

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 Tobacco Inspectorate

Effective Date: May 13, 2024

1. Division of Tobacco Inspectorate (DCSHAC).

- A. Provides advice and guidance to the Office of Inspections and Investigations (OI) and other Food and Drug Administration (FDA) leaders concerning tobacco inspectorate activities.
- B. Addresses tobacco inspectorate activities in collaboration with the Center for Tobacco Products (CTP) and other FDA Offices.
- C. Provides managerial direction to the FDA's field programs for the tobacco products regulated by the CTP.
- D. Manages resource allocations, funding, and people and evaluates use of the resources to assure tobacco program accomplishments.

2. Tobacco Investigations Branch 1 (DCSHAC1).

- A. Conducts investigations and inspections for which the FDA has regulatory responsibility as part of enforcing tobacco regulations; collects samples for analysis; performs field examinations; and prepares reports on findings of each inspection.
- B. Evaluates inspectional and analytical findings relative to compliance or noncompliance and recommends appropriate follow-up.
- C. Recommends legal action to the CTP in response to regulatory activities.

- D. Manages and evaluates OII tobacco program activities, measures accomplishments against annual tobacco field work plan objectives and annual performance agreement, and initiates management and program analyses.
- E. Receives and responds to consumer inquiries received by the FDA and requiring response from OII in coordination with FDA Centers and Offices.

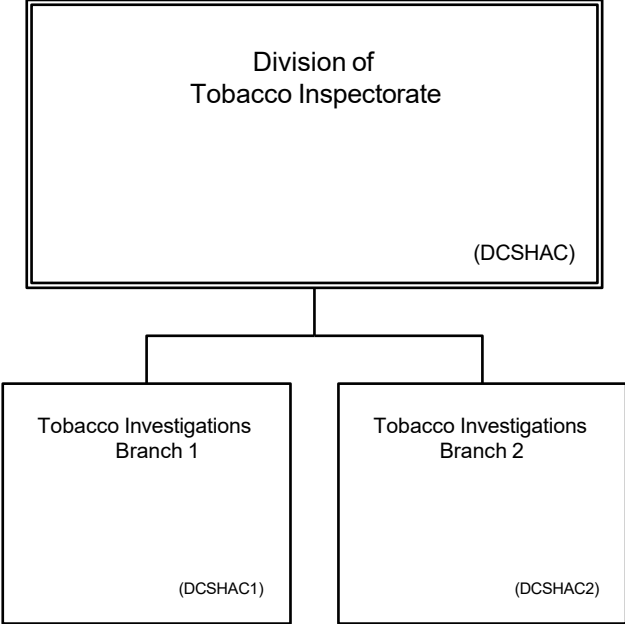
3. Tobacco Investigations Branch 2 (DCSHAC2).

- A. Conducts investigations and inspections for which the FDA has regulatory responsibility as part of enforcing tobacco regulations; collects samples for analysis; performs field examinations; and prepares reports on findings of each inspection.
- B. Evaluates inspectional and analytical findings relative to compliance or noncompliance and recommends appropriate follow-up.
- C. Recommends legal action to the CTP in response to regulatory activities.
- D. Manages and evaluates OII tobacco program activities, measures accomplishments against annual tobacco field work plan objectives and annual performance agreement, and initiates management and program analyses.
- E. Receives and responds to consumer inquiries received by the FDA and requiring response from OII in coordination with FDA Centers and Offices.

4. Authority and Effective Date.

The functional statements for the Division of Tobacco Inspectorate 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
Division of Tobacco Inspectorate**



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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 Tobacco Inspectorate organization structure depicting all the organizational structures reporting to the Director:

Tobacco Investigations Branch 1 (DCSHAC1)

Tobacco Investigations Branch 2 (DCSHAC2)