SMG 1117A.262

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 Governance

Effective Date: May 13, 2024

1. Division of Information Governance (DCNAFA).

A. Provides oversight of the Food and Drug Administration (FDA) History, Dockets Management, Records Management, and eDiscovery programs and services.

B. Ensures applicable FDA compliance with the eGovernment Act of 2002, the Paperwork Reduction Act of 1995, the E-Government Act of 2002, the Federal Information Security Management Act, and related Executive Orders, Office of Management and Budget Memorandums, Department of Health and Human Services (HHS) and FDA policies.

C. Serves as liaison between FDA organizations, HHS, and Office of Management and Budget (OMB) on all information collection matters.

D. Provides expertise on history of FDA and predecessors; and is a key resource for historical records and resources used for FDA communication and programs.

E. Conducts research and creates content for print and online publications, social media, blogs, briefing reports, and presentations interpretive of FDA for internal and external audiences. Maintains an office research file.

F. Responds to information requests from intra-agency, governmental, and non-governmental sources. Presents information to internal and external audiences, including in workshops, briefings, and seminars.

G. Provides expertise and assesses the historical value of FDA communication materials and other resources. Leverages FDA resources through consultative partnerships with Centers and Offices.

H. Collaborates on preservation of historical materials with experts at the National Archives and Records Administration (NARA), the National Library of Medicine, the Smithsonian Institution, the Library of Congress, and other Government, academia, and private institutions.

I. Collects, process, and preserves artifacts that capture the history and breadth of FDA's work. Mounts a variety of physical and virtual exhibits to educate FDA employees and the public about FDA history and work.

J. Documents FDA history through first-person accounts of key FDA officials by means of audio-recorded oral histories, the transcripts of which are posted on the History Office website and audio records maintained in the office's collections.

K. Maintains a multi-media website with historical background on all product Centers, detailed FDA chronologies, hundreds of oral history transcripts, FDA press releases, and talking papers from 1913 to the present.

2. eDiscovery Branch (DCNAFA1).

A. Serves as the FDA expert on eDiscovery technology, policy, process, and best practices.

B. Supports the collection, processing, review, and disclosure of electronically stored information in support of authorized legal, statutory, regulatory, administrative, and investigative requests.

C. Facilitates eDiscovery in a secure, defensible, and repeatable fashion. Works collaboratively with customers, IT partners, and stakeholders to ensure the proper management of data collected in support of eDiscovery matters.

D. Provides eDiscovery services, including data collection, data processing, document review and production, meeting industry standards and legal requirements.

E. Assists authorized individuals to develop electronically stored information (ESI) search and collection strategies in keeping with legal requirements while considering risk, matter schedules, and cost controls.

F. Executes ESI search and collection from FDA information technology infrastructure, working with system owners and administrators to ensure ESI integrity.

G. Maintains the FDA Legal Hold platform and provide platform support to the HHS Office of General Counsel and the FDA Office of Chief Counsel for legal hold issuance and management.

H. Facilitates FDA preservation of ESI under legal hold through FDA Legal Hold platform access and/or periodic reporting to FDA leadership, IT, records management, or other stakeholders.

I. Develops and delivers training on eDiscovery technology, processes, workflows, and standards.

3. Records Management Branch (DCNAFA2).

A. Establishes FDA policy and procedure for FDA records management activities necessary for standardization, continuity, and organizational efficiencies across the FDA.

B. Provides oversight, guidance, and approval of FDA programmatic, administrative, and Center and Office Records Control Schedules.

C. Provides direct records management support for the Office of the Commissioner.

D. Conducts business analysis, inventories, and remediation/clean-up activities by supporting FDA Agency Records Liaison Officers (ARLOs).

E. Facilitates Federal Records Center (FRC) physical records storage and services, including coordinating and authorizing the transfer of records to authorized facilities, destruction of temporary records, and transfer of permanent records to NARA. Inspects and approves records storage facilities according to NARA guidelines.

F. Develops and administers web-based and in-person training, supporting FDA-wide annual records management training requirements, new employee training, and supplemental records related training initiatives.

G. Facilitates development of records management tools that allow ARLOs, and records management staff, to manage the disposition of electronic records in accordance with FDA, HHS, and NARA requirements.

4. Paperwork Reduction Act Branch (DCNAFA3).

A. Ensures requirements mandated by the Paperwork Reduction Act (PRA) of 1995 are followed across FDA, developing policy, procedure, and process as necessary.

B. Coordinates communication with HHS and OMB on all PRA information collection related activities.

C. Centralizes information collection requests (ICRs) entry, submission, and renewal from FDA through HHS to OMB.

D. Reviews content from Centers and Offices proposed for publication in the Federal Register and coordinates with the FDA Regulations Policy Management organization to ensure quality and compliance prior to publication in the Federal Register.

E. Reviews justification statements provided by Centers to ensure compliance with the PRA.

F. Validates PRA requirements are met prior to submission to HHS for PRA certification to OMB.

5. Privacy Branch (DCNAFA4).

A. Ensures FDA compliance with the Privacy Act of 1974 and the privacy provisions of the E-Government Act of 2002 including the Federal Information Security Management Act (FISMA).

B. Supports FDA compliance with Privacy related Executive Orders, HHS, and FDA privacy regulations and policy, OMB memoranda, and any other relevant privacy law or guidance.

C. Works with Centers and Offices to ensure that privacy concerns and compliance requirements are addressed in the design, implementation, and operation of FDA programs, systems, and/or initiatives.

D. Advances Fair Information Practice Principles (FIPPs) of notice, transparency, and appropriate data use are incorporated in the FDA's collection, maintenance, and sharing of PII.

E. Responds to privacy incidents and breaches as well as complaints involving unauthorized access, use, disclosure, or other compromising activities involving PII.

F. Provides training, education, and outreach to build and maintain a culture of privacy within FDA while enabling transparency with the public.

G. Processes all Privacy Act requests received by FDA and leads development of FDA Privacy Act System of Records Notices (Federal Register publications).

H. Conducts Privacy Impacts Assessments (PIAs) for all information systems, collections, and uses of third-party website/application services.

I. Examines all IT and information related procurements and ensures contractors and service providers are accountable for adhering to federal privacy standards (e.g., add binding FAR and HHSAR clauses).

J. Reviews documentation of proposed PRA information collections to ensure privacy requirements are accurately determined and described before submission to OMB.

K. Reviews and approves program requests to conduct external collaborations involving PII.

L. Conducts privacy risk assessments of mobile apps developed by, or on behalf of, the FDA.

M. Reviews U.S., HHS, and FDA privacy policies and participates in working groups, committees, councils to provide privacy guidance.

6. Dockets Management Branch (DCNAFA5).

A. Ensures FDA compliance with the eRulemaking programmatic components of the eGovernment Act of 2002.

B. Ensures public access to FDA regulatory and rulemaking activities impacting regulated products under FDA oversight and authority.

C. 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. Serves as the FDA authority on submission examination and processing for FDA administrative proceedings and creates and maintains the official record of FDA administrative proceedings.

E. Supports the development of policies, procedures, and processes impacting FDA administrative proceedings.

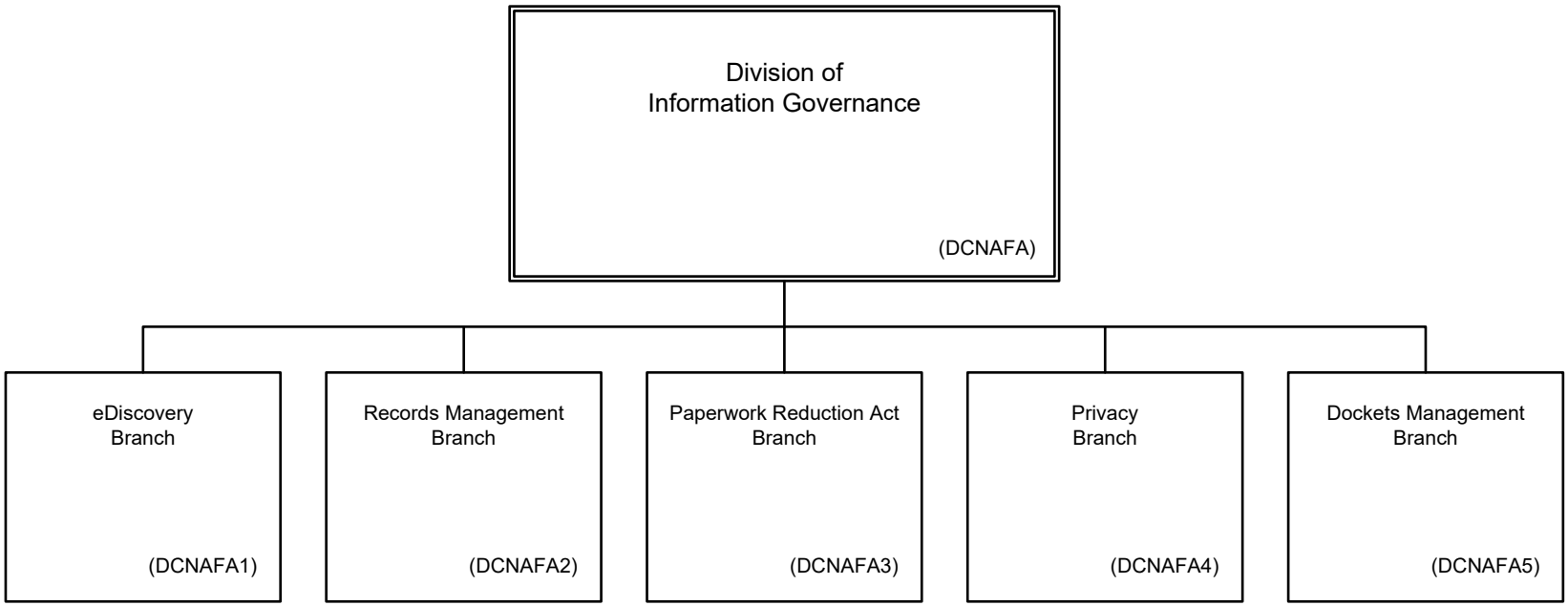
F. Provides dockets research and compilation in support of FDA rulemaking activities. Determines the compliance of petitions, comments, requests for hearings, motions, briefs, and objections with FDA regulations.

G. Provides information access via the intranet and internet, maintains a public reading room, and provides support for Freedom of Information Act inquiries made by the public.

7. Authority and Effective Date.

The functional statements for the Division of Information Governance 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
Division of Information Governance



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

eDiscovery Branch (DCNAFA1)
Records Management Branch (DCNAFA2)
Paperwork Reduction Branch (DCNAFA3)
Privacy Branch (DCNAFA4)
Dockets Management Branch (DCNAFA5)