

SMG 1121.63

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Partnerships and Operational Policy

Office of Strategic Planning and Operational Policy

Effective Date: December 14, 2018

1. Office of Strategic Planning and Operational Policy (DCIHC).

- A. Provides direction and counsel to the Associate Commissioner for Regulatory Affairs (ACRA), Deputy ACRA, and other Office of Regulatory Affairs (ORA) officials concerning information that may affect current or proposed Food and Drug Administration (FDA) policies.
- B. Supports development of new or modified FDA compliance policies and coordinates the development of regulatory procedures for all products regulated by the FDA.
- C. Directs and coordinates the preparation and maintenance of operational policy publications including the Compliance Policy Guides Manual and the Regulatory Procedures Manual.
- D. Establishes compliance and enforcement strategies for inclusion in Compliance Programs in collaboration with Centers and Office of Chief Counsel.
- E. Develops ORA policy and coordinates information sharing with foreign governments, Federal agencies, state and local government agencies, and other stakeholders.
- F. Analyzes and evaluates field performance data and overall accomplishments.
- G. Facilitates the development of ORA's strategic priorities and oversees its performance management process.

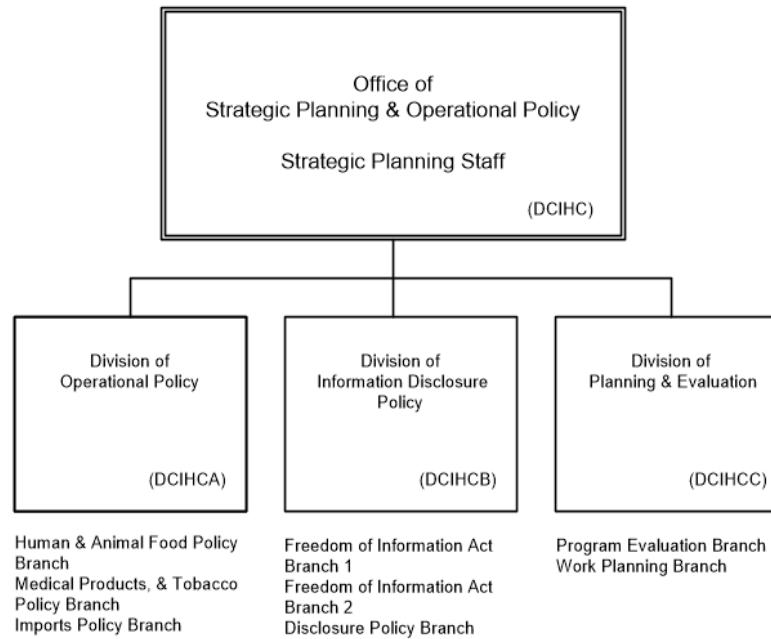
2. Strategic Planning Staff (DCIHC1)

- A. Develops and manages ORA's strategic planning and performance management process, including coordinating the development of ORA's strategic priorities and plans with input from relevant ORA offices. Ensures ORA's strategic priorities support those of the FDA. Integrates ORA strategic priorities within the budget formulation cycle.
- B. Develops performance goals and measures to identify progress toward both short- and long-term objectives. Monitors ORA's progress in achieving those objectives and performs gap analysis on ORA's performance measures. Incorporates findings into the development and improvement of ORA's strategic priorities.
- C. Identifies appropriate ORA stakeholders for each of ORA's goals and objectives. Works with the appropriate offices to develop concrete strategies and facilitates the development of Office-level action plans in support of ORA's priorities.

3. Authority and Effective Date.

The functional statements for the Office of Strategic Planning and Operational 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 Regulatory Affairs
Office of Partnerships and Operational Policy
Office of Strategic Planning and Operational Policy**



Staff Manual Guide 1121.63
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Partnerships and Operational Policy, Office of Strategic Planning and Operational Policy organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Strategic Planning and Operational Policy (DCIHC):

Strategic Planning Staff

Division of Operational Policy (DCIHCA)

Division of Information Disclosure Policy (DCIHCB)

Division of Planning & Evaluation (DCIHCC)

These organizations report to the Division of Operational Policy (DCIHCA)

Human & Animal Food Policy Branch

Medical Products, & Tobacco Policy Branch

Imports Policy Branch

These organizations report to the Division of Information Disclosure Policy (DCIHCB)

Freedom of Information Act Branch 1

Freedom of Information Act Branch 2

Disclosure Policy Branch

These organizations report to the Division of Planning & Evaluation (DCIHCC)

Program Evaluation Branch

Work Planning Branch