

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF MANAGEMENT

DIVISION OF FINANCIAL MANAGEMENT

Effective Date: 07/23/2016

1. DIVISION OF FINANCIAL MANAGEMENT (DKKWKB).

- A. Provides Center-wide services and support for budget formulation, budget execution, and financial accountability activities.
- B. Provides leadership and oversight of a comprehensive financial management program for the Center for Devices and Radiological Health (CDRH) encompassing the areas of automated financial systems, fiscal accountability, internal controls, risk assessment, financial services related to user fees, Full-Time Employee (FTE) tracking and analysis, and financial reporting.
- C. Develops, implements, and recommends program priorities and allocation of Center resources, including the identification of new programs. Evaluates and monitors program output with respect to plans, resources, and budgets.
- D. Monitors the development and operation of planning and financial systems for Center activities and resource allocations and advises the Center Director on financial and budgetary policies and guidelines.

2. BUDGET EXECUTION BRANCH (DKKWKB1).

- A. Provides Center-wide oversight, analysis, support, and guidance in the implementation of policies and procedures on budget execution.
- B. Oversees the execution of CDRH's current year resources, and formulates, develops, and executes budget and financial operating plans for the Center.

- C. Provides support and tracks Operating Authorizations and Transfers for the Center, including entering these into iProcurement.
- D. Manages and monitors the Center's payroll budget resources.
- E. Plans, monitors, and evaluates CDRH's financial activities, including advising Center leadership regarding resource allocation strategies, resource utilization trends to inform financial planning, and preparation of multi-year financial plans for all user fee funds.
- F. Advises on Cooperative Research and Development Agreements (CRADAS), Reimbursable Inter-Agency Agreements (IAAs) and Grants Administration.
- G. Oversees the Center's Unified Financial Management System (UFMS)/iProcurement, Financial Systems Implementation.

3. BUDGET FORMULATION BRANCH (DKKWKB2).

- A. Formulates Center budget plans and budget submissions and reviews and provides input on the annual reports to Congress for Medical Device User Fee (MDUFA).
- B. Develops and implements Center long-range budget planning, operational planning, and financial management systems; recommends program priorities and allocation of Center resources, including the identification of new programs.
- C. Monitors the Center's FTE ceilings and provides resource utilization tracking and analysis, coordinates and prepares reports, and advises Center leadership regarding current and future FTE resource allocation needs.
- D. Prepares detailed analyses and estimates of annual funding needs for future budget years.
- E. Analyzes budget trends and funding levels for the Center's programs and activities.
- F. Coordinates Congressional briefing papers as well as Congressional Questions for the Record (QFRs).
- G. Provides core logistical operations support to CDRH's time reporting system coordination and associated resource analysis CDRH Time Reporting System (CTRS), including data collection and time reporting

compliance activities, communications to users, training support, and policy development.

4. FINANCIAL ACCOUNTABILITY BRANCH (DKKWKB3).

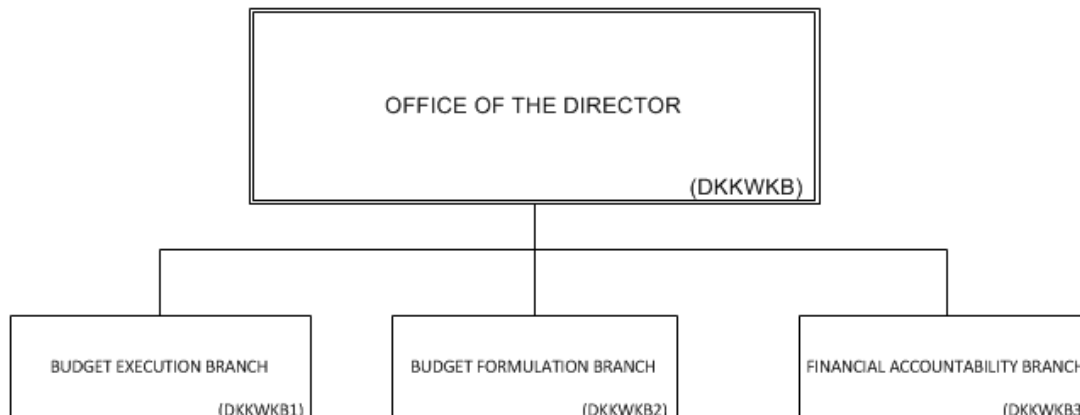
- A. Oversees financial accountability and internal controls activities, conducts risk management assessments and analyses, and provides support, policy development, and guidance to Senior Leadership Officials and program contacts to ensure or improve program integrity.
- B. Manages and oversees the functions of the Federal Managers Financial Integrity Act (FMFIA) for the Center.
- C. Conducts review/research of recurring lists compiled by the Office of Financial Management (OFM) of all payment identifications associated with unearned funds in an effort to locate a linked submission using applicable databases.
- D. Oversees the quarterly Undelivered Orders (UDO) reconciliation and reporting for the Center.
- E. Prepares the Medical Device User Fee (MDUFA) Financial Report.

5. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Deputy Commissioner for Medical Products and Tobacco on February 17, 2016 and effective July 23, 2016.

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STAFF MANUAL GUIDE 1251.13
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: July 23, 2016

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Management, Division of Financial Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKWKB):

- BUDGET EXECUTION BRANCH (DKKWKB1)
- BUDGET FORMULATION BRANCH (DKKWKB2)
- FINANCIAL ACCOUNTABILITY BRANCH (DKKWKB3)