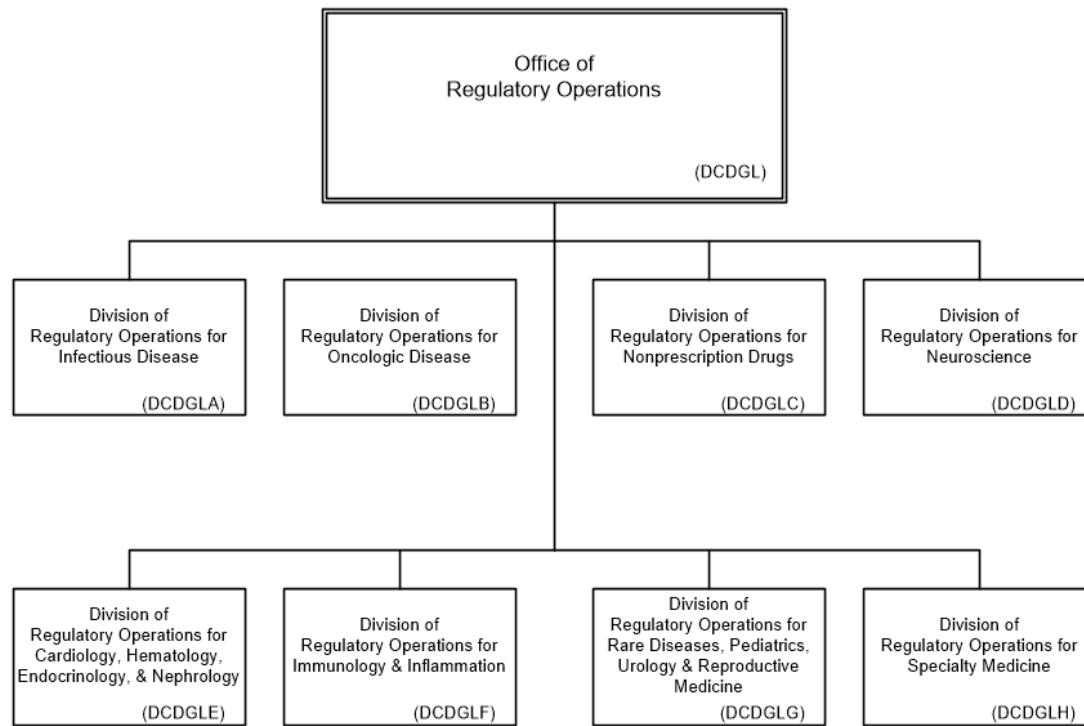
1. Office of Regulatory Operations (DCDGL).

- A. Leads and manages regulatory processes associated with the new drugs regulatory program, in collaboration with other functional office leadership.
- B. Directs the development of operational policies, processes, and tools that guide the work of project management staff across the office.
- C. Standardizes office-wide expectations of project management skill sets, performance levels, and functional knowledge.

2. Authority and Effective Date.

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

**Department of Health and Human Services
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Staff Manual Guide 1263.15a
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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 Regulatory Operations organization structure depicting all the organizational structures reporting to the Director.

Office of Regulatory Operations (DCDGL).