

SMG 1117A.1

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Effective Date: December 14, 2018

1. Office of Operations (DCN).

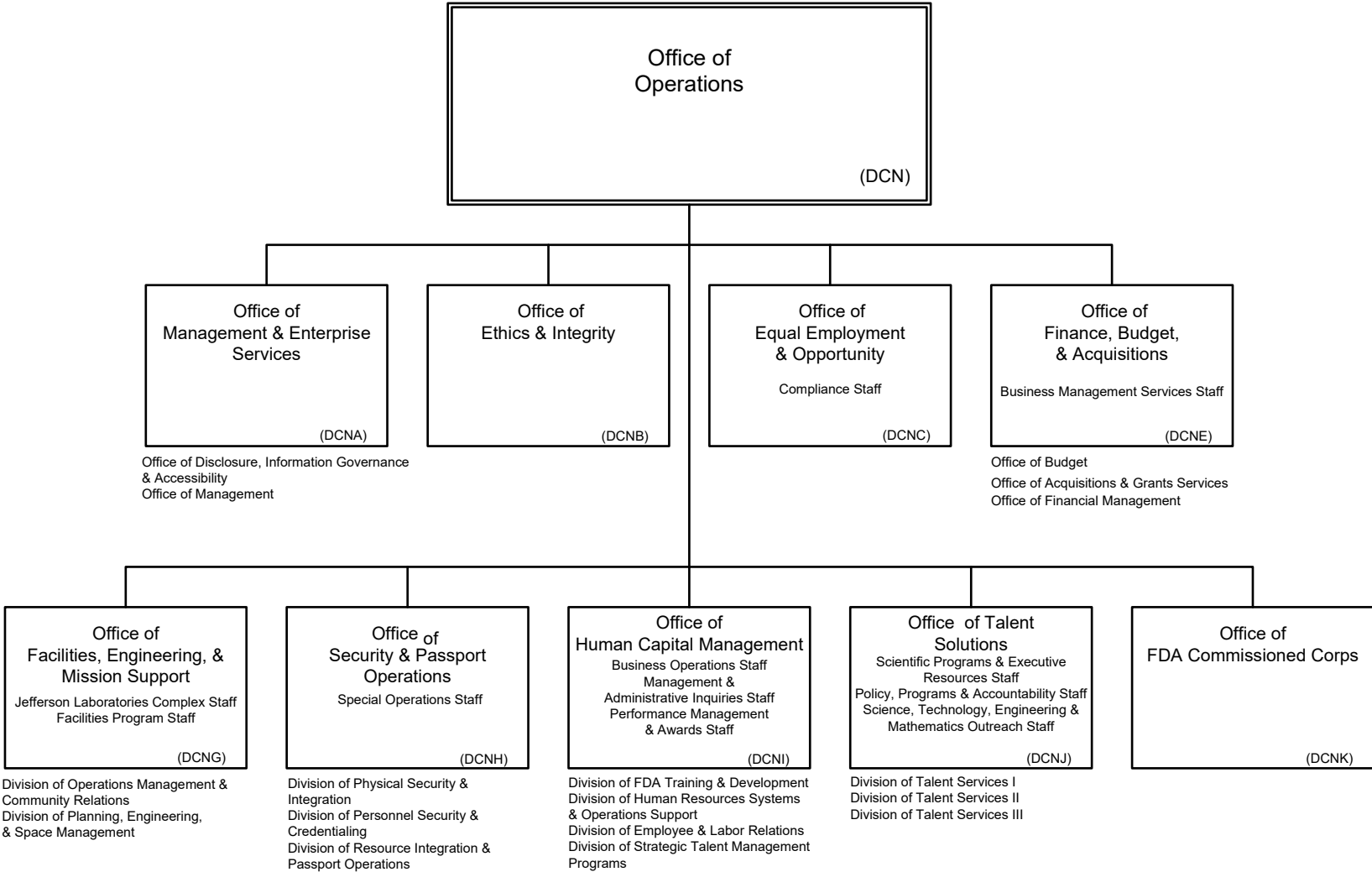
- A. Provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative operations to ensure the timely and effective implementation and high-quality delivery of services across the Food and Drug Administration (FDA), its Centers and Offices.
- B. Advises and assists the Commissioner, Deputy Commissioners, and other key officials on various administrative management and business activities.
- C. Chairs all FDA user fee programs which oversee financial management and provide financial management support.
- D. Participates in international initiatives to ensure FDA's capability and readiness to work with foreign counterparts in responding to international emergencies involving or impacting FDA-regulated products and to share information with international counterparts during such emergencies.
- E. Plans, directs, and coordinates a comprehensive financial management program for the FDA that encompasses the areas of automated financial systems, fiscal accounting, voucher audit, and financial reporting. Issues periodic reports regarding the status of the FDA'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 FDA 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 FDA Operations. Establishes and oversees implementation of the FDA information management policy and governance, procedures and processes to ensure the FDA is in compliance with the Clinger/Cohen Act.
- K. Establishes, directs and leads FDA 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.
- L. Provides oversight and advises on 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.
- M. Provides continued program effectiveness and technical expertise in support for various programs within the Office of Operations.
- N. 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. Authority and Effective Date.

The functional statements for the Office of Operations were approved by the Secretary for Health and Human Services, and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Operations**



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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 Director:

Office of Management and Enterprise Services (DCNA)

Office of Ethics and Integrity (DCNB)

Office of Equal Employment and Opportunity (DCNC)

Office of Finance, Budget, and Acquisitions (DCNE)

Office of Facilities Engineering and Mission Support Services (DCNG)

Office of Security and Passport Operations (DCNH)

Office of Human Capital Management (DCNI)

Office of Talent Solutions (DCNJ)

Office of FDA Commissioned Corps (DCNK)

The organizations below report to the Office of Management and Enterprise Services (DCNA):

Office of Disclosure, Information Governance and Accessibility

Office of Management

The organizations below report to the Office of Ethics and Integrity (DCNB):

The organizations below report to the Office of Equal Employment and Opportunity (DCNC):

Compliance Staff

The organizations below report to the Office of Finance, Budget, and Acquisitions (DCNE):

Business Management Services Staff

Office of Budget

Office of Acquisitions and Grants Services

Office of Financial Management

The organizations below report to the Office of Facilities, Engineering, and Mission Support Services (DCNG):

Jefferson Laboratories Complex Staff

Facilities Program Staff

Division of Operations Management and Community Relations

Division of Planning, Engineering and Space Management

The organizations below report to the Office of Security and Passport Operations (DCNH):

Special Operations Staff

Division of Physical Security and Integration

Division of Personnel Security and Credentialing

Division of Resource Integration and Passport Operations

The organizations below report to the Office of Human Capital Management (DCNI):

Business Operations Staff

Management and Administrative Inquiries Staff

Performance Management and Awards Staff

Division of FDA Training and Development

Division of Human Resources Systems and Operations Support

Division of Employee and Labor Relations

Division of Strategic Talent Management Programs

The organizations below report to the Office of Talent Solutions (DCNJ):

Scientific Programs and Executive Resources Staff

Policy, Programs, and Accountability Staff

Science, Technology, Engineering, & Mathematics Outreach Staff Division of Talent Services I

Division of Talent Services II

Division of Talent Services III

The organizations below report to the Office of FDA Commissioned Corps (DCNK):