

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 Management

Division of Management Planning and Analysis

Effective Date: January 6, 2022

1. Division of Management Planning and Analysis (DCBBE).

- A. Provides comprehensive, strategic analysis of Center for Biologics Evaluation and Research (CBER) operations based on management science and organizational behavior disciplines.
- B. Formulates and develops CBER budget requests and submissions to the Agency, Department (HHS), Office of Management and Budget (OMB) and Congress.
- C. Conducts independent studies and analysis relating to long term resource needs of the Center, utilizing management science methods to forecast and optimize resources.
- D. Supports user fee activities including negotiations and providing input on the annual reports to Congress for the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee Act (MDUFA), the Generic Drug User Fee Act (GDUFA) and the Biosimilar User Fee Act (BsUFA).
- E. Directs all strategic planning, performance management, and internal control for the Center.
- F. Manages employee engagement activities for the Center.

2. Capacity Planning and Management Analysis Branch (DCBBE1).

- A. Leads CBER's Resource Capacity Planning function in coordination with other medical product Centers at FDA.
- B. Manages CBER's modernized time reporting system, which captures activity time reporting data for the Center.
- C. Supports user fee activities including negotiations and providing input on the

annual reports to Congress for the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee Act (MDUFA), the Generic Drug User Fee Act (GDUFA) and the Biosimilar User Fee Act (BsUFA).

- D. Administers the CBER Internal Control Program which implements FDA policy and procedures in carrying out the requirements set forth in the OMB Circular A-123, Management's Responsibility for Internal Control, and identification of the Center's enterprise risks and submission of the Center's Enterprise Risk Management tool.
- E. Evaluates Center programs' effectiveness and efficiencies ensuring consistency with the overall Center philosophy and consistency with policy and management goals.

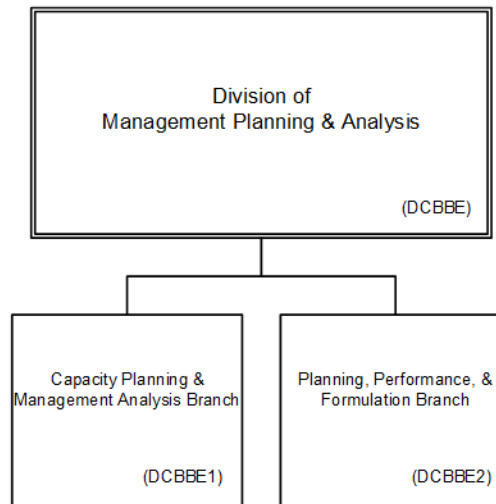
3. Planning, Performance and Formulation Branch (DCBBE2).

- A. Coordinates the development and reporting of CBER's planning initiatives including the Food and Drug Administration's (FDA) Strategic Plan, CBER Strategic Plan, and other Agency and Center-driven planning processes.
- B. Prepares the Center budget requests and submissions to the agency, department, OMB and Congress including the performance appendix for the budget submission, estimates resource needs for special initiatives and new legislation, and provides program descriptions and accomplishments to accompany the budget request.
- C. Coordinates and prepares budget issue papers, responses to stakeholder inquiries on regarding the Center's use of and need for resources, and responses to questions raised in the congressional appropriations process.
- D. Coordinates CBER's performance measurement efforts. Develops, tracks and analyzes CBER performance measures; briefs senior leadership on progress; and coordinates the development and reporting of CBER performance related requirements.
- E. Coordinates strategic planning and development for the Center. Provides Center input and direction for the agency planning activities.
- F. Monitors the results of CBER's Office of Personnel Management (OPM) Federal Employee Viewpoint Survey (FEVS) and prepares the Center's Improvement Plan tailored to needs that are identified in the FEVS.

4. Authority and Effective Date.

The functional statements for the Office of Management, Division of Management Planning and Analysis 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 Evaluation and Research
Office of Management
Division of Management Planning and Analysis**



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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 Management, Division of Management Planning and Analysis organization structure depicting all the organizational structures reporting to the Director:

Division of Management Planning and Analysis (DCBBE)

These organizations report to the Division of Management Planning and Analysis:

Capacity Planning and Management Analysis Branch (DCBBE1)

Planning, Performance and Formulation Branch (DCBBE2)