SMG 1231A.921

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

Division of Critical Foods and Dietary Supplements Enforcement

Effective Date: May 13, 2024

1. Division of Critical Foods and Dietary Supplements Enforcement (DCRIBA).

A. Implements compliance and enforcement strategies to address regulatory issues or compliance challenges in critical foods, dietary supplements, and labeling.

B. Leads the development of enforcement strategies related to critical foods, dietary supplements, and labeling including those for novel, complex, and precedent-setting regulatory problems, including those with critical foods shortage concerns.

C. Manages engagement between Human Foods Program (HFP) Subject Matter Experts, Food and Drug Administration's (FDA) Regulatory Field Investigations, and state regulatory partners to assist with compliance assessment, efficient evidence collection, and enforcement action execution related to critical foods, dietary supplements, and labeling.

D. Evaluates firm responses to FDA action and proposed corrective measures related to critical foods, dietary supplements, and labeling for adequacy and determines if any additional follow-up actions are necessary or case closeout, such as a warning letter closeout, is warranted.

E. Collaborates with FDA Centers and Offices, other agencies, and other relevant stakeholders concerning multijurisdictional products and/or cross-cutting regulatory or enforcement actions related to critical foods, dietary supplements, and labeling.

F. Reviews and evaluates foreign and domestic Establishment Inspection Reports (EIRs), inspectional evidence and associated analytical findings to assess compliance with applicable laws and regulations and determines the most suitable and regulatory strategy for critical foods, dietary supplements, and labeling.

G. Establishes final classification for Official Action Indicated (OAI) and select Voluntary Action Indicated (VAI) and/or No Action Indicated (NAI) inspections for critical foods, dietary supplements, and labeling, as agreed upon with FDA's regulatory program.

H. Leads development of critical foods, dietary supplements, and labeling compliance and enforcement cases and manages the development of scientifically and legally supportable advisory, administrative and judicial actions.

I. Issues untitled letters, warning letters and other types of compliance and enforcement correspondence to regulated industry related to critical foods, dietary supplements, and labeling.

J. Leads regulatory meetings related to critical foods, dietary supplements, and labeling with regulated industry.

K. Identifies need and scope for compliance follow up inspection assignments related to critical foods, dietary supplements, and labeling.

L. Liaises with stakeholders, including the United States (U.S.) Marshalls, FDA's legal counsel, inspections and investigations program, criminal investigations, state and local governments, as necessary, to develop and execute enforcement actions related to critical foods, dietary supplements, and labeling.

M. Provides post-action oversight and monitoring related to matters involving critical foods, dietary supplements, and labeling by ensuring court-ordered actions and actions required after administrative action are completed.

N. Reviews critical foods, dietary supplements, and labeling EIRs and develops import detention/refusal and Detention Without Physical Examination (DWPE) letter/Warning Letter (WL) cases based on foreign inspections.

2. Dietary Supplements Enforcement Branch (DCRIBA1).

A. Implements compliance and enforcement strategies to address regulatory issues or compliance challenges in dietary supplements.

B. Leads the development of enforcement strategies including those for novel, complex, and precedent-setting regulatory problems.

C. Manages engagement between HFP Subject Matter Experts, Office of Inspections and Investigations (OII), other federal agencies and state regulatory partners to assist with compliance assessment, efficient evidence collection, and enforcement action execution.

D. Evaluates firm responses to FDA action and proposed corrective measures for adequacy and determines if any additional follow-up actions are necessary or case closeout, such as a warning letter closeout, is warranted.

E. Collaborates with FDA Centers, other Agencies, and other relevant stakeholders concerning multijurisdictional products and/or cross-cutting regulatory or enforcement actions.

F. Reviews and evaluates foreign and domestic EIRs, inspectional evidence and associated analytical findings to assess compliance with applicable laws and regulations and determines the most suitable regulatory strategy.

G. Determines final classification for OAI and VAI inspections, other workload arrangements may be made for VAI inspections by agreement with OII.

H. Leads development of dietary supplement related compliance and enforcement cases and manages the development of scientifically and legally supportable advisory, administrative and judicial actions.

I. Issues Untitled Letters, Warning Letters and other types of compliance and enforcement correspondence to regulated industry.

J. Coordinates and leads Regulatory Meetings with regulated industry.

K. Identifies need and scope for compliance follow up inspection assignments.

L. Liaises with stakeholders, including the US Marshalls, Office of Chief Counsel (OCC), FDA's inspections and investigations program, Office of Criminal Investigations (OCI), state and local officials, as necessary, to develop and execute enforcement actions.

M. Provides post-action oversight and monitoring of required activities for court-ordered judicial actions and administrative actions.

N. Reviews EIRs and develops import detention/refusal and DWPE/WL cases based on foreign inspections.

3. Critical Foods and Labeling Enforcement Branch (DCRIBA2).

A. Implements compliance and enforcement strategies to address regulatory issues or compliance challenges in critical foods and labeling.

B. Leads the development of innovative enforcement strategies including those for novel, complex, and precedent-setting regulatory problems, including those with critical foods shortage concerns.

C. Manages engagement between HFP Subject Matter Experts, OII, other federal agencies and state regulatory partners to assist with compliance assessment, efficient evidence collection, and enforcement action execution.

D. Evaluates firm responses to FDA action and proposed corrective measures for adequacy and determines if any additional follow-up actions are necessary or case closeout, such as a warning letter closeout, is warranted.

E. Collaborates with FDA Centers, other Agencies, and other relevant stakeholders concerning multijurisdictional products and/or cross-cutting regulatory or enforcement actions.

F. Reviews and evaluates foreign and domestic EIRs, inspectional evidence and associated analytical findings to assess compliance with applicable laws and regulations and determines the most suitable and regulatory strategy.

G. Determines final classification for OAI and VAI inspections, other workload arrangements may be made for VAI inspections by agreement with OII.

H. Leads development of critical foods or labeling related compliance and enforcement cases and manages the development of scientifically and legally supportable advisory, administrative and judicial actions.

I. Untitled Letters, Warning Letters and other types of compliance and enforcement correspondence to regulated industry.

J. Coordinates and leads Regulatory Meetings with regulated industry.

K. Identifies need and scope for compliance follow up inspection assignments.

L. Liaises with stakeholders, including the US Marshalls, OCC, FDA's inspections and investigations program, OCI, state and local officials, as necessary, to develop and execute enforcement actions.

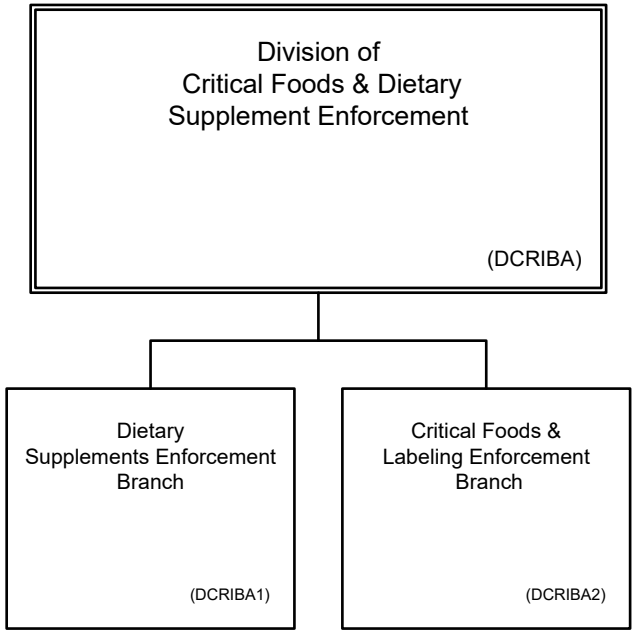
M. Provides post-action oversight and monitoring of required activities for court-ordered judicial actions and administrative actions.

O. Reviews EIRs and develops import detention/refusal and Detention Without Physical Examination DWPE/WL cases based on foreign inspections.

4. Authority and Effective Date.

The functional statements for the Division of Critical Foods and Dietary Supplements 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
Division of Critical Foods and Dietary Supplement 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, Office of Enforcement, Division of Critical Foods and Dietary Supplement Enforcement organization structure depicting all the organizational structures reporting to the Director:

Dietary Supplements Enforcement Branch (DCRIBA1)

Critical Foods and Labeling Enforcement Branch (DCRIBA2)