# FDA Staff Manual Guides, Volume I – Organizations and Functions

# **Department of Health and Human Services**

#### Food and Drug Administration

#### Human Foods Program

# **Office of Compliance and Enforcement**

# Office of Compliance Operations and Implementation

# Division of Compliance Implementation

Effective Date: May 13, 2024

#### 1. Division of Compliance Implementation (DCRIAB).

- A. Develops, implements, and actively monitors Human Foods Program (HFP) issued assignments to the Food and Drug Administration's (FDA) inspections and investigations program, including compliance follow-up assignments.
- B. Provides HFP compliance and enforcement policy-related support for FDAwide crosscutting initiatives (like economic adulteration and cannabidiol (CBD) matters).
- C. Develops and/or coordinates across Office of Compliance and Enforcement (OCE) in the development of compliance and enforcement related aspects of FDA training courses covering HFP information.
- D. Provides compliance and enforcement review, input, problem-solving and technical assistance for HFP guidance documents, regulations, and priorities.
- E. Provides OCE leadership for HFP enforcement and compliance quality management and Standard Operating Procedure (SOP) development.
- F. Provides HFP leadership for the maintenance of crosscutting compliance and enforcement policy documents, such as the Regulatory Procedures Manual (RPM) and Staff Manual Guides (SMGs).

### 2. Compliance Policy and Procedures Branch (DCRIAB1).

- A. Provides compliance and enforcement policy-related input for office-wide crosscutting initiatives (like economic adulteration and CBD).
- B. Develops or coordinates across OCE in the development of HFP compliance and enforcement related aspects of FDA training courses.
- C. Provides compliance and enforcement review, input, problem-solving and technical assistance for HFP guidance documents, regulations, and priorities.
- D. Provides leadership for enforcement and compliance quality management and SOP development.
- E. Provides HFP leadership for the maintenance of crosscutting policy documents, such as the RPM and SMG.

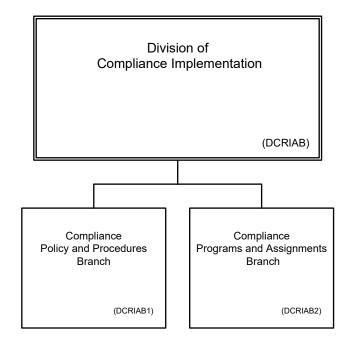
#### 3. Compliance Programs and Assignments Branch (DCRIAB2).

- A. Develops, issues, and actively monitors field assignments, including compliance follow-up assignments.
- B. Develops, updates and issues Compliance Programs for foods and dietary supplement products. Actively monitors work completed under established Compliance Programs, including compliance follow-up assignments.
- C. Develops compliance program- and field assignment-related aspects of FDA training courses.
- D. Facilitates cross-organizational discussion to establish inspectional or sampling approaches for use in assignments and compliance programs.

#### 4. Authority and Effective Date.

The functional statements for the Division of Compliance Implementation 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 Human Foods Program Office of Compliance and Enforcement Office of Compliance Operations and Implementation Division of Compliance Implementation



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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Compliance and Enforcement, Office of Compliance Operations and Implementation, Division of Compliance Implementation organization structure depicting all the organizational structures reporting to the Director:

Compliance Policy and Procedures Branch (DCRIAB1)

Compliance Programs and Assignments Branch (DCRIAB2)