

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Food and Drug Administration**

**Office of the Commissioner**

**Office of Digital Transformation**

**Office of Information Security**

Effective: August 24, 2021

**1. Office of Information Security (DCADB).**

- A. Under the authority of the Chief Information Security Officer (CISO), directs and implements the FDA Cybersecurity, Counterintelligence, and Insider Threat Program to ensure security controls are appropriately applied to FDA systems for the protection of privacy and to ensure the confidentiality, integrity, and availability of data and sensitive information.
- B. Enforce cybersecurity standards and other security requirements that comply with OMB, FISMA, FedRAMP, HHS, and other federal government security requirements.
- C. Provide near real-time cybersecurity capabilities and risk management methodologies to protect sensitive data and information systems in support of the U.S. Food and Drug Administration’s public health mission.
- D. Provide advice and consultation to the FDA Chief Information Officer (CIO), Centers, and Offices on the implementation and management of FDA’s cybersecurity program and related activities.
- E. Operate and manage the FDA Systems Management Center (SMC), a capability that unified the Network and Security Operations Centers, and is the central command and control center for the monitoring, triaging, troubleshooting, and escalation of cybersecurity incidents, performance issues, enterprise services, and infrastructure operations.
- F. Provide cybersecurity, threat and vulnerability management, counterintelligence, foreign travel support, advanced forensics, insider threat, and other operational capabilities to support law enforcement investigations and national security inquiries.
- G. Provide strategic direction, operations, and integration of cybersecurity capabilities, infrastructure operations, and technical requirements to develop a best-in-class, intelligence-driven cybersecurity program that directly supports the FDA’s mission to protect and promote U.S. public health.

H. Develop, standardize, and prioritize the Agency cybersecurity program workforce, budgetary, contract, and programmatic requirements to ensure the effective implementation of cybersecurity related capabilities and technologies in direct support of FDA IT Enterprise.

**2. Authority and Effective Date**

The functional statements for the Office were approved by the Acting Commissioner of Food and Drugs on July 22, 2021 and effective on August 24, 2021.

**Department of Health and Human Services  
Food and Drug Administration  
Office of the Commissioner  
Office of Digital Transformation  
Office of Information Security**

Office of  
Information Security

(DCADB)

---

Staff Manual Guide 1111.52a  
Organizations and Functions  
Effective Date: August 24, 2021

The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Digital Transformation, Office of Information Security organization structure depicting all the organizational structures reporting to the Director:

Office of Information Security (DCADB)