

SMG 1121A.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of the Associate Commissioner for Inspections and Investigations

Effective Date: May 13, 2024

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

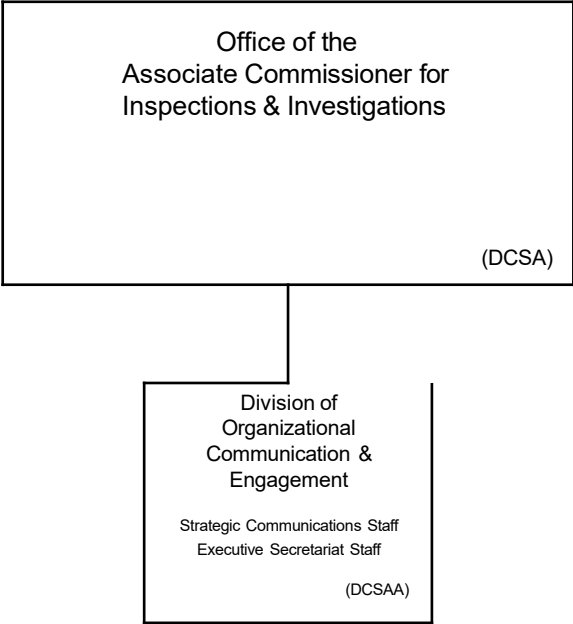
- A. Advises and assists the Commissioner, Deputy Commissioners, and other key officials on Food and Drug Administration's (FDA) regulatory field operation matters that have an impact on strategic direction, inspectorate policy development, and long-range program goals.
- B. Coordinates, interprets, and evaluates the FDA overall domestic and international field investigations, inspections, and import activities; works with key FDA officials, Centers, and Offices to establish strategic alignment on operational resource management and inspectorate policy recommendations.
- C. Provides direction and guidance to the Office of Inspections and Investigations (OII) leaders in the implementation of operational policies and operational guidelines that form the framework for the management of FDA field activities.
- D. Evaluates and establishes the overall management and capabilities of FDA field operations; initiates action to improve the management of field activities, and coordinates the formulation and management of career development plans.
- E. Advises the Commissioner, Deputy Commissioners, and other key officials on activities between the FDA field and other federal, State, territorial, tribal, and local regulatory and public health agencies in collaboration with Centers and Offices.
- F. Coordinates with the Commissioner, Deputy Commissioners, Office of the Chief Scientist, Centers, and Offices on the coordination of scientific resources necessary to effectuate field operations.

- G. Provides direction and guidance to the Director of the FDA emergency response organization to support emergency response to natural, unintentional, and intentional disasters and outbreaks impacting FDA regulated products or impacting FDA regulated industries.
- H. Provides direction guidance to the Director of the Office of Criminal Investigations in the coordination and execution of criminal investigations to align with FDA, Center, and Office priorities.
- I. Directs the OII activities related to planning, coordination, and evaluation of training and development programs in collaboration with Centers and Offices.
- J. Coordinates information technology (IT) alignment with the FDA IT modernization plan in support of field operations.
- K. Directs and consults on the performance of organization and management studies for OII and directs implementation of study recommendations.
- L. Directs and consults on OII's partnership and inspectorate policy activities with internal and external stakeholders in collaboration with Centers and Offices.
- M. Develops and coordinates OII engagement on Government Accountability Office (GAO) studies, Department of Health and Human Services (HHS) studies, and Office of the Inspector General (OIG) audits.
- N. Directs and consults on OII's enterprise-wide strategic vision and planning.
- O. Provides leadership, oversight and direction for emerging technologies and the advanced manufacturing program.
- P. Directs and consults on OII's enterprise-wide international engagement efforts in collaboration with Centers and Offices.

2. Authority and Effective Date.

The functional statements for the Office of the Associate Commissioner for Inspections and Investigations were approved by the Secretary of 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, Office of the Associate Commissioner for Inspections and Investigations organization structure depicting all the organizational structures reporting to the Associate Commissioner:

Office of the Associate Commissioner for Inspections and Investigations (DCSA):
Division of Organizational Communication and Engagement (DCSAA)

These organizations report to the Division of Organizational Communication and Engagement (DCSAA):

Strategic Communications Staff
Executive Secretariat Staff