

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 the Chief Counsel

Effective Date: December 14, 2018

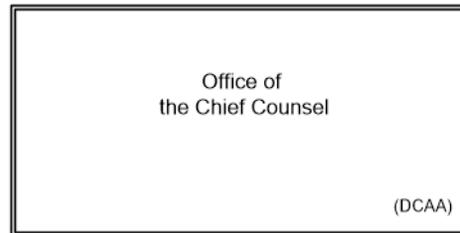
1. Office of the Chief Counsel (DCAA).

- A. Subject to the professional supervision and control of the General Counsel, Department of Health and Human Services (HHS), and represents the Food and Drug Administration (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 the Office of the Chief Counsel 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 Chief Counsel**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Chief Counsel organization structure depicting all the organizational structures reporting to the Chief Counsel:

Office of the Chief Counsel (DCAA)