

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

Division of Operational Policy

Effective Date: December 14, 2018

1. Division of Operational Policy (DCIHCA).

- A. Reviews proposed regulations, final regulations, and other Food and Drug Administration (FDA) documents regarding the practice and policies of the Office of Regulatory Affairs' (ORA) surveillance and regulatory operations.
- B. Addresses intra-agency regulatory policy issues. Coordinates the activities of the Compliance Policy Council regarding FDA regulatory policy.
- C. Reviews all FDA-planned regulatory initiatives in consultation with other ORA components to determine the need for an enforcement strategy. Reviews initiatives and makes recommendations concerning the adequacy of enforcement strategies.

2. Human and Animal Food Policy Branch (DCIHCA1)

- A. Supports the development of, coordinates, and manages new or modified FDA compliance policies, procedures, and guidance for human and animal food regulated by the FDA.
- B. Reviews all human and animal food-related regulatory initiatives to determine the need for an enforcement strategy.

3. Medical Products and Tobacco Policy Branch (DCIHCA2)

- A. Supports the development of, coordinates, and manages new or modified FDA compliance policies, procedures and guidance for medical products and tobacco products regulated by the FDA.
- B. Reviews all medical products and tobacco-related regulatory initiatives to determine the need for an enforcement strategy.

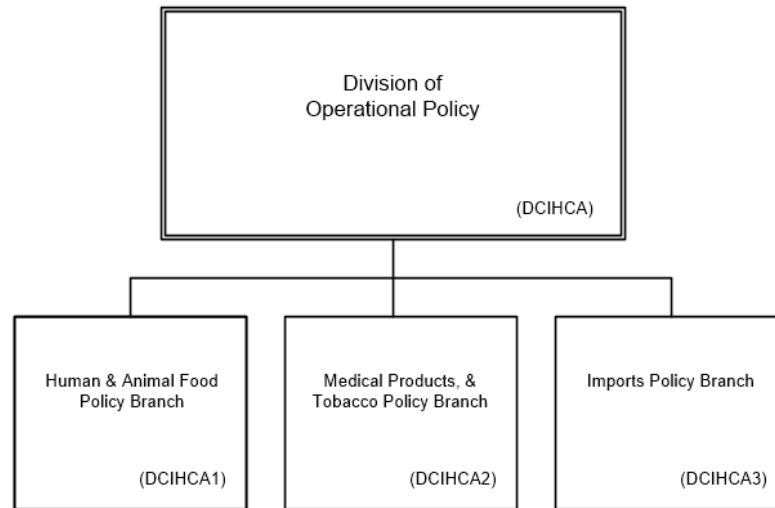
4. Imports Policy Branch (DCIHCA3)

- A. Supports the development of, coordinates, and manages new or modified FDA compliance policies, procedures and guidance for imported products regulated by the FDA.
- B. Reviews all import-related regulatory initiatives to determine the need for an enforcement strategy.

5. Authority and Effective Date.

The functional statements for the Division of 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
Division of Operational Policy**



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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, Division of Operational Policy organization structure depicting all the organizational structures reporting to the Director:

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

Human & Animal Food Policy Branch (DCIHCA1)

Medical Products, & Tobacco Policy Branch (DCIHCA2)

Imports Policy Branch (DCIHCA3)