

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Regulatory Management Operations

Office of Budget, Facilities and Travel Support

Division of Financial Operations

Effective Date: February 9, 2022

1. Division of Financial Operations (DCIBBA).

- A. Provides overall guidance and strategic planning for all aspects of financial management for Office of Regulatory Affairs (ORA) senior leaders. This includes budget execution, acquisitions, and budget formulation.
- B. Provides guidance related to Office of Management and Budget (OMB) and Government Accountability Office (GAO) financial inquiries to include statutes, regulations, policies, procedures and instructions.
- C. Provides guidance related to the Federal Manager's Financial Integrity Act (FMFIA), the Government Performance and Results Act (GPRA), Chief Financial Officer Act, and other legislation, regulations, and applicable laws.
- D. Prepares the ORA's annual budget estimates. This includes all phases of budget analysis, formulation, execution, and presentation. Assists staff in justifying for anticipated needs.

2. Budget Execution Branch (DCIBBA1).

- A. Provides budgetary guidance to all ORA Senior Leaders and managers to ensure critical mission needs are met. Serves as Liaison with the Office of Budget, Division of Budget Execution and Control.
- B. Prepares, monitors, and analyzes current year budget setting funding and FTE levels for each organization within ORA.

- C. Provides guidance related to the Federal Managers' Financial Integrity Act (FMFIA), the Government Performance and Results Act, Chief Financial Officer Act, and other legislation, regulations, and applicable laws.
- D. Serves as ORA lead on the annual FMFIA report on the financial vulnerabilities of ORA.
- E. Serves as ORA Point of Contact for Financial Management Systems access and delegation of responsibilities.

3. Budget Formulation Branch (DCIBBA2).

- A. Prepares the ORA's annual budget estimates for review by the Department of Health and Human Services (DHHS), OMB, and Congress. Serves as liaison with the Office of Budget, Division of Budget Formulation.
- B. Serves as liaison with ORA's Division of Planning, Evaluation and Management on work-planning and resource utilization allocations.
- C. Directs and coordinates the ORA budget activities; develops data and justification to support the ORA budget formulation activities.
- D. Analyzes, formulates and develops the annual budget for the ORA in accordance with Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), Office of Management and Budget (OMB), and Congressional guidelines.
- E. Develops and coordinates ORA's long range funding plans.

4. Funds Control and Policy Branch (DCIBBA3)

- A. Manages and coordinates ORA's role in FDA User Fee programs
- B. Plan, develop, and execute over \$100M in ten User Fees supported by ORA.
- C. Ensures that the ORA budget of \$1.2 Billion is executed within the required Congressional program, projects, and activities.
- D. Oversees monthly reconciliation of each office for monitoring of funding commitments and obligations.
- E. Develops and train on financial management agency and internal ORA policy.
- F. Serves as financial experts for user fee renegotiations.

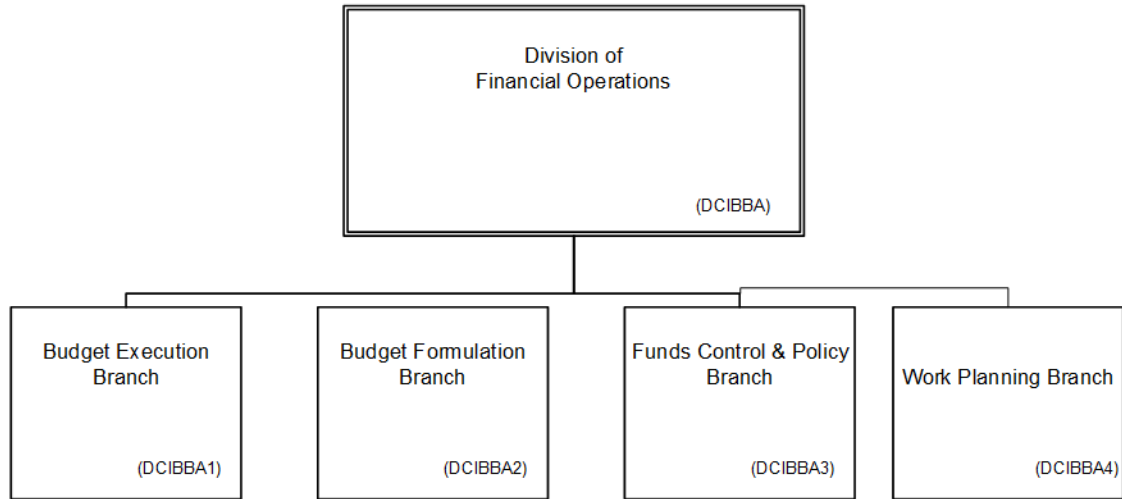
5. Work Planning Branch (DCIBBA4)

- A. Develops and maintains domestic and import workload information.
- B. Coordinates with other FDA components in the development of annual workplans.

6. Authority and Effective Date.

The functional statements for the Division of Financial Operations were approved by the Deputy Secretary of Health and Human Services on December 22, 2021, and effective on February 9, 2022.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Regulatory Management Operations
Office of Budget, Facilities, and Travel Support
Division of Financial Operations**



Staff Manual Guide 1121.151a
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Effective Date: February 9, 2022

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Management Operations, Office of Budget, Facilities, and Travel Support, Division of Financial Operations organization structure depicting all the organizational structures reporting to the Director:

Budget Execution Branch (DCIBBA1)

Budget Formulation Branch (DCIBBA2)

Funds Control and Policy Branch (DCIBBA3)

Work Planning Branch (DCIBBA4)