SMG 1220.3

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

Division of Regulatory Operations and Programs

Effective Date: January 6, 2022

1. Division of Regulatory Operations and Programs (DCBIB).

A. Oversees the CBER Managed Review Process (MRP), governance of regulatory operations, review policy and procedures, and review-related committees.

B. Interacts with offices on review and regulatory issues to facilitate application of statutes, regulations, guidance, and processes

C. Initiates and oversees strategic assessments of review and regulatory processes and submissions.

2. Regulatory Affairs and Business Operations Branch (DCBIB1).

A. Responsible for implementation and interpretation of regulatory statues and mandates related to review, including user fee acts, and legislative initiatives.

B. Advises and provides oversight of select regulatory programs, including post marketing commitments and regulatory science review issues.

C. Directs the CBER Managed Review Process (MRP) governance of regulatory operations, review policy and procedures, and other review-related committees.

D. Manages the policy formulation, process engineering/re-engineering, and implementation of all Center-level review policies, procedures, review tools, and regulatory templates for use by CBER reviewers in the managed review process.

E. Represents CBER on working groups and committees with stakeholders, including regulatory science initiatives, guidance document development, and user fee implementation activities.

F. Develops and delivers training related to regulatory review and the tools used during the regulatory review cycle.

3. Regulatory Programs Branch (DCBIB2).

A. Manages the User Fee billing policy and procedures, application assessment, waivers evaluation and processing.

B. Tracks implementation of user fees, legislative and other assigned initiatives within CBER.

C. Manages CBER regulatory pediatric programs including Pediatric Research Equity Act (PREA), and Pediatric Review Committee.

D. Develops policies and procedures and manages interactions for Combination Products.

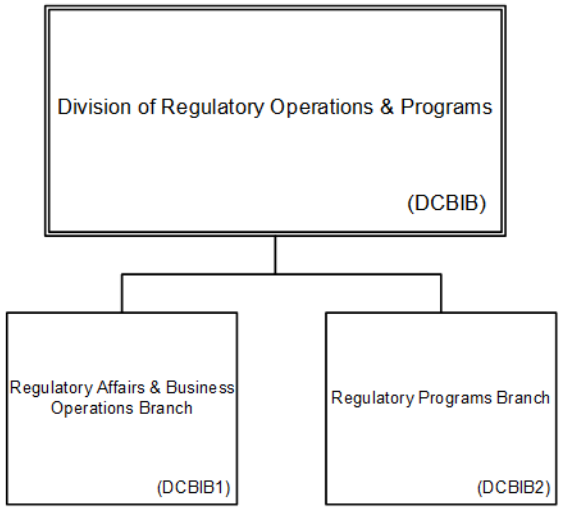
E. Manages and oversees review vouchers and exclusivity assessments.

F. Responsible for policy formulation, process engineering/re-engineering, and implementation of all Center-level review policies, procedures, review tools, and regulatory templates for use by CBER device reviewers in the managed review process.

4. Authority and Effective Date.

The functional statements for the Office of Regulatory Operations, Division of Regulatory Operations and Programs, 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, Division of Regulatory Operations and Programs organization structure depicting all the organizational structures reporting to the Director:

Division of Regulatory Operations and Programs (DCBIB)

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

Regulatory Affairs and Business Operations Branch (DCBIB1)

Regulatory Programs Branch (DCBIB2)