

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

Division of Field Enforcement

Effective Date: May 13, 2024

1. Division of Field Enforcement (DCSHAA).

- A. Upon the request of the Food and Drug Administration (FDA), Center, or office, when authorities or the FDA Center and office roles are not yet defined, provides advice to the Office of Inspections and Investigations (OII) Programs and to the FDA Centers and offices on enforcement actions and procedures and coordinates cross-Center and office enforcement initiatives.
- B. Provides support and review of compliance casework which falls exclusively under OII purview, so that the FDA can manage, measure, and improve the quality of that compliance work in coordination with OII quality operations.
- C. Provides management and oversight of the FDA's debarment program, working in consultation with the Centers as appropriate, and coordinates development of standardized inspectorate procedures.
- D. Upon the request of the FDA Centers and Offices, exercises responsibility for enforcement strategy and execution, in collaboration with OII Programs, and the FDA Centers and Offices, for non-compliant domestic and imported products that fall outside of individual Center and office jurisdiction.

2. Health Fraud Inspectorate Branch (DCSHAA1).

- A. Directs and coordinates OII's operational activities related to the investigation of health fraud; performs internet investigations of fraudulent and tainted products, including obtaining samples for analysis; evaluates and supports the transfer of cases to the FDA Centers and offices to determine appropriate compliance actions related to fraudulent and tainted products.

- B. Serves as OII's health fraud liaison on case-specific questions to the FDA Centers and offices, other federal agencies, and foreign governments.
- C. Supports the development of procedures relative to fraudulent and tainted products.
- D. Meets with industry representatives to exchange information and to provide information regarding fraudulent and tainted products consistent with applicable laws, regulations, and FDA policies.
- E. Upon the request of the Centers and offices, analyzes and determines adequacy of proposed cosmetic compliance actions by field offices.
- F. Supports the activities of the Compliance Policy Council.
- G. With respect to inspectorate and health fraud matters, serves as a fact witness in court cases dealing with regulated products; as necessary and designated, acts as a case agent, and may testify in court trials as necessary.

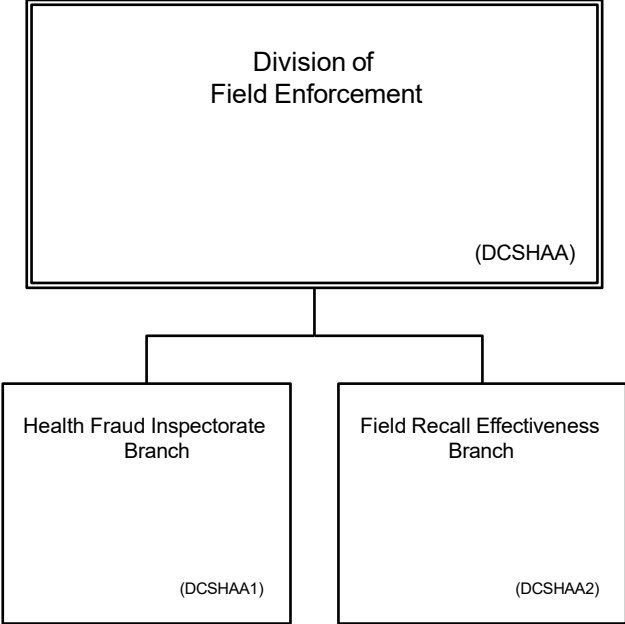
3. Field Recall Effectiveness Branch (DCSHAA2).

- A. Provides guidance to OII's program operations inspectorates in managing, coordinating, and evaluating field recall workload, and impact and risk mitigation strategies in response to the FDA Centers and offices-initiated recalls.
- B. Provides advice and instruction on field recall procedures.
- C. Provides advice related to inspectorate activities on recall policy and procedures developed by the FDA Centers and offices which impact field operations.
- D. Maintains liaison with FDA components, industry, and other domestic and foreign government agencies to provide appropriate and efficient assistance and coordination of recalls, and to ensure proper implementation of completion of recall plans and activities.
- E. Maintains liaison with other FDA components in coordination of the FDA Centers and offices driven recall follow-up activities.

4. Authority and Effective Date.

The functional statements for the Division of Field Enforcement 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
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Division of Field Enforcement**



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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, Division of Field Enforcement organization structure depicting all the organizational structures reporting to the Director:

Health Fraud Inspectorate Branch (DCSHAA1)

Field Recall Effectiveness Branch (DCSHAA2)