

SMG 1121A.81

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 Field Operations and Response

Office of Field Regulatory Operations

Effective Date: May 13, 2024

1. Office of Field Regulatory Operations (DCSHA).

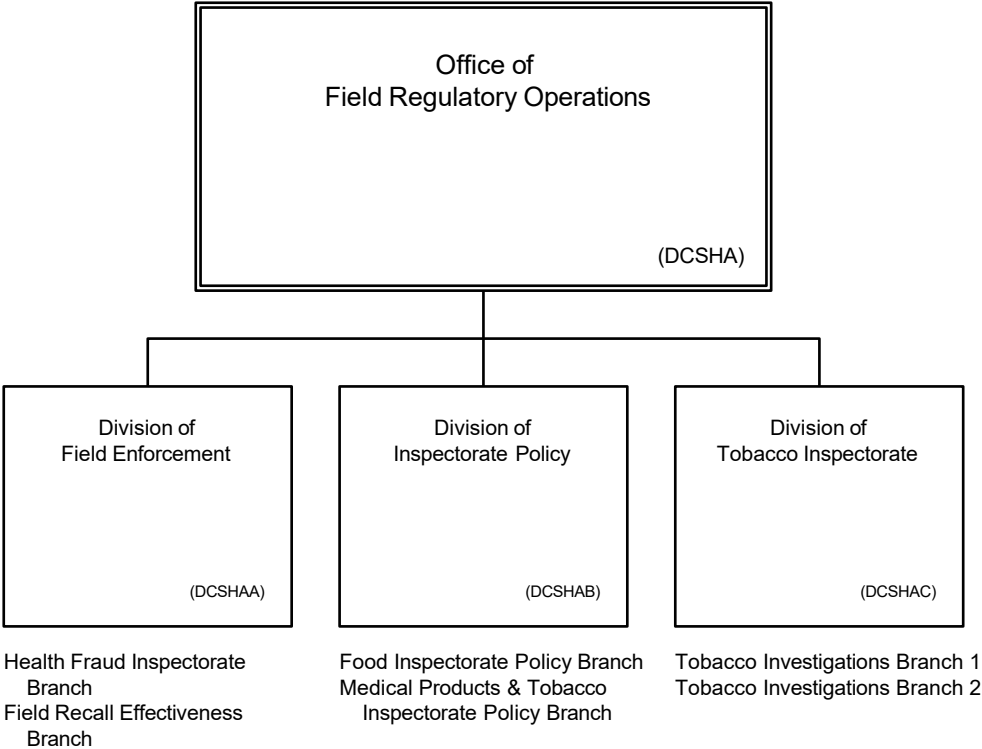
- A. Provides advice and guidance to the Office of Inspections and Investigations (OII) senior leaders and other Food and Drug Administration (FDA) senior leaders concerning information that may affect current or proposed FDA inspectorate policies.
- B. Coordinates OII review of new, proposed, or modified FDA regulations and coordinates the development of procedures which impact inspectorate policy for all products regulated by the FDA.
- C. Directs and coordinates the preparation and maintenance of inspectorate policy publications including the Investigations Operations Manual and coordinates the preparation and maintenance of the Regulatory Procedures Manual.
- D. Addresses intra-agency inspectorate policy in collaboration with, and upon the request of, OII Programs, and the FDA Centers and offices.
- E. With the authorization of the Office of the Commissioner, coordinates cross-center, program, and commodity initiatives including where authorities and Center and office roles are not yet defined.
- F. Serves on the Compliance Policy Council regarding FDA inspectorate policy.
- G. Upon request of the FDA Centers and offices, reviews all FDA-planned policy which impact inspectorate policy.

- H. Directs and coordinates OII's activities related to the investigation of health fraud; serves as the health fraud liaison to the FDA Centers, offices, and Human Foods Program, other Federal agencies, and foreign governments.
- I. Provides management and oversight of the FDA debarment program working in consultation with the Centers as appropriate.
- J. Manages cosmetics inspection and investigation efforts in support of and in collaboration with the Office of Chief Scientist.
- K. Coordinates the Cosmetics Compliance Program in support of the Office of Chief Scientist cosmetics policy.

2. Authority and Effective Date.

The functional statements for the Office of Field Regulatory Operations 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
Office of Field Operations and Response
Office of Field Regulatory Operations**



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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 Field Operations and Response, Office of Field Regulatory Operations organization structure depicting all the organizational structures reporting to the Director:

Division of Field Enforcement (DCSHAA)

Division of Inspectorate Policy (DCSHAB)

Division of Tobacco Inspectorate (DCSHAC)

These organizations report to the Division of Field Enforcement (DCSHAA):

Health Fraud Inspectorate

Branch

Field Recall Effectiveness

Branch

These organizations report to the Division of Inspectorate Policy (DCSHAB):

Food Inspectorate Policy Branch

Medical Products and Tobacco

Inspectorate Policy Branch

These organizations report to the Division of Tobacco Inspectorate (DCSHAC):

Tobacco Investigations Branch 1

Tobacco Investigations Branch 2