

SMG 1118A.1

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF POLICY, PLANNING, LEGISLATION, AND ANALYSIS

Effective Date: September 26, 2014

1. OFFICE OF POLICY, PLANNING, LEGISLATION, AND ANALYSIS (DNN).

- A. Advises the Commissioner and other key agency officials on matters relating to agency policy, regulations development, legislative issues, budget formulation, risk communication, and planning and evaluation activities.
- B. Provides strategic policy direction, planning, and data-driven analysis for Agency to more effectively and efficiently protect and promote public health.
- C. Acts as Office of the Commissioner and Agency resource for quantitative research and analysis on emerging issues, including helping to develop policy options and understanding the expected impact of those options on public health outcomes.
- D. Acts as Agency lead for interactions with Reagan-Udall Foundation (RUF), leads and coordinates Agency strategy for RUF's public-private collaborations to promote safety and better evidence, improve regulatory science processes and build scientific capacity.
- E. Manages the Government Accountability Office (GAO) and Office of the Inspector General (OIG) studies and interactions on behalf of the Agency.
- F. Develops significant and cross-cutting policy and engages in strategic problem solving.
- G. Serves as Agency's focal point for the development, coordination, oversight, and processing of regulations, guidance and other policy documents.
- H. Conducts economic analyses, program evaluations, and special studies.
- I. Leads overall Agency strategic, performance and business process planning, including the development of performance measures.

- J. Leads and coordinates agency-wide efforts to plan, evaluate and improve Agency risk communication.

2. MANAGEMENT AND OPERATIONS STAFF (DNN1).

- A. Provides overall guidance and leadership on cross-cutting resource and strategic management activities including budget execution, formulation, internal controls and process improvement as well as other management analysis needs.
- B. Coordinates and delivers a wide range of administrative services to the Directorate including human capital, budgetary, information technology, and program management activities. Serves as liaison on human capital and performance management initiatives.
- C. Conducts special projects and assignments on behalf of the Deputy Commissioner in support of the office's priorities and management initiatives.

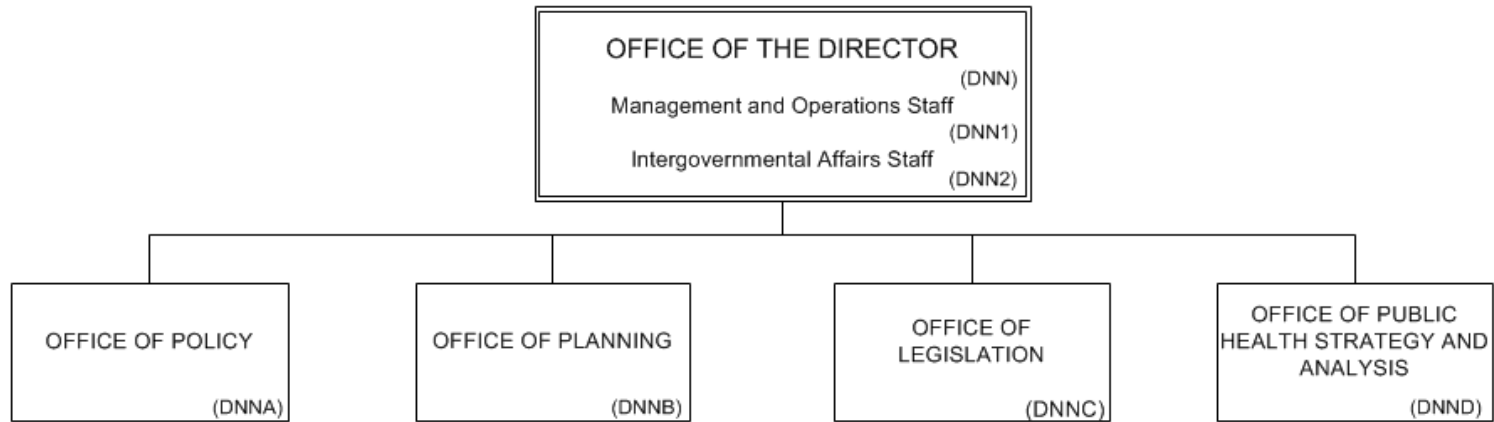
3. INTERGOVERNMENT AFFAIRS STAFF (DNN2).

- A. Coordinates strategically across Agency Directorates, Centers and Offices to respond to inquiries from States and to engage in proactive outreach to States on critical Agency policy issues.
- B. Develops collaborative relationships with policy making State and Tribal partners to ensure engagement and representation on Agency policy issues.
- C. Collaboratively engage in proactive outreach to policy making state partners on important cross-cutting Agency policy issues as well as facilitate resolution to concerns around policy issues.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Human Services, and effective on September 26, 2014.

FOOD AND DRUG ADMINISTRATION OFFICE OF POLICY, PLANNING, LEGISLATION, AND ANALYSIS



STAFF MANUAL GUIDE 1118A.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Policy, Planning, Legislation, and Analysis organization structure depicting all the organizational structures reporting to the Office Director.

Office of the Director