

SMG 1357.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Tobacco Products

Office of Compliance and Enforcement

Division of Enforcement and Manufacturing

Effective: January 6, 2022

1. Division of Enforcement and Manufacturing (DCFFA).

- A. Coordinates all field planning activities and issues all field assignments for the Center. Coordinates with the Office of Regulatory Affairs (ORA) to prepare inspection and investigation work plans and allocate resources for the Center inspection programs.
- B. Provides advice to FDA field offices and reviews proposed regulatory actions submitted by field offices and evaluates regulated industry activities to assure compliance with regulations.
- C. Reviews establishment inspection reports and investigation memoranda prepared by ORA and evaluates for regulatory follow-up.
- D. Develops, monitors, and evaluates the Center's Bioresearch Monitoring Programs and their investigative and regulatory follow-up.
- E. Provides technical support and guidance in the development and review of guidance documents, regulations, strategies, training programs, and policies to ensure that regulated tobacco products meet regulatory requirements.
- F. Develops, processes information for, and maintains the tobacco registration and product listing system; ensures industry compliance with reporting requirements.
- G. Participates, develops, and implements Center programs to register Tobacco establishments and product lists.

2. Authority and Effective Date.

The functional statements for the Division were approved by the Deputy Secretary of Health and Human Services on October 22, 2021, and effective on January 6, 2022.

**Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
Division of Enforcement and Manufacturing**

Division of
Enforcement and Manufacturing

(DCFFA)

Staff Manual Guide 1357.2
Organizations and Functions
Effective Date: January 6, 2022

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Office of Compliance and Enforcement, Division of Enforcement & Manufacturing organization structure depicting all the organizational structures reporting to the Division Director.

Division of Enforcement & Manufacturing (DCFFA)