

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Partnerships and Operational Policy

Office of Information Systems Management

Division of Special Initiatives and Coordination

Effective Date: December 14, 2018

1. Division of Special Initiatives and Coordination (DCIHDA).

- A. Supports Office of Regulatory Affairs (ORA) employees with information technology (IT)-related software and hardware requests and purchases.
- B. Interacts with the Food and Drug Administration's (FDA) Information Management and Technology program to discuss needs, service agreements, management and problem escalation.
- C. Researches, reviews, and manages new and innovative information technologies to support processes and policies having the potential to materially affect ORA capabilities, business models, or mission.
- D. Manages and coordinates enterprise-wide information technology development and support across ORA.
- E. Develops and maintains a business solution architecture for ORA.
- F. Manages ORA's Information Technology Capital Planning and Investment Control Process.
- G. Coordinates enterprise IT initiatives between ORA and the FDA's Information Management and Technology program and facilitates planning and acquisition of hardware and software in support of ORA's business priorities.

2. Client Services and Governance Branch (DCIHDA1)

- A. Gathers customer-specific business needs, translates needs into requirements and communicates the needs to FDA's Information Management and Technology program.
- B. Implements the provisions of IT-related laws, regulations, and other directives regarding the acquisition, management, and use of resources.
- C. Coordinates hardware and software purchases and ORA IT Portfolio with FDA's Information Management and Technology program.
- D. Escalates IT service requests and issues, and triages problems.
- E. Communicates IT project status to internal and external customers.
- F. Manages and evaluates the performance of the ORA applications help desk.
- G. Performs analytical and technical work related to the management of ORA's electronic information.
- H. Performs onboarding and administrative support of contractor resources to include management and tracking of badging, network access and property.

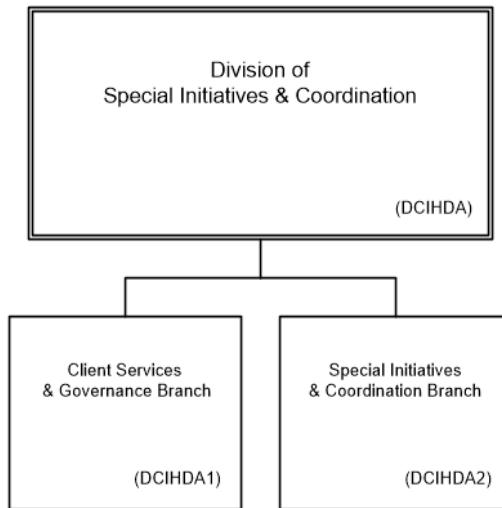
3. Special Initiatives, and Coordination Branch (DCIHDA2)

- A. Promotes use of the proper project management methodologies and best practice standards to ensure successful delivery and completion of high priority IT projects and special cross-program initiatives.
- B. Advises the ORA business community and FDA's Information Management and Technology program on IT program and project management procedures and practices as applied to ORA's distributed field environment.
- C. Supports enterprise-wide and high priority IT system development projects. Coordinates with other divisions to ensure system development is aligned to regulatory and legislative authorities.
- D. Integrates and coordinates key initiatives with outside FDA and entities to ensure compliance with new laws and program initiatives.

4. Authority and Effective Date.

The functional statements for the Division of Special Initiatives and Coordination 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 Regulatory Affairs
Office of Partnerships and Operational Policy
Office of Information Systems Management
Division of Special Initiatives and Coordination**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Partnerships and Operational Policy, Office of Information Systems Management, Division of Special Initiatives and Coordination organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Special Initiatives & Coordination (DCIHDA):

Client Services & Governance Branch (DCIHDA1)

Special Initiatives & Coordination Branch (DCIHDA2)