SMG 1117A.264

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Management and Enterprise Services

Office of Disclosure, Information Governance, and Accessibility

Division of Information Disclosure

Effective Date: May 13, 2024

1. Division of Information Disclosure (DCNAFB)

A. Supports information sharing, disclosure operations, and compliance with the Freedom of Information Act (FOIA).

B. Reviews proposed guidance documents, regulations, final regulations, and other FDA documents relative to the practice and policies of sharing agency information.

C. Serves as the Food and Drug Administration (FDA) lead in reviewing, establishing, coordinating, and collaborating with FDA offices and centers, and agency stakeholders on interagency information sharing agreements, including but not limited to, agreements with other federal agencies made pursuant to 21 C.F.R. Section 20.85, agreements with state and local agencies made pursuant to 21 C.F.R. Section 20.88.

D. Consults with FDA Office and Centers, including OGPS, on agreements with international organizations made pursuant to 21 C.F.R. Section 20.89.

E. Serves as the FDA focal point for handling testimony requests, processing legal demands, subpoenas, court orders, and litigation matters within the purview of the FDA, pursuant to 21 C.F.R. Section 20.1 and 20.2.

F. Provides training on information sharing and agreements to internal and external stakeholders.

G. Reviews all FDA Memoranda of Understanding (MOU) for information sharing content and coordinates with Office of Chief Counsel Disclosure to ensure compliance with laws and regulations.

H. Coordinates FOIA activities and prepares responses to FOIA requests by researching the inventory for responsive records, reviewing, and redacting the records to comply with FDA laws and regulations, and negotiating with requestors.

I. Analyzes FOIA processes and data and develops procedures, guides, and tools to continuously improve and promote consistency in FDA operations.

J. Processes and responds to agency stakeholder information requests by researching, reviewing, and redacting documents related to records that are requested from state, federal, or foreign partners, for litigation, or in response to a congressional inquiry to comply with FDA laws and regulations, and negotiating with stakeholders.

K. Redacts records for public posting and coordinates with the responsible web team for 508 compliance and web posting.

2. Freedom of Information Act Branch (DCNAFB1)

A. Coordinates FOIA activities and prepares responses to FOIA requests by researching the inventory for responsive records, reviewing, and redacting the records to comply with FDA laws and regulations, and negotiating with requestors.

B. Identifies and redacts documents related to inspections, compliance, and analysis of human and animal food and imported products that are requested through FOIA.

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

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

E. Analyzes FOIA processes and data and develops procedures, guides, and tools to continuously improve and promote consistency in FDA operations.

3. Disclosure Branch (DCNAFB2)

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

B. Develops policies, procedures and guidelines and coordinates the implementation of provisions related to the Privacy Act of 1974 and FOIA.

C. Analyzes FOIA processes and data and develops procedures, guides, and tools to continuously improve and promote consistency in FDA operations.

D. Coordinates FOIA activities and prepares responses to FOIA requests by researching the inventory for responsive records, reviewing, and redacting the records to comply with FDA laws and regulations, and negotiating with requestors.

E. Identifies and redacts documents related to the most complex and sensitive records including but not limiting to records related to inspections, compliance, and analysis of human and animal food and imported products that are requested through FOIA.

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

G. Processes and responds to agency stakeholder information requests by researching, reviewing, and redacting documents related to records that are requested from state, federal, or foreign partners, for litigation, or in response to a congressional inquiry to comply with FDA laws and regulations, and negotiating with stakeholders.

H. Collaborates, consults, and negotiates with other federal, state, local, and foreign regulators for disclosure of information.

4. Authority and Effective Date.

The functional statements for the Division of Information Disclosure were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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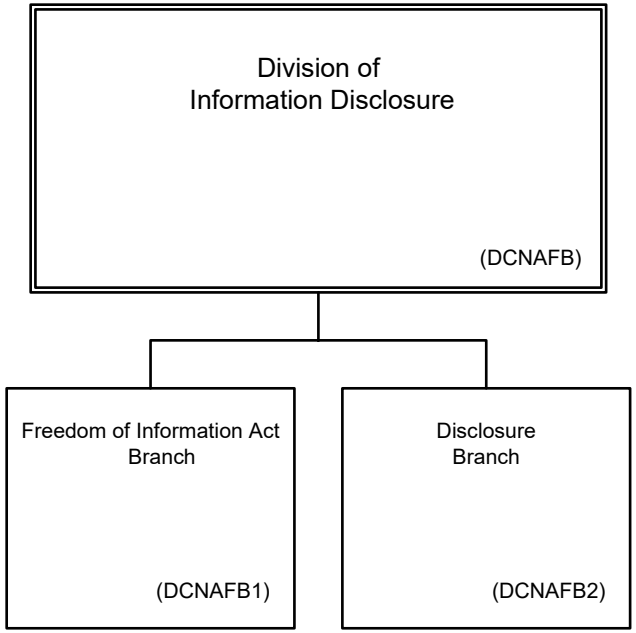

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Management and Enterprise Services, Office of Disclosure, Information Governance, and Accessibility, Division of Information Disclosure organization structure depicting all the organizational structures reporting to the Director:

Freedom of Information Act Branch (DCNAFB1)
Disclosure Branch (DCNAFB2)