

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 Regulatory Operations

Division of Regulatory Operations for Oncologic Diseases

Effective Date: September 25, 2019

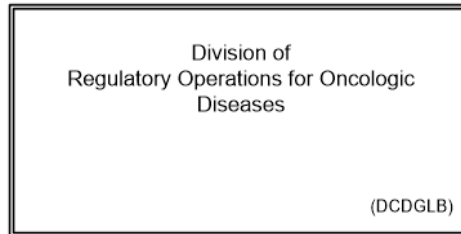
1. Division of Regulatory Operations for Oncologic Diseases (DCDGLB).

- A. Serves as the regulatory leader on product-specific review teams, providing day-to-day regulatory guidance to review staff on product-specific issues.
- B. Provides office and division leadership with regulatory expertise on oncologic diseases products and cross-cutting programs, ensuring consistency with legal and regulatory requirements, as well as office-wide policies.
- C. Manages and coordinates regulatory operations for a portfolio of regulated products, from the investigational stage through marketing application review and post-marketing oversight.
- D. Functions as the communication liaison between other Office of New Drugs offices, centers, Food and Drug Administration and the regulated industry for product-specific interactions.
- E. Collaborates in the design and implementation of processes and policies as needed to ensure compliance with relevant laws, regulations, and user fee program commitments.

2. Authority and Effective Date.

The functional statements for the Division of Regulatory Operations for Oncologic Diseases 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 Regulatory Operations
Division of Regulatory Operations for Oncologic Diseases**



Staff Manual Guide 1263.152
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 Regulatory Operations, Division of Regulatory Operations for Oncologic Disease organization structure depicting all the organizational structures reporting to the Director.

Division of Regulatory Operations for Oncologic Disease (DCDGLB).