

SMG 1117A.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF OPERATIONS

Effective Date: August 17, 2015

1. OFFICE OF OPERATIONS (DMM).

- A. Provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative operations to ensure the timely and effective implementation and high quality delivery of services across the Food and Drug Administration (FDA), its Directorates, and Centers.
- B. Advises and assists the Commissioner, Deputy Commissioners, and other key officials on various administrative management and business activities.
- C. Chairs all Agency user fee programs which oversee financial management and provide financial management support.
- D. Participates in international initiatives to ensure Agency's capability and readiness to work with foreign counterparts in responding to international emergencies involving or impacting Agency-regulated products and to share information with international counterparts during such emergencies.
- E. Plans, directs, and coordinates a comprehensive financial management program for the Agency that encompasses the areas of automated financial systems, fiscal accounting, voucher audit, and financial reporting. Issues periodic reports regarding the status of the Agency's financial management and develops financial inputs for programs and financial plans.
- F. Provides leadership and direction regarding all aspects of a variety of management programs including organization management, delegations of authority, environmental and safety management, and programs related to ethics and conflict of interest matters.
- G. Plans, organizes and carries out annual and multi-year budgeting in support of FDA's public health mission and programs.

- H. Advises the Commissioner and other key Agency officials on administrative management and budget matters for components within the Office of the Commissioner (OC). Provides advice and guidance with regard to formulation and development of administrative management policies, procedures, and controls.
- I. Provides management direction and leadership for acquisitions, grants, cooperative agreements, technology transfers, and interagency agreements.
- J. Provides advice and assistance to the Commissioner and senior management officials on information management resources and programs. Establishes and oversees implementation of the Agency information management policy and governance, procedures and processes to ensure the Agency is in compliance with the Clinger/Cohen Act. Establishes, directs and leads Agency level programs and all strategic aspects of information management including: information technology (IT) shared services, telecommunications, crisis management and security operations, strategic planning, capital planning and investment control, and enterprise architecture.
- K. Provides top level leadership for the development and management of emergency and crisis management policies and programs including strategic oversight of emergency exercises, overseeing and evaluating emergency and crisis situations, and security operations.
- L. Provides program effectiveness, technical expertise and support for various programs within OO.
- M. Provides assessments on the effectiveness of the organizational components programs (e.g. policies and procedures, regulations and guidance documents) based on information/feedback received from both inside and outside the Office's regarding to any trends or consistent problems and makes recommendations for change or improvement.

2. OMBUDSMAN & CONFLICT PREVENTION AND RESOLUTION (CPR) STAFF (DMM4).

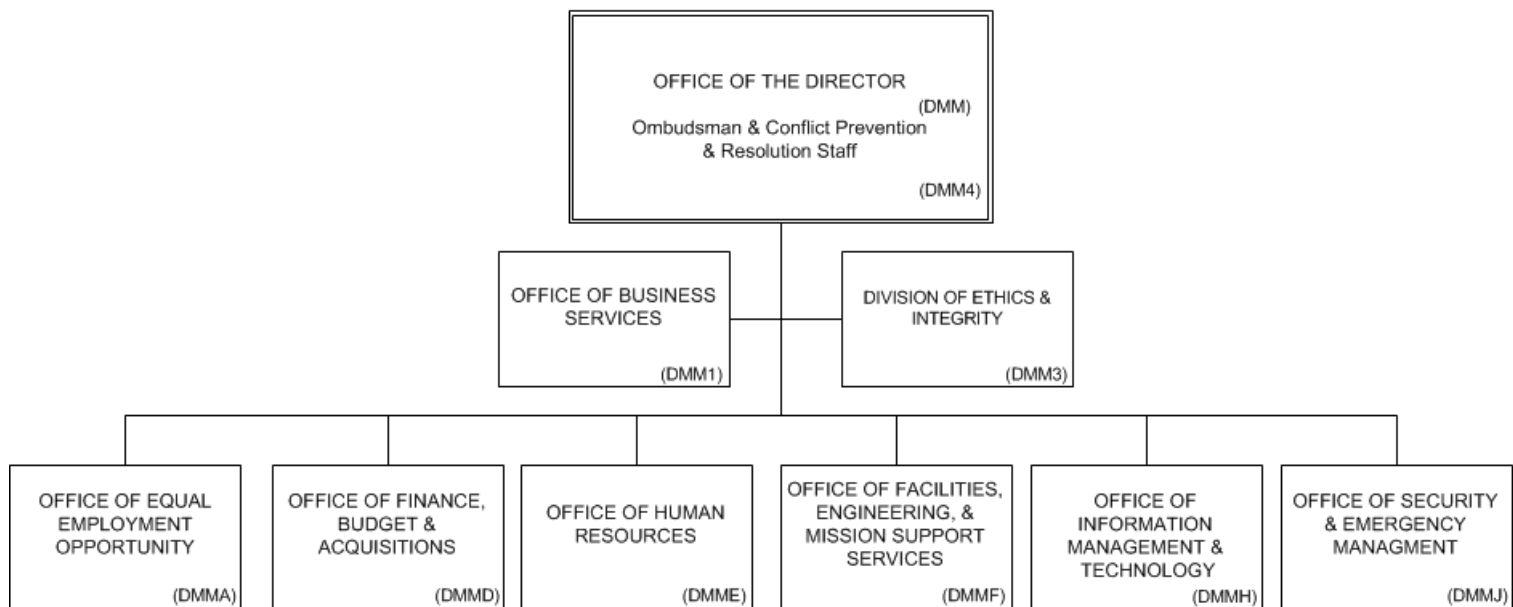
- A. Develops and coordinates conflict effective resolution processes and procedures.
- B. Provides confidential, informal assistance to employees and managers for conflict resolution for work-related concerns.

- C. Offers a variety of services and programs to address likely sources of conflict such as performance appraisals, harassment, mentoring relationships, and scientific collaboration.
- D. Operates as a neutral, independent, and confidential resource providing informal assistance to Agency scientists, administrators, and support staff in addressing work-related issues. Assists in resolving conflicts and addressing concerns prior to and within established grievance processes. (This came for conflict management)

3. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner of Food and Drugs, and effective on August 17, 2015.

FOOD AND DRUG ADMINISTRATION OFFICE OF OPERATIONS



STAFF MANUAL GUIDE 1117A.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 30, 2016

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, organization structure depicting all the organizational structures reporting to the Deputy Commissioner for Operations and Chief Operating Officer.

OFFICE OF OPERATIONS (DMM):

- Ombudsman & Conflict Prevention & Resolution Staff (DMM4)
- OFFICE OF BUSINESS SERVICES (DMM1)
- DIVISION OF ETHICS & INTEGRITY (DMM3)
- OFFICE OF EQUAL EMPLOYMENT OPPORTUNITY (DMMA)
- OFFICE OF FINANCE, BUDGET & ACQUISITIONS (DMMD)
- OFFICE OF HUMAN RESOURCES (DMME)
- OFFICE OF FACILITIES, ENGINEERING, & MISSION SUPPORT SERVICES (DMMF)
- OFFICE OF INFORMATION MANAGEMENT & TECHNOLOGY (DMMH)
- OFFICE OF SECURITY & EMERGENCY MANAGEMENT (DMMJ)