

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

Effective Date: May 13, 2024

1. Office of Disclosure, Information Governance, and Accessibility (DCNAF).

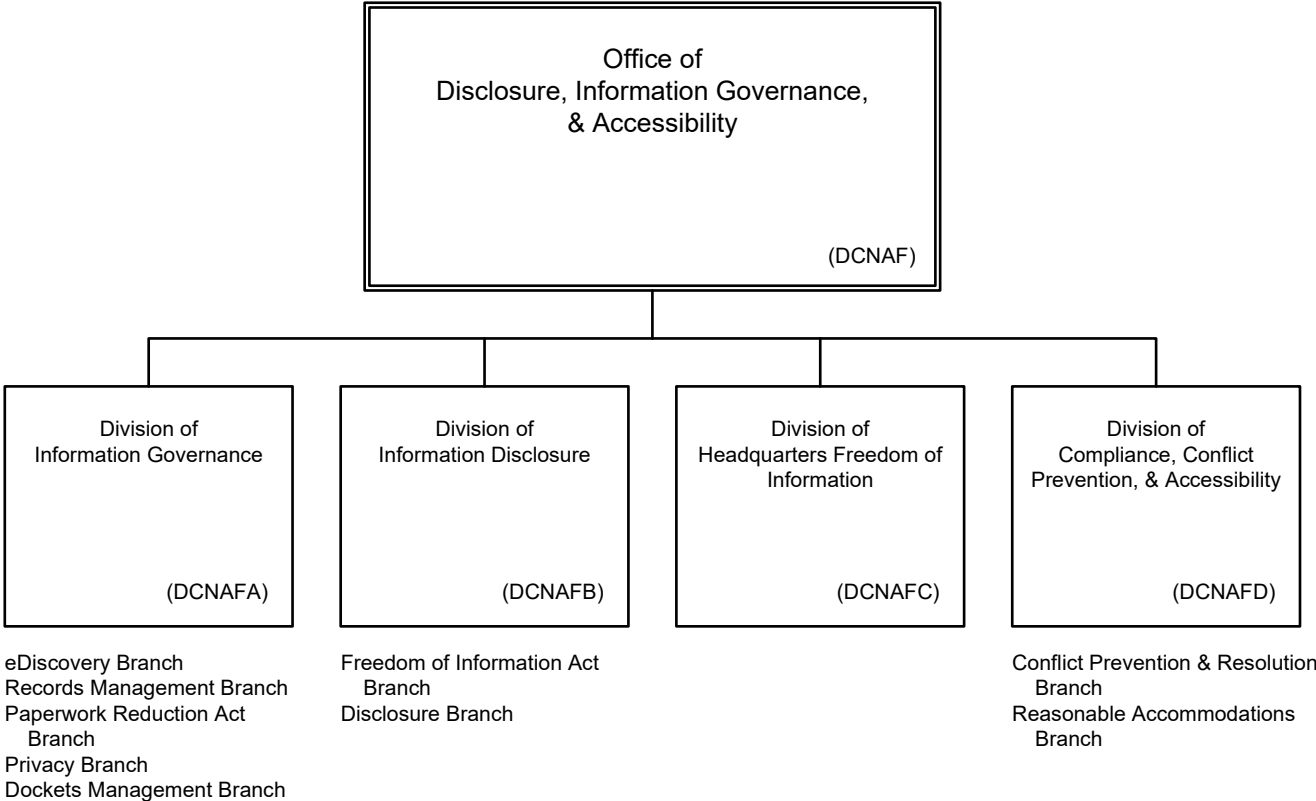
- A. Manages and protects Food and Drug Administration (FDA's) valuable records and information to ensure that internal and external requests for information are done in accordance with applicable laws, regulations, rules, and directives.
- B. Provides expertise on history of FDA and predecessors; and is a key resource for historical records and resources used for FDA communication and programs.
- C. Provides oversight to the docket management activities to ensure compliance with policy and guidelines. Represents FDA interests as applicable in the Federal Dockets Management System (FDMS) and Regulations.gov working groups. Provides administrative control and support for FDA FDMS including user access, docket creation, and document upload.
- D. Ensures requirements mandated by the Paperwork Reduction Act of 1995 are followed across FDA, developing policy, procedure, and process as necessary.
- E. Serves as FDA expert on eDiscovery technology, policy, process, and best practices. Supports the collection, processing, review, and disclosure of electronically stored information in support of authorized legal, statutory, regulatory, administrative, and investigative requests.
- F. Ensures FDA compliance with the Privacy Act of 1974, privacy provisions of the E-Government Act of 2002, including the Federal Information Security Management Act (FISMA).

- G. Supports information sharing, disclosure operations, and compliance with the Freedom of Information Act for the FDA's inspections and investigations program.
- H. Coordinates Freedom of Information Act (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. Ensures FDA personnel are aware of FDA's policies and procedures regarding the "Standards of Ethical Conduct for Employees of the Executive Branch" (5 C.F.R., Part 2635) including the Department of Health and Human Services (DHHS) supplemental regulations (5 C.F.R., Part 5501).
- J. Facilitates the administration of reasonable accommodations and dispute resolution training for supervisors, managers, administrative staff, special government employees and other FDA employees.
- K. Operates as a neutral, independent, and confidential resource providing informal assistance to FDA scientists, administrators, and support staff in addressing work-related issues. Assists in resolving conflicts and addressing concerns prior to and within established grievance processes FDA-wide.
- L. Provides oversight and management of FDA reasonable accommodation programs and ensures information on reasonable accommodations, policies, and procedures are disseminated to all FDA employees.
- M. Provides support to FDA Headquarters ethics filers and liaises with FDA's Ethics and Integrity Programs.

2. Authority and Effective Date.

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

**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**



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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 organization structure depicting all the organizational structures reporting to the Director:

Division of Information Governance (DCNAFA)
Division of Information Disclosure (DCNAFB)
Division of Headquarters Freedom of Information (DCNAFC)
Division of Compliance, Conflict Prevention, and Accessibility (DCNAFD)

These organizations report to the Division of Information Governance (DCNAFA): eDiscovery Branch
Records Management Branch
Paperwork Reduction Branch
Privacy Branch
Dockets Management Branch

These organizations report to the Division of Information Disclosure (DCNAFB):
Freedom of Information Act Branch
Disclosure Branch

These organizations report to the Division of Compliance, Conflict Prevention, and Accessibility (DCNAFD):
Conflict Prevention and Resolution Branch
Reasonable Accommodation Branch