SMG 1121.632

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 Information Disclosure Policy

Effective Date: December 14, 2018

1. Division of Information Disclosure Policy (DCIHCB).

A. Reviews proposed regulations, final regulations, and other Food and Drug Administration (FDA) documents relative to the practice and policies of sharing agency information.

B. Develops, coordinates, and oversees Office of Regulatory Affairs (ORA) engagement on Government Accountability Office (GAO) studies, Department of Health and Human Services (DHHS) and Office of the Inspector General (OIG) audits.

C. Reviews, establishes, coordinates, collaborates with ORA's Partnerships program on interagency information sharing agreements, including agreement with other federal agencies made pursuant to 21 C.F.R. § 20.85 and agreements with state and local agencies made pursuant to 21 C.F.R. § 20.88. Provides training on information agreements to stakeholders.

D. Serves as the ORA focal point for handling testimony requests, Department of Justice (DOJ) litigation holds, processing legal demands, subpoenas, court orders, Memoranda of Understanding (MOU), and litigation matters within the purview of the Agency, pursuant to 21 C.F.R. § 20.1 and 20.2.

E. Coordinates Freedom of Information Act (FOIA) activities and prepares responses to FOIA requests.

2. Freedom of Information Act Branch 1 (DCIHCB1)

A. Identifies and redacts documents related to inspections of human and animal food and imported products that are requested through FOIA.

B. Serves as subject matter experts on the redaction of sensitive information, including trade secret and confidential commercial information.

3. Freedom of Information Act Branch 2 (DCIHCB2)

A. Identifies and redacts documents related to inspections of medical products, tobacco products, and the bioresearch monitoring program that are requested through FOIA.

B. Serves as subject matter experts on the redaction of sensitive information, including trade secret and confidential commercial information.

4. Disclosure Policy Branch (DCIHCB3)

A. Supports, coordinates, and manages new or modified FDA policies and regulatory procedures for information sharing with all stakeholders.

B. Develops guidelines for ORA and coordinates the implementation of provisions related to the Privacy Act of 1974 and FOIA.

C. Coordinates ORA's responses to GAO studies and OIG audits and develops guidelines and processes for ensuring clear, consistent, and contextually relevant responses.

5. Authority and Effective Date.

The functional statements for the Division of Information Disclosure Policy were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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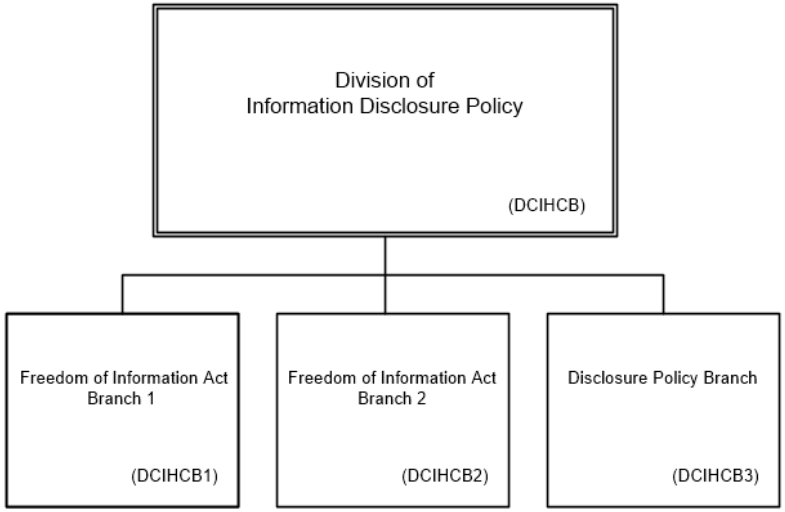

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Partnerships and Operational Policy, Office of Strategic Planning and Operational Policy, Division of Information Disclosure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

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

Freedom of Information Act Branch 1 (DCIHCB1)

Freedom of Information Act Branch 2 (DCIHCB2)

Disclosure Policy Branch (DCIHCB3)