

**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 Compliance Consultation**

Effective Date: May 13, 2024

**1. Division of Compliance Consultation (DCRICB).**

- A. Reviews, and coordinates appropriate follow-up and communication to stakeholders for non-inspection related Human Foods Program (HFP) regulated product sample results, including but not limited to, referral to recall coordinators, Emergency Response Coordinators (ERCs) and State Liaisons as appropriate.
- B. Evaluates state and third-party non-inspection related HFP regulated product sample results and ensures communication through appropriate stakeholder channels of results and appropriate follow-up.
- C. Facilitates compliance and enforcement information sharing, including issuance of Voluntary Action Indicated (VAI)/Official Action Indicated (OAI) case-related Field Manual Directive (FMD)-145 letters with regulated industry, state, and Food and Drug Administration's regulatory inspection, as appropriate.
- D. Performs triage to assess significance of findings and transfers matters to the enforcement component, as appropriate, for advisory, administrative, or judicial action.
- E. Supports quality management, by assisting with Standard Operating Procedure (SOP) development, developing template language for Human Foods Program related compliance and enforcement actions, monitoring timeliness, and analyzing the consistency of compliance and enforcement activities.

- F. Manages regulatory misconduct and trade complaint process for HFP regulated products including the receipt, triage, evaluation, and monitoring of complaints received in the HFP.

## **2. Compliance Consultation Branch 1 (DCRICB1).**

- A. For matters assigned, Branch reviews, and coordinates appropriate follow-up and communication to stakeholders for non-inspection related FDA sample results, including referral to Recall Coordinators, ERCs and State Liaisons as appropriate.
- B. For matters assigned, Branch evaluates state and third-party-related non-inspection sample results and ensures communication through appropriate stakeholder channels of results and appropriate follow-up.
- C. For matters assigned, Branch facilitates compliance and enforcement information sharing with regulated industry, state, and FDA's inspections and investigations program, as appropriate. Issues FMD-145 correspondence for enforcement cases managed by Office of Compliance and Enforcement (OCE).
- D. Answers general compliance and enforcement related inquiries from FDA's inspections and investigations program (including Inspectorates, State Liaisons, and Emergency Response Coordinators (ERCs)), regulator Technical Assistance Network (rTAN) and the Technical Assistance Network (TAN), other federal agencies, State and local officials, foreign and industry stakeholders regarding interpretations of FDA-enforced laws and regulations, evidence thresholds, case status and enforcement policies.
- E. Performs triage to assess significance of findings and transfers potential cases and/or evidentiary packages to the Office of Enforcement, as appropriate, for an advisory, administrative, or judicial action.
- F. Supports quality management, by assisting with SOP development, developing template language for compliance and enforcement actions, monitoring timeliness, and analyzing the consistency of enforcement activities.
- G. Manages regulatory misconduct and trade complaint process including the receipt, triage, evaluation, and monitoring of complaints received by the HFP.

## **3. Compliance Consultation Branch 2 (DCRICB2).**

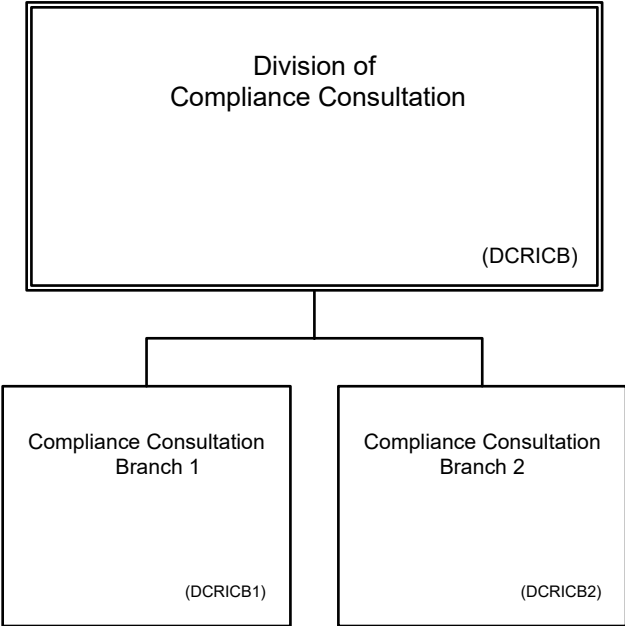
- A. For matters assigned, Branch reviews, and coordinates appropriate follow-up and communication to stakeholders for non-inspection related FDA sample results, including referral to Recall Coordinators, ERCs and State Liaisons as appropriate.

- B. For matters assigned, Branch evaluates state and third party related non-inspection related sample results and ensures communication through appropriate stakeholder channels of results and appropriate follow-up.
- C. For matters assigned, Branch facilitates compliance and enforcement information sharing with regulated industry, state, and FDA's inspections and investigations programs, as appropriate. Issues FMD-145 correspondence for enforcement cases managed by OCE
- D. Answers general compliance and enforcement related inquiries from FDA's inspections and investigations program (including Inspectorates, State Liaisons, and Emergency Response Coordinators (ERCs)), regulator Technical Assistance Network (rTAN) and the Technical Assistance Network (TAN), other federal agencies, state and local officials, foreign and industry stakeholders regarding interpretations of FDA-enforced laws and regulations, evidence thresholds, case status and enforcement policies.
- E. Performs triage to assess significance of findings and transfers potential cases and/or evidentiary packages to the Office of Enforcement, as appropriate, for an advisory, administrative, or judicial action.
- F. Supports quality management, by assisting with SOP development, developing template language for compliance and enforcement actions, monitoring timeliness, and analyzing the consistency of enforcement activities.
- G. Manages regulatory misconduct and trade complaint process including the receipt, triage, evaluation, and monitoring of complaints received in the HFP.

#### **4. Authority and Effective Date.**

The functional statements for the Division of Compliance Consultation 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 Intervention and Consultation  
Division of Compliance Consultation**



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

Compliance Consultation Branch 1 (DCRICB1)

Compliance Consultation Branch 2 (DCRICB2)