

SMG 1112.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF THE CHIEF COUNSEL

Effective Date: 08/07/2009

1. OFFICE OF THE CHIEF COUNSEL (DAA).

- A. Subject to the professional supervision and control of the General Counsel, Department of Health and Human Services (HHS), and represents FDA in court proceedings and administrative hearings with respect to programs administered by FDA.
- B. Provides legal advice and policy guidance for programs administered by FDA.
- C. Acts as liaison to the Department of Justice and other Federal agencies for programs administered by FDA.
- D. Drafts or reviews proposed and final regulations, Federal Register notices, and other documents prepared by FDA.
- E. Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to FDA.
- F. Reviews proposed legislation affecting FDA that originates in HHS or on which Congress requests the views of the Department.
- G. Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the Office of the Chief Counsel.

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Secretary of the Department of Health and Human Services on August 7, 2009.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/23/2007	N/a	OC/OO/ OM/OMP	Secretary of the Department of Health and Human Services
Revision	08/07/2009	N/a	OC/OA/OM/ OBOHCP/OMP	Secretary of the Department of Health and Human Services

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

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