

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

Effective Date: May 13, 2024

1. Office of Compliance and Enforcement (DCRI).

- A. Operationalizes Human Foods Program (HFP) goals and priorities through direction, implementation and analysis of HFP inspectional and related activities.
- B. Plans, develops, and directs compliance and enforcement strategies and actions that are in alignment with HFP goals and priorities.
- C. Advises the HFP and other officials on the Food and Drug Administration's (FDA) regulatory and enforcement responsibilities and possible risks associated with HFP-regulated products, in coordination with risk managers and HFP's Surveillance Strategy and Risk Prioritization.
- D. Develops and provides operational management of HFP compliance strategies and enforcement actions and ensures uniform interpretation of standards.
- E. Designs and develops procedures and processes to support work quality, and oversight of implementation, and monitoring for HFP compliance and enforcement activities.
- F. Oversees case development and supports recall execution for HFP-regulated products by establishing medically, scientifically and legally supportable advisory, administrative and judicial actions.

2. Administrative Staff (DCRI1).

- A. Provides leadership, guidance and support services for Office leadership and personnel on all aspects of administrative operations including travel, timekeeping, purchasing and property management.

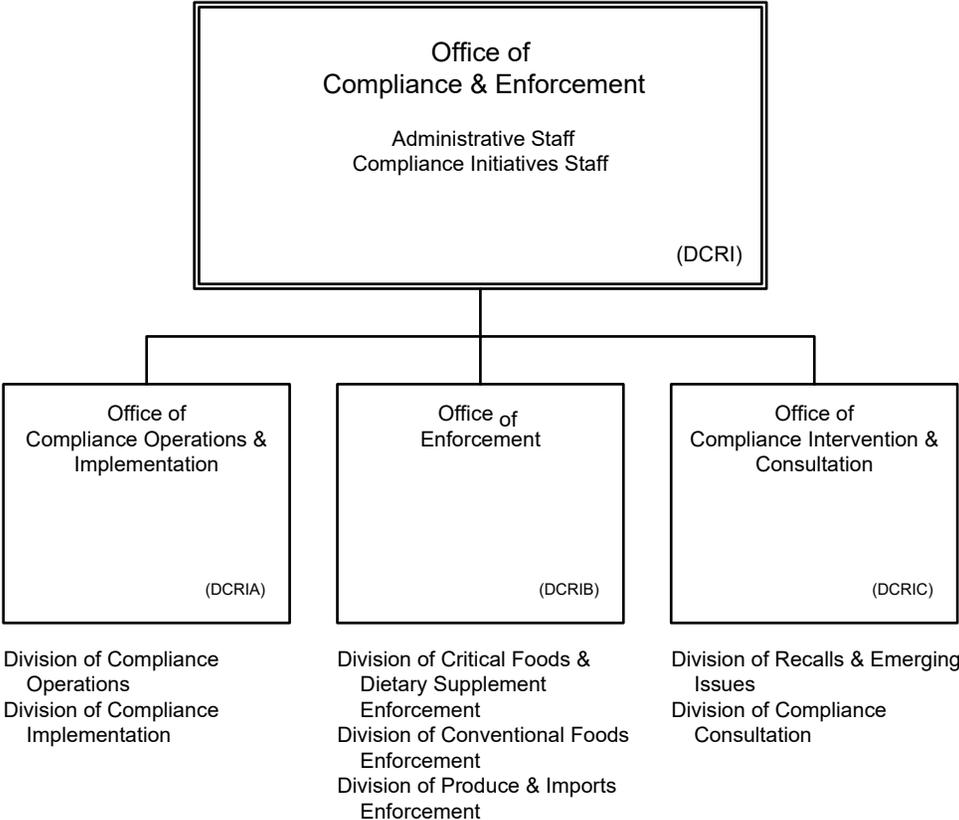
3. Compliance Initiatives Staff (DCRI2).

- A. Monitors and reports to the Office Director and other key HFP officials on activities associated with Office cross-cutting programs, projects, and initiatives.
- B. Provides direct support to Office leadership by development and maintenance of materials, including briefing documents, training and presentation materials, and responses to outside inquiries.
- C. Performs Office-wide projects and initiatives involving complex problems and issues related to FDA programs, strategies and activities, including preparation of special reports or other materials.
- D. Coordinates internal Office communications and liaises for external communications with relevant offices including HFP's Office of Communications, Education, and Engagement, HFP leadership, and FDA's External Affairs organization to provide Office input.

4. Authority and Effective Date.

The functional statements for the Office of Compliance and 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**



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

Administrative Staff (DCRI1)

Compliance Initiatives Staff (DCRI2)

Office of Compliance Operations and Implementation (DCRIA)

Office of Enforcement (DCRIB)

Office of Compliance Intervention and Consultation (DCRIC)

These organizations report to the Office of Compliance Operations and Implementation (DCRIA):

Division of Compliance Operations (DCRIAA)

Division of Compliance Implementation (DCRIAB)

These organizations report to the Office of Enforcement (DCRIB):

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 Office of Compliance Intervention and Consultation (DCRIC):

Division of Recalls and Emerging Issues (DCRICA)

Division of Compliance Consultation (DCRICB)