

SMG 1261.10

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF MANAGEMENT

Effective Date: November 17, 2014

1. OFFICE OF MANAGEMENT (DKKNB).

- A. Monitors the development and operation of planning systems for Center activities and resource allocations and advises the Center Director on Center administrative policies and guidelines.
- B. Directs and counsels Center managers through program evaluation and forecasting.
- C. Plans and directs Center operations for financial, personnel, and facilities management, and Office services.
- D. Directs Center organization and management programs.
- E. Manages studies designed to improve processes and resource allocations in the Center.
- F. Advises the Center on contract and grant proposals, metrics, and management.
- G. Educates, mentors, and oversees development of Center for Drug Evaluation and Research (CDER) Manual Administrative Policies and Procedures Team, Administrative Office, and Front Office Staff.
- H. Provides oversight and strategic direction for Center for Drug Evaluation (CDER) activities relating to ethics policy and operational activities.
- I. Participates in resetting user fees, prepares Federal Register notices, and determines denominators.

2. STRATEGIC PROGRAMS AND INITIATIVE STAFF (DKKNB1).

- A. Leads CDER Executive Workforce Management including Executive Recruiting and Pipeline Development, Onboarding, Development and Workforce Analysis.
- B. Provides program and project management support for Center-wide and Office of Management administrative initiatives.
- C. Leads Office-wide business process analysis and business process planning for the improvement of Center-wide and Office of Management administrative programs.
- D. Facilitates Office of Management strategic planning and prioritization processes.
- E. Assesses organizational structure functionality, roles/responsibilities, performance measurement and reporting.
- F. Establishes Office of Management governance processes and mechanisms that enable alignment with mission and goals
- G. Facilitates the Office of Management Communications Program, including the coordination of internal/external communications for the Office of Management.
- H. Develops and implements a systematic and continuous Risk Management Program that proactively identifies, mitigates, reduces and/or eliminates risks to achieve the Office of Management mission.
- I. Leads and/or monitors the development and implementation of technological initiatives for the Office of Management.

3. ETHICS LIAISON STAFF (DKKNB2).

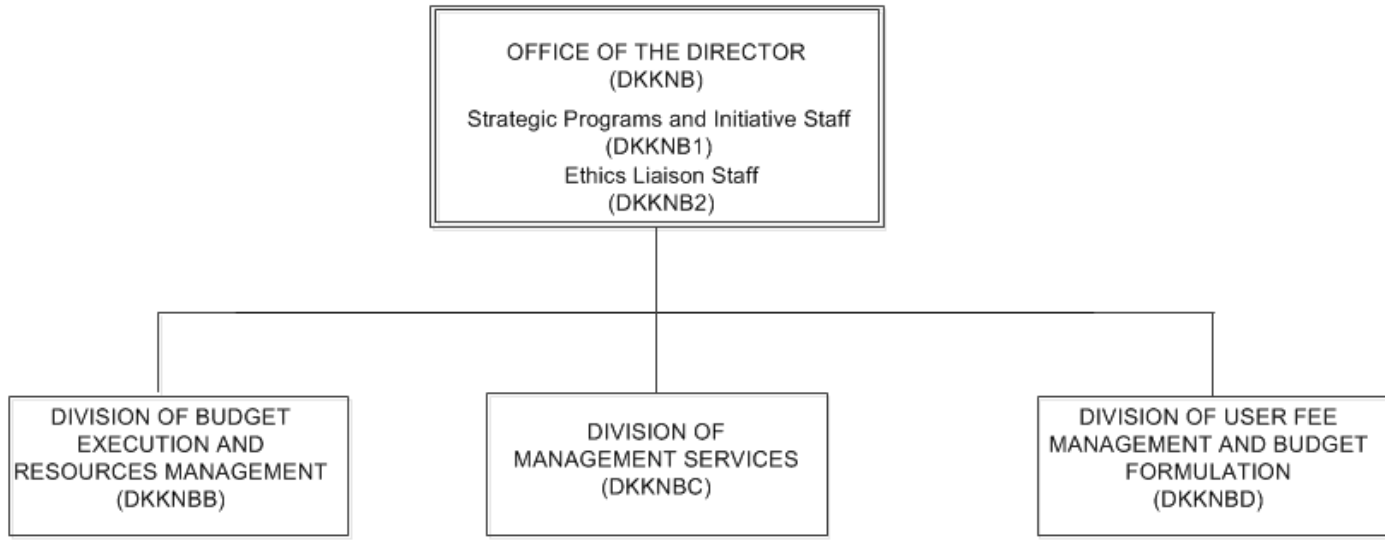
- A. Serves as primary Liaison and point of contact between the Center and the Agency's Ethics Office.
- B. Ensures staff compliance with Federal ethics laws, regulations and policies.
- C. Provides guidance to managers, supervisors, and employees on the statutes, regulations, and policies governing standards of conduct, outside activities, representational activities, post-employment, financial disclosure, and other ethics-related issues.
- D. Reviews and makes recommendations on outside activity requests by employees for conformance with statutes, regulations, and policies.

- E. Coordinates the public and confidential financial disclosure reporting systems in accordance with the regulations, including any supplemental reporting requirements and Health and Human Services (HHS) policies. This also includes providing oversight to ensure staff complete any required reports.
- F. Serves as a primary resource to staff to provide guidance and address questions, review forms/requests as well as distribute information on a variety of ethics topics.
- G. Organizes training and various forums to raise employee awareness to ensure compliance ethics requirements.
- H. Coordinates procurement integrity ethics provisions, including any and all procurement integrity advisory opinions.
- I. Assesses information provided by employees or others to ascertain the application of conflict of interest statutes, regulations, and policies and resolves actual or potential conflicts or the appearance of a loss of impartiality.
- J. Serves as a resource and provides oversight to ethics clearance for sponsored travel reimbursement authorities.

4. AUTHORITY AND EFFECTIVE DATE.

This Office was approved by the Director, Center for Drug Evaluation and Research, and effective on November 17, 2014.

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Strategic Programs and Initiatives Staff
- Ethics Liaison Staff
- DIVISION OF BUDGET EXECUTION AND RESOURCE MANAGEMENT
- DIVISION OF MANAGEMENT SERVICES
- DIVISION OF USER FEE MANAGEMENT AND BUDGET FORMULATION