

**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 Enforcement**

Effective Date: May 13, 2024

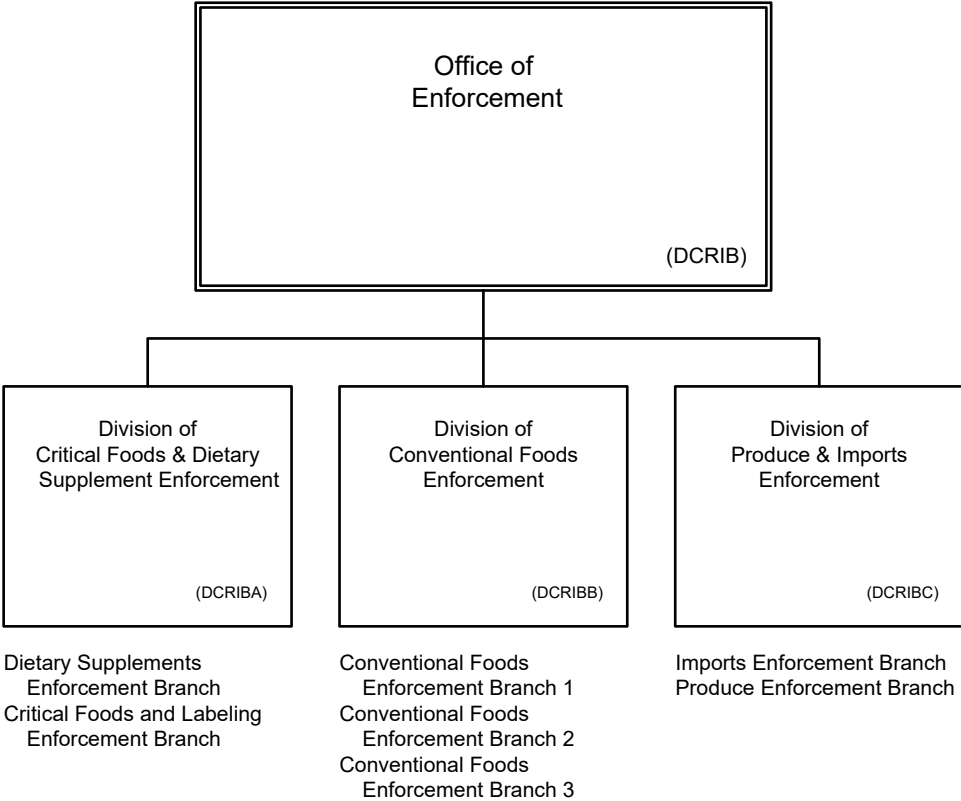
**1. Office of Enforcement (DCRIB).**

- A. Oversees development and implementation of compliance and enforcement strategies to address regulatory issues or compliance challenges in the Human Foods Program (HFP).
- B. Manages the development of HFP compliance and enforcement cases, including analyzing such cases for adequate medical, scientific and legal support resulting in the execution of advisory, administrative and judicial actions.
- C. Maintains relationships with stakeholders, including the United States (US) Marshalls, Food and Drug Administration's (FDA) legal counsel, inspections and investigations program, criminal investigations, state and local government officials, as necessary, to develop and execute HFP related enforcement actions.
- D. Manages engagement between HFP Subject Matter Experts, and FDA's field investigations and other regulatory stakeholders to assist with compliance assessment, efficient evidence collection and enforcement action execution.
- E. Oversees the reviews and evaluations of foreign and domestic inspection documentation, inspectional evidence and associated analytical findings to assess compliance with applicable laws and regulations and determines the most suitable regulatory strategy.
- F. Manages regulatory meetings and the issuance of untitled letters, warning letters and other types of compliance and enforcement correspondence to regulated industry.

## **2. Authority and Effective Date.**

The functional statements for the Office of 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  
Human Foods Program  
Office of Compliance and Enforcement  
Office of Enforcement**



Staff Manual Guide 1231A.92  
Organizations and Functions  
Effective Date: May 13, 2024

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

Division of Critical Foods and Dietary Supplement Enforcement (DCRIBA)

Division of Conventional Foods Enforcement (DCRIBB)

Division of Produce and Imports Enforcement (DCRIBC)

These organizations report to the Division of Critical Foods and Dietary Supplement Enforcement (DCRIBA):

Dietary Supplements Enforcement Branch (DCRIBA1)

Critical Foods and Labeling Enforcement Branch (DCRIBA2)

These organizations report to the Division of Conventional Foods Enforcement (DCRIBB):

Conventional Foods Enforcement Branch 1(DCRIBB1)

Conventional Foods Enforcement Branch 2 (DCRIBB2)

Conventional Foods Enforcement Branch 3 (DCRIBB3)

These organizations report to the Division of Produce and Imports Enforcement (DCRIBC):

Imports Enforcement Branch (DCRIBC1)

Produce Enforcement Branch (DCRIBC2)