

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 Intervention and Consultation

Division of Recalls and Emerging Issues

Effective Date: May 13, 2024

1. Division of Recalls and Emerging Issues (DCRICA).

- A. Leads case development and provides enforcement expertise for high profile, emerging, urgent, or complex regulatory problems related to Human Foods Program (HFP) regulated products such as compliance and enforcement follow-up to outbreaks.
- B. Liaises with stakeholders, including Food and Drug Administrations (FDA) coordinated outbreak response, evaluation, and emergency preparedness, legal counsel, regulatory, criminal investigations, and other emergency response personnel, as well as State, local, and foreign regulatory counterpart officials, to mitigate urgent foodborne illness hazards and to develop and execute related compliance and enforcement actions, such as advisory, administrative, and/or judicial actions.
- C. Provides recall expertise and leads recall decision-making process including recall related HFP policy development, final classification, and scoping decision-making.
- D. Provides recall termination support to stakeholders including FDA's inspections and investigations program, the recalling firm for Class 1 Recalls, and others for HFP regulated products, as appropriate.
- E. Evaluates recall recommendations from FDA's regulatory program and obtains medical, scientific, and technical support to document health risks associated with recalled products.

- F. Evaluates and makes determinations on HFP firm reconditioning proposals and diversion requests.

2. Recalls Branch (DCRICA1).

- A. Provides recall expertise and leads recall decision-making process including recall related HFP policy development, final classification, and scoping decision-making.
- B. Provides recall termination support to stakeholders including FDA's inspections and investigations program recall staff and inspectorates and recalling firm for Class 1 Recalls and others, as appropriate.
- C. Evaluates recall recommendations from FDA's inspections and investigations program Recall staff to document medical, scientific, and technical support as appropriate.
- D. Evaluates and makes determinations on firm reconditioning proposals and diversion requests.
- E. Facilitates the Health Hazard Evaluation process to support recall determination.
- F. Provides technical expertise for communication with industry and the development of communications materials and consumer notifications related to recalls.
- G. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.

3. Emerging Issues Branch (DCRICA2).

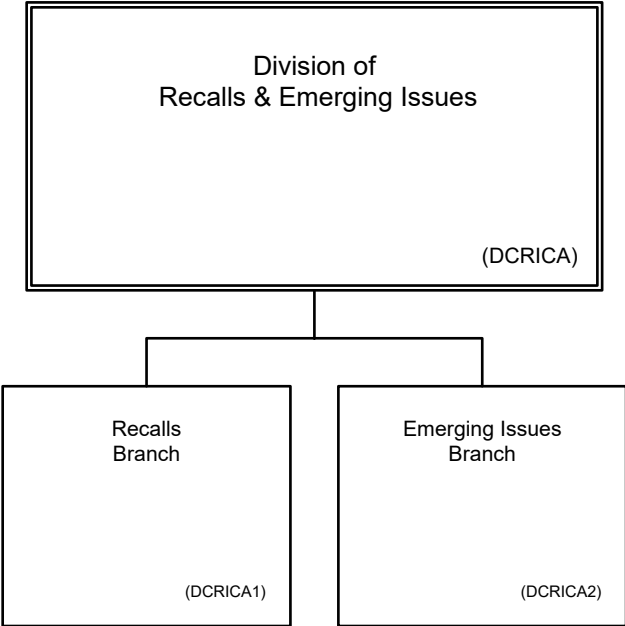
- A. Leads case development and provides enforcement expertise for select high profile, emerging, urgent, or complex regulatory problems such as compliance and enforcement follow-up to outbreaks, recalls, or other high-profile issues or other novel regulatory issues assigned to Branch.
- B. Liaises with stakeholders, including FDA's outbreak response and evaluation program, Office of Chief Counsel (OCC), FDA's inspections and investigations program, Office of Criminal Investigations (OCI) and emergency response personnel, as well as state and local officials, to mitigate imminent foodborne illness hazards and to develop and execute related compliance and enforcement actions, such as advisory, administrative, and/or judicial actions.
- C. Provides surge capacity for resource intensive enforcement activities by supporting all types of advisory, administrative, and judicial actions.

D. Provides briefings, updates, and other internal communication support necessary inform leadership regarding enforcement activities led by the branch.

4. Authority and Effective Date.

The functional statements for the Division of Recalls and Emerging Issues 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
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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 Intervention and Consultation, Division of Recalls and Emerging Issues organization structure depicting all the organizational structures reporting to the Director:

Recalls Branch (DCRICA1)

Emerging Issues Branch (DCRICA2)