

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Effective Date: May 13, 2024

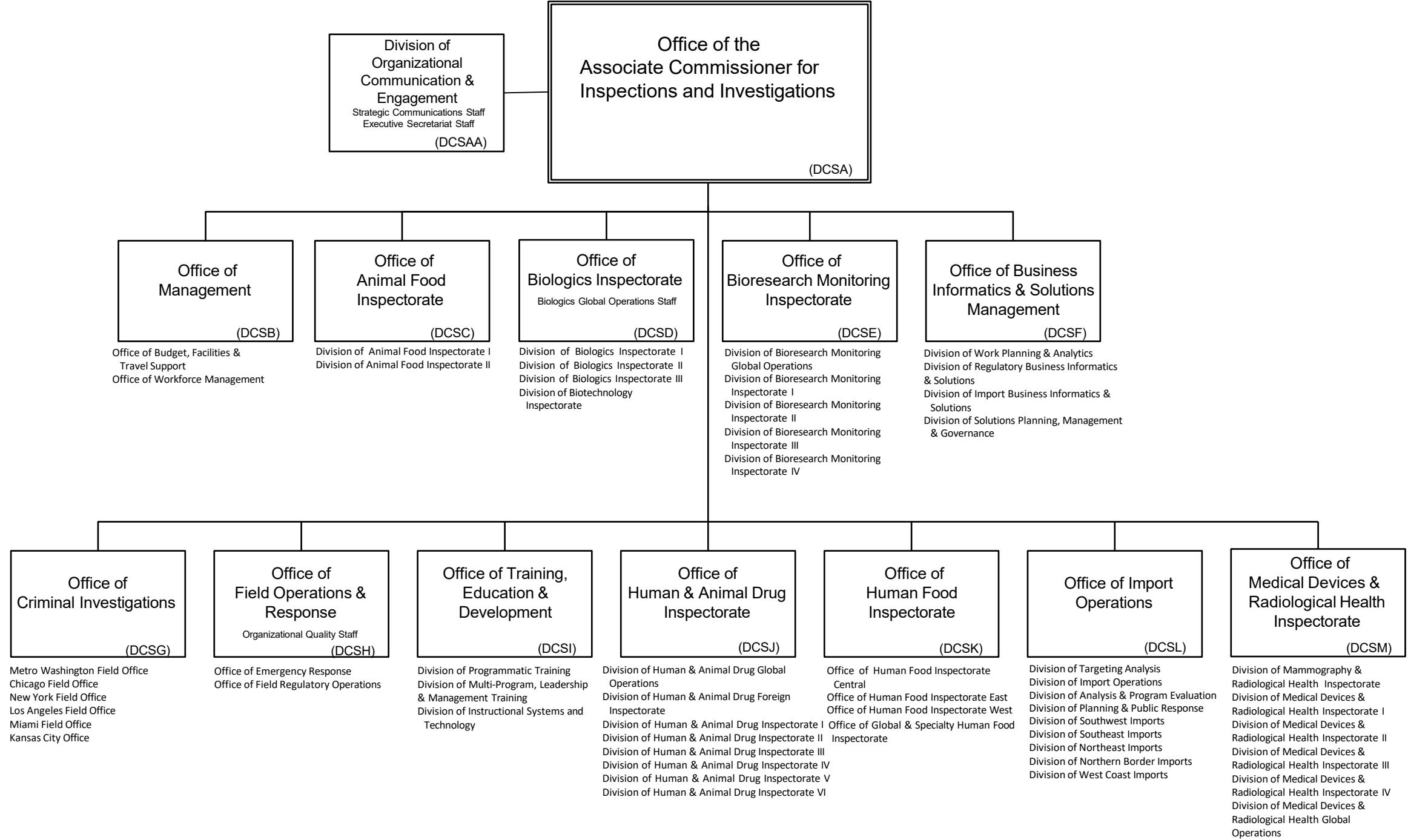
1. Office of Inspections and Investigations (DCS).

- A. Coordinates, interprets, and executes the Food and Drug Administration's (FDA) overall inspection, investigations, and import operations.
- B. Recommends proposed administrative and legal actions to ascertain compliance with regulatory policy and enforcement objectives for imports and cosmetics policy.
- C. 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, Human Food Program, and Centers obtain field support services.
- D. Conducts criminal investigations on behalf of the FDA, providing coordination with other FDA components and with other international, Federal, State, and local law enforcement agencies.
- E. 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.
- F. 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 Inspections and Investigations were approved by the Secretary for Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
 Food and Drug Administration
 Office of Inspections and Investigations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations organization structure depicting all the organizational structures reporting to the Director:

Office of the Associate Commissioner for Inspections and Investigations (DCSA)

Office of Management (DCSB)

Office of Animal Food Inspectorate (DCSC)

Office of Biologics Inspectorate (DCSD)

Office of Bioresearch Monitoring Inspectorate (DCSE)

Office of Business Informatics and Solutions Management (DCSF)

Office of Criminal Investigations (DCSG)

Office of Field Operations and Response (DCSH)

Office of Training, Education, and Development (DCSI)

Office of Human and Animal Drug Inspectorate (DCSJ)

Office of Human Food Inspectorate (DCSK)

Office of Import Operations (DCSL)

Office of Medical Device and Radiological Health Inspectorate (DCSM)

These organizations report to the Office of the Associate Commissioner for Inspections and Investigations (DCSA):

Division of Organizational Communication and Engagement (DCSAA)

These organizations report to the Office of Management (DCSB):

Office of Budget, Facilities and Travel Support (DCSBA)

Office of Workforce Management (DCSBB)

These organizations report to the Office of Animal Food Inspectorate (DCSC):

Division of Animal Food Inspectorate I (DCSCA)

Division of Animal Food Inspectorate II (DCSCB)

These organizations report to the Office of Biologics Inspectorate (DCSD):

Division of Biologics Inspectorate I (DCSDB)

Division of Biologics Inspectorate II (DCSDC)

Division of Biologics Inspectorate III (DCSDD)

Division of Biotechnology Inspectorate (DCSDE)

These organizations report to the Office of Bioresearch Monitoring Inspectorate (DCSE):

Division of Bioresearch Monitoring Global Operations (DCSEA)

Division of Bioresearch Monitoring Inspectorate I (DCSEB)

Division of Bioresearch Monitoring Inspectorate II (DCSEC)

Division of Bioresearch Monitoring Inspectorate III (DCSED)

Division of Bioresearch Monitoring Inspectorate IV (DCSEF)

These organizations report to the Office of Business Informatics and Solutions Management (DCSF):

Division of Import Business Informatics and Solutions (DCSFB)

Division of Regulatory Business Informatics and Solutions (DCSFC)

Division of Solutions Planning, Management and Governance (DCSFD)

Division of Work Planning and Analytics (DCSFE)

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

Metro Washington Field Office (DCSGA)

Chicago Field Office (DCSGB)

New York Field Office (DCSGC)

Los Angeles Field Office (DCSGD)

Miami Field Office (DCSGE)

Kansas City Field Office (DCSGF)

These organizations report to the Office of Field Operations and Response (DCSH):

Organizational Quality Staff (DCSH1)

Office of Field Regulatory Operations (DCSHA)

Office of Emergency Response (DCSHB)

These organizations report to the Office of Training, Education, and Development (DCSI):

Division of Programmatic Training (DCSIA)

Division of Multi-Program, Leadership, and Management Training (DCSIB)

Division of Instructional Systems and Technology (DCSIC)

These organizations report to the Office of Human and Animal Drug Inspectorate (DCSJ):

Division of Human and Animal Drug Foreign Inspectorate (DCSJA)

Division of Human and Animal Drug Global Operations (DCSJB)

Division of Human and Animal Drug Inspectorate I (DCSJC)

Division of Human and Animal Drug Inspectorate II (DCSJD)

Division of Human and Animal Drug Inspectorate III (DCSJE)

Division of Human and Animal Drug Inspectorate IV (DCSJF)

Division of Human and Animal Drug Inspectorate V (DCSJG)

Division of Human and Animal Drug Inspectorate VI (DCSJH)

These organizations report to the Office of Human Food Inspectorate (DCSK):

Office of Human Food Inspectorate Central (DCSKA)

Office of Human Food Inspectorate East (DCSKB)

Office of Human Food Inspectorate West (DCSKC)

Office of Global and Specialty Human Food Inspectorate (DCSKD)

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

Division of Targeting and Analysis (DCSLA)

Division of Import Operations (DCSLB)

Division of Analysis and Program Evaluation (DCSLC)

Division of Southwest Imports (DCSLD)

Division of Southeast Imports (DCSLE)

Division of Northeast Imports (DCSLF)

Division of Northern Border Imports (DCSLG)

Division of West Coast Imports (DCSLH)

Division of Planning and Public Response (DCSLI)

These organizations report to the Office of Medical Device and Radiological Health Inspectorate (DCSM):

Division of Mammography and Radiological Health Inspectorate (DCSMA)

Division of Medical Device and Radiological Health Inspectorate I (DCSMB)

Division of Medical Device and Radiological Health Inspectorate II (DCSMC)

Division of Medical Device and Radiological Health Inspectorate III (DCSMD)

Division of Medical Device and Radiological Health Global Operations (DCSME)

Division of Medical Device and Radiological Health Inspectorate IV (DCSMF)