

**SMG 1118A.6**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of the Commissioner**

**Office of Policy, Legislation and International Affairs**

**Office of Policy**

Effective Date: December 14, 2018

**1. Office of Policy (DCOE).**

- A. Leads Food and Drug Administration (FDA)-wide strategic policy initiatives.
- B. Advises and assists the Deputy Commissioner, the Commissioner and other key FDA officials on matters relating to FDA policy, and on regulations and guidance development.
- C. Provides strategic policy direction and develops innovative policies for FDA to more effectively and efficiently protect and promote public health.
- D. Oversees and coordinates the FDA's rulemaking and guidance development activities.
- E. Serves as the FDA focal point for communications and policies with regard to development of regulations and guidance.
- F. Initiates new and more efficient systems and procedures to accomplish FDA goals in the rulemaking and guidance development processes.
- G. Administers FDA's Quality System for Regulations.
- H. Reviews FDA policy documents to ensure consistency in statements regarding FDA policies.

**2. Policy Engagement and Coordination Staff (DCOE1)**

- A. Advises and assists the Deputy Commissioner and other key FDA officials concerning information that may affect current or proposed FDA policies.
- B. Engages in strategic problem solving.

- C. Serves as FDA liaison for intergovernmental policy development.
- D. Coordinates the review, and clearance of regulations and guidances.
- E. Reviews policy documents to assess and achieve consistency in policies across documents.
- F. Establishes procedures for FDA policy formulation and coordinates policy formulation activities throughout the FDA.
- G. Negotiates the resolution of policy issues involving more than one component of the FDA.
- H. Initiates and participates in interagency discussions on FDA regulations, plans, and policies to improve coordination of Federal, State, or local agencies on a specific regulation or in developing an effective alternative approach.
- I. Serves on FDA task forces that are critical elements in the initiation, study, and resolution of priority policy issues.

### **3. Regulations Policy and Management Staff (DCOE2)**

- A. Serves as the FDA's focal point with the Department of Health and Human Services (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 FDA policy documents.
- B. Reviews proposed regulations, final regulations, and other FDA documents to be published in the Federal Register. Ensures regulations are necessary; consistent with established FDA policy; clearly written; enforceable; coordinated with other FDA 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 FDA 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 FDA components during the preparation of Federal Register documents.

- E. Manages the FDA's regulation and guidance review and clearance processes.
- F. Coordinates the FDA's Unified Agenda and Regulatory Plan entries.
- G. Provides policy direction for and assistance with the FDA's Federal Register Document Tracking System.

#### **4. Regulations Editorial Section (DCOE21)**

- A. FDA's official liaison with the Office of Federal Register. Edits, processes, and prepares finished manuscript material for the issuance of FDA proposed and final regulations and other documents published in the Federal Register. Maintains a database that contains FDA'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 FDA master print books of current Code of Federal Regulation (CFR) materials). Maintains the Federal Register Drafting Resources section of the FDA intranet, which includes templates, standard paragraphs and other resources.
- C. Controls numbering and organization of FDA codified material to ensure proper structure of regulations being issued.
- D. Provides FDA Government Printing Office Style Manual guidance to FDA 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 FDA and the Office of the Federal register, negotiates editorial changes for FDA's Federal Register documents with the Office of the Federal Register.

Serves as FDA's focal point for electronic signatures, and submission, of Federal Register documents.

#### **5. Authority and Effective Date.**

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

**Department of Health and Human Services  
Food and Drug Administration  
Office of the Commissioner  
Office of the Policy, Legislation and International Affairs  
Office of Policy**

Office of  
Policy

Policy Development & Coordination Staff  
Regulations Policy & Management Staff  
Regulations Editorial Section

(DCOE)

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Policy, Legislation and International Affairs, Office of Policy organization structure depicting all the organizational structures reporting to the Director.

These organizations report to the Office of Policy (DCOE):

- Policy Engagement & Coordination Staff
- Regulations Policy Management Staff
- Regulations Editorial Section