

SMG 1118.6

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF POLICY, PLANNING, LEGISLATION, AND ANALYSIS

OFFICE OF POLICY

Effective Date: September 26, 2014

1. OFFICE OF POLICY (DNNA).

- A. Leads agency-wide strategic policy initiatives.
- B. Advises and assists the Commissioner and other key agency officials on matters relating to agency policy, and on regulations and guidance development.
- C. Serves as the lead Agency focal point for developing broad agency policy.
- D. Provides strategic policy direction and develops innovative policies for Agency to more effectively and efficiently protect and promote public health.
- E. Develops significant and cross-cutting policy and engages in strategic problem solving.
- F. Oversees, directs, and coordinates the agency's rulemaking and guidance development activities.
- G. Serves as the agency focal point for communications and policies with regard to development of regulations and guidance.
- H. Initiates new and more efficient systems and procedures to accomplish agency goals in the rulemaking and guidance development processes.
- I. Administers Agency's Quality System for Regulations.
- J. Reviews agency policy documents to ensure consistency in statements regarding agency policies.
- K. Provides strategic policy direction for agency budget formulation.

2. POLICY DEVELOPMENT AND COORDINATION STAFF (DNNA1).

- A. Leads the development of cross-cutting or broad agency policies and serves as a cross-agency think tank to develop innovative policies.
- B. Advises and assists the Commissioner and other key agency officials concerning information that may affect current or proposed Agency policies.
- C. Advises the Commissioner and other key agency officials on the formulation of broad agency policy.
- D. Engages in strategic problem solving.
- E. Serves as agency liaison for intergovernmental policy development.
- F. Coordinates the development, review, and clearance of regulations and guidances.
- G. Reviews policy documents to assess and achieve consistency in policies across documents.
- H. Establishes procedures for agency policy formulation and coordinates policy formulation activities throughout the agency.
- I. Negotiates the resolution of policy issues involving more than one component of the agency.
- J. Coordinates the review and analysis of policies.
- K. Initiates and participates in interagency discussions on agency regulations, plans, and policies to improve coordination of Federal, State, or local agencies on a specific regulation or in developing an effective alternative approach.
- L. Serves on agency task forces that are critical elements in the initiation, study, and resolution of priority policy issues.

3. REGULATIONS POLICY AND MANAGEMENT STAFF (DNNA2).

- A. Serves as the agency's focal point with the DHHS, Office of Management and Budget, and other Federal agencies for policies and programs concerning regulations development and for the receipt of and response to other agency comments on Agency policy documents.

- B. Reviews proposed regulations, final regulations, and other agency documents to be published in the Federal Register. Ensures regulations are necessary; consistent with established agency policy; clearly written; enforceable; coordinated with other agency components, the Office of the Chief Counsel, and Federal, State, and local government agencies; appropriately responsive to public participation requirements and applicable executive orders; and responsive to any applicable requirements for assessment of economic and environmental effects.
- C. Coordinates, with other agency components, the evaluation of existing regulations to determine whether they are efficiently and/or effectively accomplishing their intended purpose. Identifies and makes recommendations to address regulations that require revision to correspond with current standards and those that should be revoked due to obsolescence.
- D. Resolves regulatory policy disagreements between agency components during the preparation of Federal Register documents.
- E. Manages the Agency's regulation and guidance review and clearance processes.
- F. Coordinates the agency's Unified Agenda and Regulatory Plan entries.
- G. Provides policy direction for and assistance with the agency's Federal Register Document Tracking System.

4. REGULATIONS EDITORIAL SECTION (DNNA21).

- A. Agency's official liaison with the Office of Federal Register. Edits, processes, and prepares finished manuscript material for the issuance of agency proposed and final regulations and other documents published in the Federal Register. Maintains a database that contains Agency's Federal Register publication information.
- B. Provides all Federal Register document development support functions (including cross-referencing, record retention, incorporation by reference, document tracking, and agency master print books of current CFR materials). Maintains the Federal Register Drafting Resources section of the Agency intranet, which includes templates, standard paragraphs and other resources.
- C. Controls numbering and organization of agency codified material to ensure proper structure of regulations being issued.

- D. Provides Agency Government Printing Office Style Manual guidance to Agency staff as issues and questions arise and resolves editorial issues outside of the boundaries of established style guides. To the extent that there are disagreements between Agency and the Office of the Federal register, negotiates editorial changes for Agency's Federal Register documents with the Office of the Federal Register.
- E. Serves as Agency's focal point for electronic signatures, and submission, of Federal Register documents.

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
OFFICE OF POLICY

OFFICE OF THE DIRECTOR	(DNNA)
Policy Development & Coordination Staff	(DNNA1)
Regulations Policy & Management Staff	(DNNA2)
Regulations Editorial Section	(DNNA21)

STAFF MANUAL GUIDE 1118.6
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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

OFFICE OF THE DIRECTOR--(DNNA):

- Policy Development and Coordination Staff--(DNNA1)
- Regulations Policy and Management Staff--(DNNA2)
- Regulations Editorial Section--(DNNA21)