SMG 1231A.922

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 Conventional Foods Enforcement

Effective Date: May 13, 2024

1. Division of Conventional Foods Enforcement (DCRIBB).

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

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

C. Manages engagement between HFP Subject Matter Experts, Food and Drug Administration (FDA) Regulatory Field Investigations and state regulatory partners to assist with compliance assessment, efficient evidence collection, and enforcement action execution related to conventional foods.

D. Evaluates firm responses to FDA action and proposed corrective measures related to conventional foods 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 conventional foods.

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 regulatory strategy for conventional foods.

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

H. Leads development of conventional foods 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 conventional foods.

J. Identifies need and scope for compliance follow up inspection assignments related to conventional foods.

K. Leads Regulatory Meetings related to conventional foods with regulated industry.

L. Liaises with stakeholders, including the United States (U.S.) Marshalls, FDA's legal Counsel, Regulatory, Criminal Investigations components, state and local governments, as necessary, to develop and execute enforcement actions related to conventional foods.

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

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

2. Conventional Foods Enforcement Branch 1 (DCRIBB1).

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

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, FDA Field Investigations, 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 FDA's regulatory program.

H. Leads development of conventional food 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. Identifies need and scope for compliance follow up inspection assignments

K. Coordinates and leads Regulatory Meetings with regulated industry.

L. Liaises with stakeholders, including the US Marshalls, Office of Chief Counsel (OCC), FDA's regulatory 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. Conventional Foods Enforcement Branch 2 (DCRIBB2).

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

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, FDA Field Investigations, 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 FDA's regulatory program.

H. Leads development of conventional food 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. Identifies need and scope for compliance follow up inspection assignments

K. Coordinates and leads Regulatory Meetings with regulated industry.

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

M. Provides post-action oversight and monitoring by ensuring court-ordered actions and actions required after administrative action are completed.

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

4. Conventional Foods Enforcement Branch 3 (DCRIBB3).

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

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, FDA Field Investigations, 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 FDA's regulatory program.

H. Leads development of conventional foods 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. Identifies need and scope for compliance follow up inspection assignments

K. Coordinates and leads Regulatory Meetings with regulated industry.

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

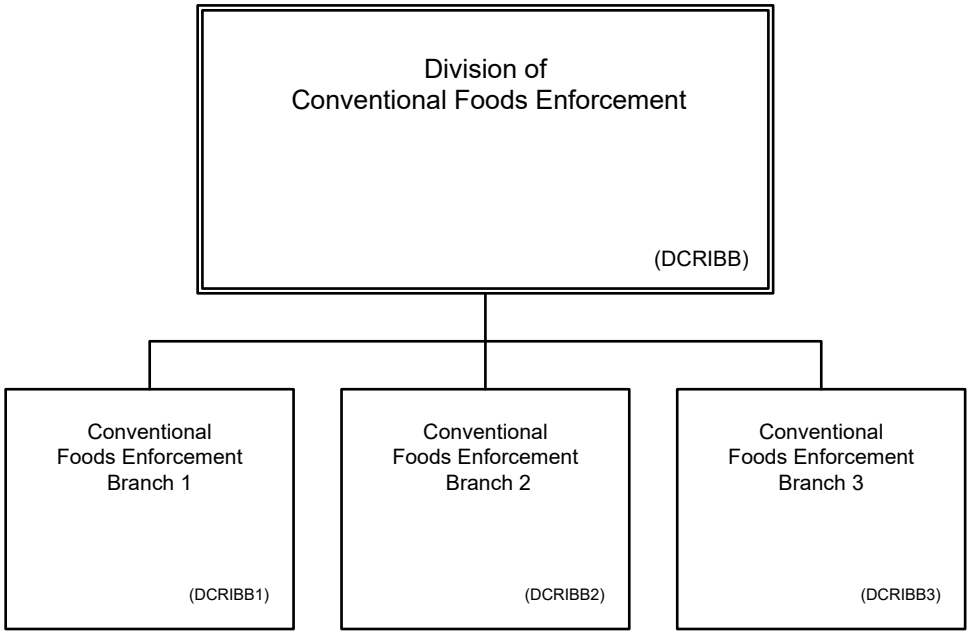
M. Provides post-action oversight and monitoring of required activities for court-ordered judicial actions and administrative actions.

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

5. Authority and Effective Date.

The functional statements for the Division of Conventional Foods 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 Conventional Foods 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 Conventional Foods Enforcement organization structure depicting all the organizational structures reporting to the Director:

Conventional Foods Enforcement Branch 1 (DCRIBB1)

Conventional Foods Enforcement Branch 2 (DCRIBB2)

Conventional Foods Enforcement Branch 3 (DCRIBB3)