

**SMG 1113A.1**

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

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF THE COMMISSIONER**

**OFFICE OF EXECUTIVE SECRETARIAT**

Effective Date: 01/20/2012

**1. OFFICE OF EXECUTIVE SECRETARIAT (DAB).**

- A. Advises the Commissioner and other key Agency officials on activities that affect Agency wide programs, projects, and initiatives. Informs appropriate agency staff of the decisions and assignments made by the Commissioner, the Deputy Commissioners, the Chief of Staff and the Associate Commissioners.
- B. Develops and maintains management information necessary for monitoring the Commissioner's and Agency's goals and priorities.
- C. Assures that materials in support of recommendations presented for the Commissioner's consideration are comprehensive, accurate, fully discussed and encompass the issues involved.
- D. Provides correspondence control for the Commissioner and controls and processes all agency public correspondence directed to the Commissioner. Develops and operates tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.
- E. Provides direct support to the Commissioner, Deputy Commissioners, Chief of Staff and Associate Commissioners including briefing materials, background information for meetings, responses to outside inquiries, and maintenance and control of the Commissioner's working files.
- F. Performs Agency-wide assignments involving complex problems and issues related to agency programs, strategies and activities, including preparation of special reports for the Department.
- G. Coordinates the agency's communications with the Public Health Service, HHS, and the White House including correspondence for the Assistant Secretary for Health and Secretarial signatures.

## **2. FREEDOM OF INFORMATION STAFF (DAB2).**

- A. Serves as the Agency expert and focal point for headquarters and field personnel in the development and implementation of effective policies and procedures in accordance with the Freedom of Information Act (FOIA), the Privacy Act, FDA regulations, and other relevant statutes. Includes establishing Agency-wide policies and providing guidance and leadership for the FOIA and Privacy Act programs. Serves as the Agency's official Call Center and Public Liaison Office for FOIA matters.
- B. Receives, reviews, controls, coordinates and routes all FOI requests to the proper action office; designs and implements control mechanisms to assure FOI and Privacy Act inquiries are processed and responded to within established timeframes.
- C. Receives and reviews all recommendations for denials submitted by headquarters and field FOI officers. Analyzes the proposals and evaluates the potential need for supplemental information and/or changes in the recommendations, and coordinates with the submitting office before issuance of a denial for a grant of access, expedited processing, or fee waivers.
- D. Analyzes, compiles, and prepares reports on privacy and FOI activities in the Agency for the annual reports to the Department and for other reporting requirements.
- E. Maintains copies of Agency manuals, indices, and other records required to be on public display in the public reading room and/or the e-reading rooms through Agency websites.

## **3. DOCKETS MANAGEMENT STAFF (DAB3).**

- A. Receives, examines and processes submissions required or permitted in Agency administrative proceedings; establishes and maintains docket files containing Agency official records relating to an administrative proceeding. Disseminates submissions to appropriate offices for action. Routinely coordinates activities of the branch with other appropriate components.
- B. Serves as the Agency expert on requirements for submissions required or permitted in Agency administrative proceedings. Participates in the development of regulations and policy impacting on Agency administrative proceedings and the release of information under the Freedom of Information Act (FOIA).
- C. Provides staff support for Agency rulemaking activities. Determines

compliance of petitions, comments, request for hearings, motions, briefs, and objections with Agency regulations.

- D. Maintains and operates a public reading room to make official Agency records available to any interested party, and provides copies upon request, under the provisions of the FOIA. Provides electronic access to these records, via the Internet, and other means, as required by the Electronic Freedom of Information Act (EFOIA).
- E. Provides information access via the Intranet and other means to FDA personnel for Dockets Management materials and to copyrighted documents.
- F. Plans and conducts Agency-wide analytical reviews and studies to assess and manage information and access concerns. Makes recommendations and assists in the implementation of the recommendations.

#### **4. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Office were approved by the Commissioner of Food and Drugs, effective January 20, 2012.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF THE COMMISSIONER  
OFFICE OF THE EXECUTIVE SECRETARIAT**

OFFICE OF THE DIRECTOR

Freedom of Information Staff  
Dockets Management Staff

---

STAFF MANUAL GUIDE 1113A.1  
ORGANIZATIONS AND FUNCTIONS  
EFFECTIVE DATE: January 20, 2012

The following is the Food and Drug Administration, Office of the Commissioner, Office of the Executive Secretariat organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Freedom of Information Staff
- Dockets Management Staff