

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of External Affairs

Effective Date: December 14, 2018

1. Office of External Affairs (DCK).

- A. Serves as the central point of communication and education about the Food and Drug Administration's (FDA) public health and regulatory activity. This includes the development, coordination, and leadership of all FDA communication and outreach efforts to the news media, health professionals, patient advocates, industry, consumer groups, and the general public. The Office of External Affairs (OEA) also serves as the focal point for internal employee communication, creative and editorial services, social media, and best practices in digital and web technology.
- B. Advises the Commissioner, Deputy Commissioners and other FDA leadership on FDA's communication to the media, stakeholder, Congress, and the general public on issues that affect FDA-wide programs, projects, strategies, partnerships and initiatives, including appropriate speaking venues and meetings. Serves as communications Liaison with the Department of Health and Human Services (HHS) on communication activities.
- C. Advises and assists the Commissioner and other FDA officials on all public information programs; acts as the focal point for disseminating news on FDA activities and as a liaison with the Public Health Service and HHS on public information programs.
- D. Advises the Commissioner, Deputy Commissioners and other FDA leadership throughout FDA on sensitive and controversial programs and initiatives that affect external stakeholder groups; provides historical expertise and records to inform those decisions.
- E. Coordinates FDA-wide communication activities.

- F. Draft speeches, informal remarks, talking points, slides, op-ed pieces and letters to the editor for the Commissioner. Advises the Commissioner and other senior FDA executives on messages about FDA's public health priorities, initiatives, and crucial priorities.
- G. Ensures consistent visual identity and messaging across the FDA.
- H. Provides communication expertise and state-of-the-art digital guidance and tools for application across the FDA.
- I. Leads efforts to enhance FDA's communication infrastructure to better serve the public.
- J. Coordinates and implements policies, programs and initiatives related to MedWatch, including websites and E-list.

2. Operations Staff (DCK1)

- A. Provides leadership and direction to the manager of the Office, and other senior managers and staff, on all areas of office and resource management, including budget formulation and execution, financial management, management analysis, personnel, safety, and administrative operations.
- B. Provides leadership and direction for the management and administrative interface with the FDA, HHS and other Federal Agencies.
- C. Oversees the management of acquisitions and contracts within the Office.
- D. Provides leadership to assure compliance with statutes, executive orders and administrative directives, such as the Chief Financial Officer Act and the Federal Financial Managers' Financial Integrity Act.
- E. Plans and directs Office operations related to financial, personnel, administrative, and safety management services.
- F. Provides leadership and guidance to the Office on all aspects of administrative management operations, physical security, safety management and property management activities in accordance with established guidelines.
- G. Directs and coordinates the Office safety program; develops plans and activities to assure the Office compliance with safety related laws and regulations.
- H. Provides services and support on human capital management activities and serves as Liaison with the FDA's Human Resources programs.

- I. Develops and coordinates short and long-range facility plans and priorities for the Office. Serves as Principal Liaison with other FDA components to assure that the Office facilities are adequate and that special issues, needs, or concerns are addressed.
- J. Serves as a key resource for historical perspectives as well as records and resources used for FDA communication and programs, including printed and online information, commemoratives, anniversaries and milestones.

3. FDA History Office (DCK2)

- 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 FDA 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. Stakeholder Engagement Staff (DCK3)

- A. Advises the Commissioner and other FDA leadership on key policy and public health issues related to stakeholder organizations representing regulated industry, health care professionals, patients, and consumers.
- B. Assists in the planning, administration, development, and evaluation of FDA policies related to stakeholders.
- C. Serves as a Liaison between FDA and stakeholder organizations to educate on key FDA-related policy and public health issues and bring information from stakeholders back to the FDA for use in developing and adapting FDA policy and strategic engagement activities.
- D. Provides internal coordination across Center and Office of the Commissioner (OC) offices on stakeholder engagement around FDA communication related to high-priority issues and policy.
- E. Plans and conducts meetings with key stakeholder organizations, ranging from small meetings on a single issue to multi-day symposiums on significant public health policy issues.
- F. Administers MedWatch, the FDA safety information and adverse event reporting program, including the MedWatch web pages, E-list, Rich Summary Site (RSS) feed, and Twitter account.

5. Web and Digital Services Staff (DCK4)

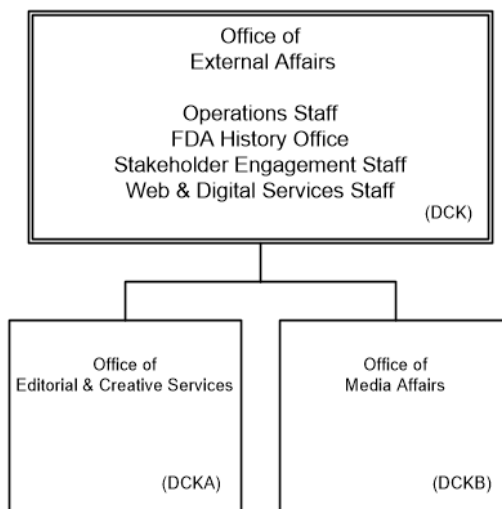
- A. Responsible for directing the design, content management, usability, and evaluation of the FDA website (www.fda.gov). Develops and interprets the FDA's web policies, and serves as advocates for FDA's web presence and catalysts for creative use of the Web and digital services by the FDA.
- B. Works closely, as partners, with the FDA Information Management program (IM), which is responsible for the technical operations of FDA's website.
- C. Serves as the focal point and contact with the FDA, HHS, and other Federal Government website programs and operations.
- D. Provides direction, strategic planning assistance, and management coordination on FDA website and digital media programs.

- E. Works closely with the website contacts in each of the Centers and principal offices of the Commissioner to plan, coordinate, execute and evaluate the FDA's website operations.
- F. Establishes, manages, and monitors the implementation of FDA standards and policies for information published on FDA websites.
- G. Provides web-related information management strategy input through a collaborative effort with FDA IM and the website communication and operations staffs in the Centers and OC.
- H. Designs, develops, implements, monitors, and manages information published on the FDA's website and external digital assets.
- I. Delivers the FDA's messages to the public via the FDA's website and strategic online partnerships in the government, private, and non-profit sectors.

6. Authority and Effective Date.

The functional statements for the Office of External Affairs were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of External Affairs**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of External Affairs organization structure depicting all the organizational structures in the immediate office reporting to the Director.

The organizations below report to the Office of External Affairs (DCK):

- Operations Staff
- FDA History Office
- Stakeholder Engagement Staff
- Web and Digital Services Staff
- Office of Editorial and Creative Services (DCKA)
- Office of Media Affairs (DCKB)