

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Effective Date: December 14, 2018

1. Office of Regulatory Affairs (DCI).

- A. Coordinates, interprets, and executes the Food and Drug Administration's (FDA) overall inspection, investigations, compliance, import operations, state programs, and regulatory science efforts.
- B. Identifies the need for prompt and positive action to assure compliance or a state of quality by regulated industries with FDA regulations to assure high public health protection; assures an effective and uniform balance between voluntary and regulatory compliance or quality to achieve the FDA's mission of consumer protection.
- C. Recommends proposed administrative and legal actions to ascertain compliance with regulatory policy and enforcement objectives, works with the Centers to establish operational and compliance policy.
- D. Executes direct line authority over all FDA field operations; develops, issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within the FDA through which the Commissioner's office and Centers obtain field support services.
- E. Executes criminal investigations on behalf of the FDA, providing coordination with other FDA components and with other international, Federal, State, and local law enforcement agencies.
- F. Administers the FDA's overall Federal-State program and policy; coordinates the program aspects of Agency funding mechanisms with State and local counterpart agencies.
- G. Evaluates the overall management and capabilities of the FDA's field organization; initiates action to improve the management of field activities and

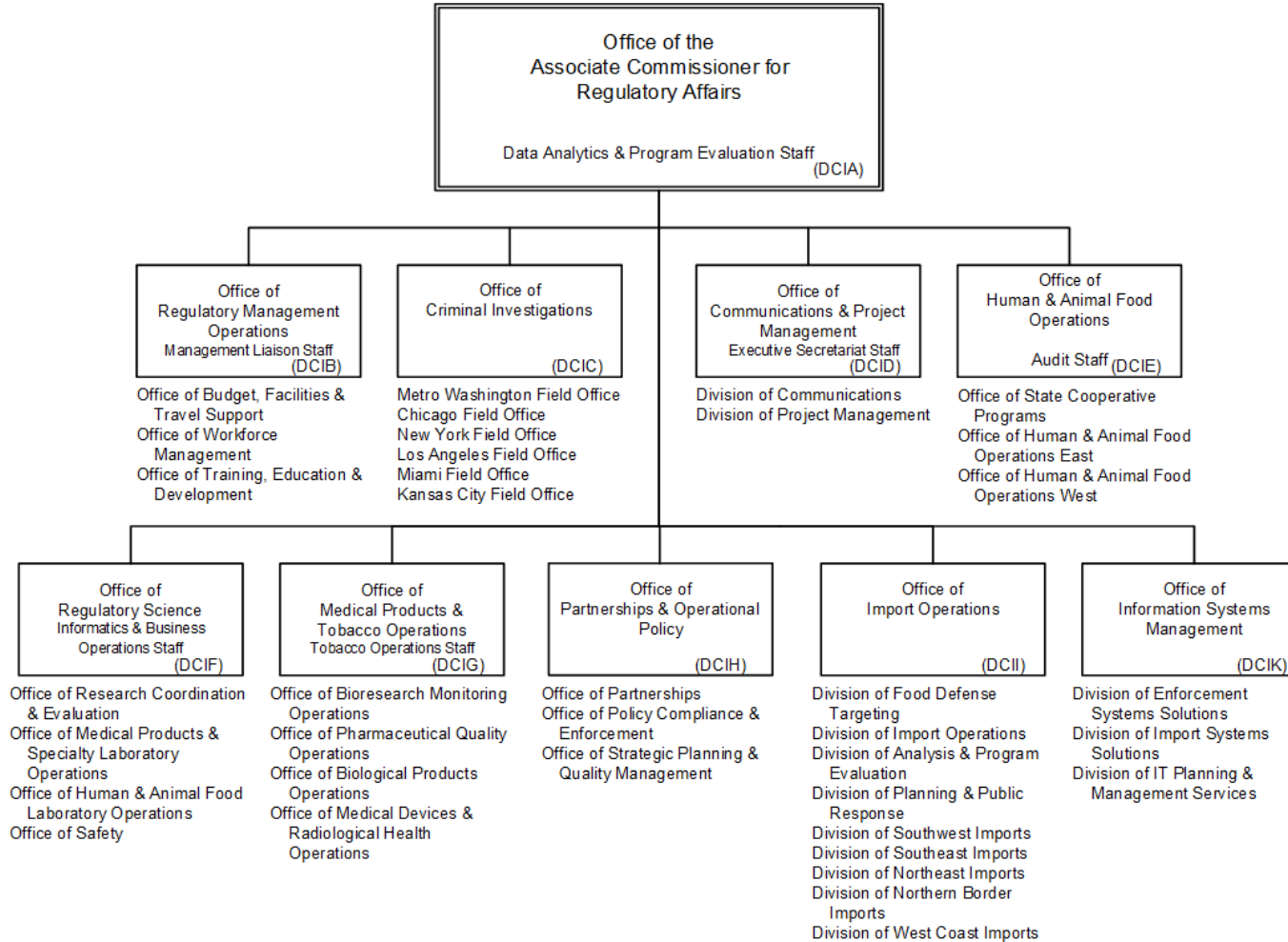
coordinates the formulation and management of career development plans and training.

H. Operates the Government-wide Quality Assurance Program for medical products for the FDA.

2. Authority and Effective Date.

The functional statements for the Office of Regulatory 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 Regulatory Affairs**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs organization structure depicting all the organizational structures reporting to the Associate Commissioner for Regulatory Affairs:

These organizations report to the Office of the Associate Commissioner for Regulatory Affairs (DCIA):

Data Analytics and Program Evaluation Staff

Office of Regulatory Management Operations (DCIB)

Office of Criminal Investigations (DCIC)

Office of Communications and Project Management (DCID)

Office of Human & Animal Food Operations (DCIE)

Office of Regulatory Science (DCIF)

Office of Medical Products & Tobacco Operations (DCIG)

Office of Partnerships & Operational Policy (DCIH)

Office of Import Operations (DCII)

Office of Information Management Systems (DCIK)

These organizations report to the Office of Regulatory Management Operations (DCIB):

Management Liaison Staff

Office of Budget, Facilities and Travel Support

Office of Workforce Management

Office of Training, Education and Development

These organizations report to the Office of Criminal Investigations (DCIC):

Metro Washington Field Office

Chicago Field Office

New York Field Office

Los Angeles Field Office

Miami Field Office

Kansas City Field Office

These organizations report to the Office of Communications & Project Management (DCID):

Executive Secretariat Staff

Division of Communications

Division of Project Management

These organizations report to the Office of Human & Animal Food Operations (DCIE):

Audit Staff

Office of State Cooperative Programs

Office of Human & Animal Food Operations East

Office of Human & Animal Food Operations West

These organizations report to the Office of Regulatory Science (DCIF):

Informatics and Business Operations Staff

Office of Research Coordination & Evaluation

Office of Medical Products, Tobacco & Specialty Laboratory Operations

Office of Human and Animal Food Laboratory Operations

Office of Safety

These organizations report to the Office of Medical Products & Tobacco Operations (DCIG):

Tobacco Operations Staff

Office of Bioresearch Monitoring Operations

Office of Pharmaceutical Quality Operations

Office of Biological Products Operations

Office of Medical Devices & Radiological Health Operations

These organizations report to the Office of Partnerships & Operational Policy (DCIH):

Office of Partnerships

Office of Policy Compliance and Enforcement

Office of Strategic Planning and Quality Management

These organizations report to the Office of Import Operations (DCII):

Division of Food Defense Targeting

Division of Import Operations

Division of Analytics and Program Evaluation

Division of Planning and Public Response

Division of Southwest Imports

Division of Southeast Imports

Division of Northeast Imports

Division of Northern Border Imports

Division of West Coast Imports

These organizations report to the Office of Information Systems Management (DCIK):

Division of Enforcement Systems Solutions

Division of Import Systems Solutions

Division of IT Planning and Management Services