SMG 1117A.23

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Enterprise Management Services

Division of Information Governance

Effective Date: September 26, 2022

1. Division of Information Governance (DCNAC).

A. Establishes Food and Drug Administration (FDA) policy and standards for Office of the Commissioner Records Management activities by providing standardized procedures and processes for continuity and organizational efficiencies.

B. Provides oversight, guidance, and approval of FDA Programmatic, Administrative, and Center Records Control Schedules.

C. Conducts business analysis, inventories, and remediation/clean-up activities by supporting Assistant Records Liaison Officers (ARLO).

D. Formulates and executes Federal Records Center physical records storage and retrieval budget. Inspects and approves record storage facilities according to NARA guidelines.

E. Develops web-based and in-person annual and new employee training.

F. Coordinates communications with Health and Human Services (HHS) and Office of Management and Budget (OMB) on all Paper Reduction Act information collection related activities and ensures FDA does not overburden the public with federally sponsored information collections.

G. Coordinates projects and timeline milestones with FDA centers. Review content in notices for publication in the Federal Register and coordinate with the Regulations Policy Management Staff for notice publication.

H. Oversees entry and transmission of information collection requests through HHS to OMB. Ensure that existing approvals by OMB are renewed on time without expiration of approval.

I. Reviews justification statements provided by centers.

J. Ensures procedures pursuant to the Paperwork Reduction Act of 1995 are followed across FDA.

K. Acts as the liaison between FDA centers, HHS and OMB on all information collection matters.

L. Assists internal and external requesting entities in the initiation of requests for electronically stored information (ESI) though the development of an appropriately narrow search scope and defined search terms.

M. Searches information technology (IT) infrastructure to collect responsive ESI in response to investigative, legal and legislative requests.

N. Facilitates litigation holds and assists in the dissemination of hold notifications to Center ARLO's to aid in the preservation of identified records.

O. Assists in the development of legal search and collection tools.

P. Coordinates and develops IT-based training for legal documentation.

Q. Ensures FDA-wide compliance with the Privacy Act of 1974, privacy provisions of the E-Government Act of 2002 (includes the Federal Information Security Management Act (FISMA)), Executive Orders, HHS and FDA privacy regulations, relevant memoranda issued by the Office of Management and Budget (OMB), HHS and FDA policies, and any other relevant law or guidance.

R. Works with FDA components and programs to ensure that privacy concerns and compliance requirements are addressed in the design, implementation, operation, and other phases of each system, program, or initiative.

S. Ensures compliance with privacy laws, regulations, and authorities

T. Responds to privacy incidents and breaches as well as complaints involving unauthorized access, use, disclosure, or other compromising of Personal Identification Information (PII).

U. Provides training, education, and outreach to build and maintain a culture of privacy within FDA and promote transparency to the public

V. Processes all Privacy Act requests received by the FDA.

W. Evaluates FDA regulatory proposals and contractual agreements involving collection, use, and disclosure of PII.

X. Ensures Fair Information Practice Principles of notice and transparency are incorporated into the FDA's collection, maintenance, and sharing of PII.

Y. Conducts Privacy Impact Assessments (PIAs) for all information systems, collections, and other publications.

2. Dockets Management Staff (DCNAC1)

A. Receives, examines, and processes submissions required or permitted in FDA administrative proceedings; establishes and maintains docket files containing FDA official records relating to an administrative proceeding. Disseminates submissions to appropriate offices for action. Routinely coordinates activities of the branch with other appropriate components

B. Serves as the FDA expert on requirements for submissions required or permitted in FDA administrative proceedings. Participates in the development of regulations and policy impacting FDA administrative proceedings

C. Provides staff support for FDA rulemaking activities. Determines compliance of petitions, comments, request for hearings, motions, briefs, and objections with FDA regulations.

D. Provides information access via the Intranet and other means to FDA personnel for Dockets Management materials and to copyrighted documents.

E. Plans and conducts FDA-wide analytical reviews and studies to assess and manage information and access concerns. Makes recommendations and assists in the implementation of the recommendations

3. FDA History Office (DCNAC2)

A. Provides expertise on history of FDA and predecessors; and is a key resource for historical records and resources used for FDA communication and programs, including printed and online information, commemoratives, anniversaries and milestones.

B. 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 extensive office research file.

C. Responds to information requests from FDA Centers, scholars, press, consumers, government agencies, industry, trade organizations, health professionals, associations, and foreign sources. Presents information to internal and external audiences, including in workshops, briefings, and seminars.

D. Provides expertise and assesses the historical value of FDA communication materials and other resources, i.e. records, photographs, films, audio-visual records, and rare or out-of-print monographs, etc. Leverages FDA resources through consultative partnerships with FDA offices.

E. Collaborates on preservation of historical materials with experts at the National Archives and Records Administration, the National Library of Medicine, the Smithsonian Institution, and other Government, Academic, and Private Institutions.

F. Collects, processes, and preserves artifacts that capture the history of FDA's work, represent the commodities it regulates, and document the breadth of its responsibilities. Mounts a variety of exhibits in collaboration with other public and private institutions to educate agency employees and the public about the history and work of the FDA.

G. Partners with the National Library of Medicine, History of Medicine Division, to create and make available transcripts and recordings of an oral history program that documents FDA's institutional history, through personal interviews with key exiting FDA employees.

4. Authority and Effective Date.

The functional statements for the Division of Information Governance were approved by the Secretary of Health and Human Services on September 26, 2022, and effective on September 26, 2022.

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Office of Enterprise Management Services
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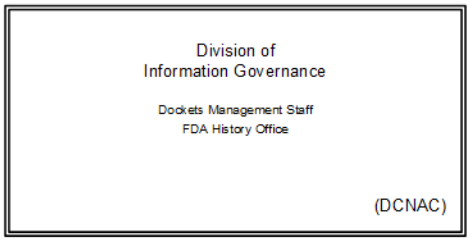

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Enterprise Management Services, Division of Information Governance organization structure depicting all the organizational structures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

Division of Information Governance (DCNAC):
Documents Management Staff
FDA History Office