

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Enforcement and Import Operations

Division of Enforcement

Effective Date: December 14, 2018

1. Division of Enforcement (DCIIA).

- A. Oversees a quality assurance function in compliance casework across programs that permits the Food and Drug Administration (FDA) to manage, measure, and improve the quality of its compliance work product in coordination with Office of Regulatory Affairs' (ORA) Quality Management Staff.
- B. Provides management and oversight of the FDA's debarment program.
- C. Supports training relevant to FDA compliance.
- D. Serves as the ORA clearance point and coordinator for all administrative warrants and actions; liaises with ORA and Centers to ensure coordination of evidence.

2. Recall Operations Branch (DCIIA1)

- A. Provides advice and guidance on recall policy and recall procedures.
- B. Provides consultation to ORA's program operations offices in managing and coordinating field recall workload.
- C. Maintains liaison with other FDA components, industry, and other domestic and foreign government agencies to provide appropriate and efficient assistance and coordination of recalls, and to ensure proper implementation and completion of recall plans and activities.

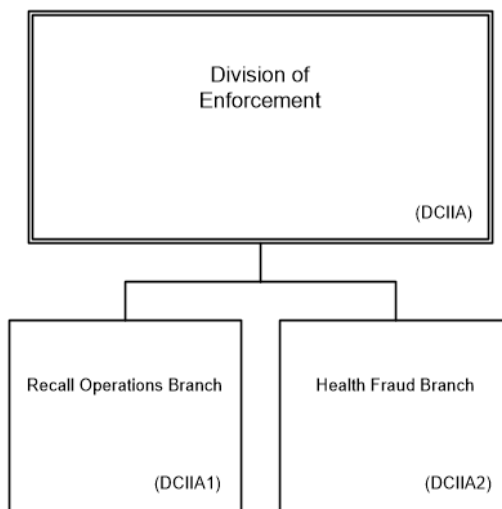
3. Health Fraud Branch (DCIIA2)

- A. Directs and coordinates ORA's activities related to the investigation of health fraud; performs internet investigations of fraudulent and tainted products, including performing undercover buys and the collection of samples for analysis; evaluates and makes recommendations on compliance actions related to fraudulent and tainted products.
- B. Serves as the health fraud liaison to the Centers, other Federal agencies and foreign governments.
- C. Supports the development of policies relative to fraudulent and tainted products.
- D. Meets with industry representatives to exchange information and to provide advice and guidance regarding fraudulent and tainted products. Develops and participates in outreach activities relative to fraudulent and tainted products.

4. Authority and Effective Date.

The functional statements for the Division of Enforcement were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Enforcement and Import Operations
Division of Enforcement**



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

These organizations report to the Division of Enforcement (DCIIA):

Recall Operations Branch (DCIIA1)

Health Fraud Branch (DCIIA2)