SMG 1220.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Regulatory Operations

Effective Date: January 6, 2022

1. Office of Regulatory Operations (DCBI).

A. Coordinates the Center for Biologics Evaluation and Research (CBER) activities regarding planning and evaluation of programs, functional activities, and resource utilization related to regulatory review and governance of regulatory, information technology (IT), data and other regulatory operations.

B. Manages the CBER Managed Review Process (MRP), maps processes, develops guidance, regulations, standard operating procedures, job aids, and tools associated with the regulatory review process.

C. Promotes and coordinates the development and management of regulatory data standards for review of regulatory submissions and represents CBER in several areas of national and international data standards formulation/implementation.

D. Coordinates and oversees development of Center-level Chemistry, Manufacturing and Control (CMC) policy, standards as applied to review.

E. Coordinates and manages regulatory data, performs analytics, and issues reports to Center and Agency management and to external stakeholders, such as industry and Congress.

F. Plans and manages CBER's IT Investments to support and ensure CBER's review, scientific, and administrative needs are met.

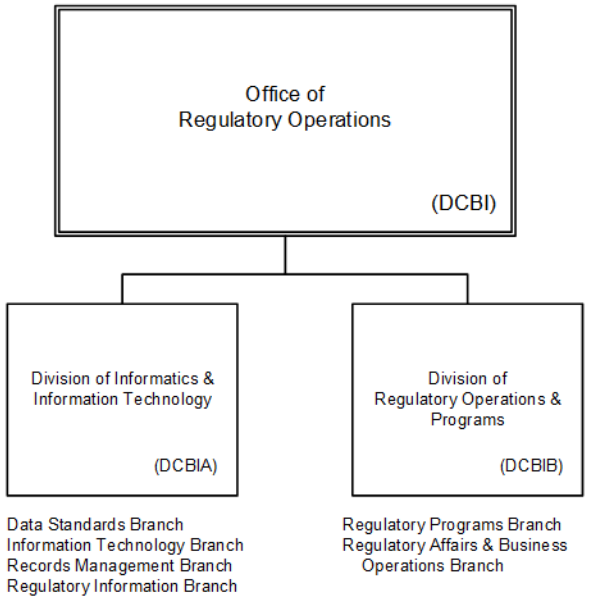
G. Coordinates and manages CBER's life-cycle program for regulatory, program and office administration records, and manages the CBER Document Control Center.

H. Manages Quality Systems for CBER review process.

2. Authority and Effective Date.

The functional statements for the Office of Regulatory Operations and Regulatory Affairs were approved by the Deputy Secretary of Health and Human Services and effective on January 6, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluations and Research
Office of Regulatory Operations



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Regulatory Operations organization structure depicting all the organizational structures reporting to the Director:

Office of Regulatory Operations (DCBI)

These organizations report to the Office of Regulatory Operations:

Division of Regulatory Operations and Programs (DCBIB)

Division of Informatics and Information Technology (DCBIA)

These organizations report to the Division of Regulatory Operations and Programs:

Regulatory Programs Branch (DCBIB2)

Regulatory Affairs and Business Operations Branch (DCBIB1)

These organizations report to the Division of Informatics and Information Technology:

Data Standards Branch (DCBIA1)

Information Technology Branch (DCBIA2)

Records Management Branch (DCBIA3)

Regulatory Information Branch (DCBIA4)