

SMG 1244.14

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Veterinary Medicine (CVM)

Office of Surveillance and Compliance (OSC)

Division of Food Compliance (DFC)

Effective Date: May 13, 2024

1. Division of Food Compliance (DCGDE).

- A. Oversees the Centers post-market animal food surveillance and compliance activities.
- B. Coordinates and prepares compliance and enforcement-oriented replies to inquiries from consumers, State and Federal governments, Congress, industry, etc.
- C. Works directly with Office of Inspections and Investigations (OII) to develop and execute FDA's animal food inspection program.
- D. Advises on regulatory and administrative policy issues and develops enforcement strategies involving animal food. Prepares and issues guidance to the field offices. Coordinates and prepares compliance and enforcement-oriented replies to inquiries from consumers, State and Federal governments, Congress, industry, etc.

2. Complaints, Emergencies, and Recall Branch (DCGDE1).

- A. Evaluates complaints received related to CVM animal food regulated products.
- B. Coordinates animal food recalls, including necessary coordination with OII.
- C. Manages emergency response incidents (e.g., foodborne illness outbreaks, natural disasters).
- D. Triage animal food complaints and coordinates with the OSC Division of Drug Compliance as necessary.
- E. Serves as the animal food Office liaison with CVM's OR Vet-LIRN.

3. Field Operations & Investigations Branch (DCGDE2).

- A. Coordinates investigative and regulatory follow-up through consultation with field, management, legal, and scientific advisors. Supports proposed regulatory actions submitted by the field and evaluated by the Compliance Action Branch by recommending whether such actions should be pursued further by the FDA.
- B. Serves as the primary Center liaison in DFC for field investigations related to for-cause and regulatory follow-up inspections (e.g., those resulting from recalls, reportable food registry reports, or previous compliance concerns). Provides technical expertise for matters related to the planning, and tasking of inspectional and sampling activities.
- C. Serves as the Center focal point to triage and respond to inquiries from OII and State staff to provide technical support on inspectional approach, policy support, compliance support and scientific inquiries.
- D. Answers general compliance and enforcement related inquiries from OII (including Inspectorates, State Liaisons, 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.

4. Regulatory Policy and Program Branch (DCGDE3).

- A. Develops, monitors, and evaluates the Center's compliance and surveillance programs pertaining to tissue residue and National Drug Residue Milk Monitoring and the Animal Food program.
- B. Evaluates regulatory approaches to human food safety concerns including monitoring the prevalence of violative levels of harmful drugs and chemicals in meat and poultry based on findings reported to the Center by the United States Department of Agriculture / Food Safety Inspection Service (USDA/FSIS) and develops strategies designed to prevent food safety problems associated with known and emerging hazards.
- C. Develops animal food program, compliance and enforcement policy related support for Division-wide crosscutting initiatives.
- D. Develop and deliver animal food regulator training in coordination with OII.

5. Science Policy Branch (DCGDE4).

- A. Directs FDA sampling of animal food commodities to obtain information on and control the presence of biological, chemical and physical hazards in animal food.
- B. Evaluates data to develop scientific policy on known and emerging animal food contaminants to protect human and animal health.

- C. Identifies and reviews potential safety signals within post-market adverse event reports received by FDA CVM for animal foods, including pet food.
- D. Provides advice and scientific support to FDA compliance officers and investigators regarding the safety of animal food contaminated with biological, chemical and/or physical contaminants.

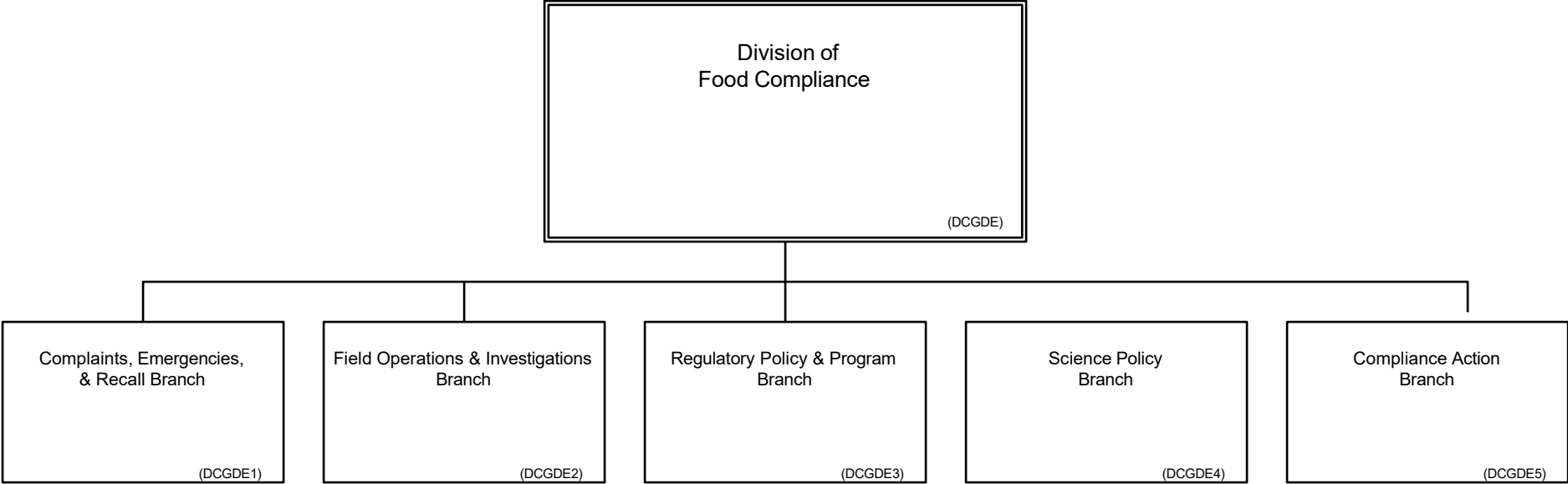
6. Compliance Action Branch (DCGDE5).

- A. Reviews and evaluates 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 in consultation with other Center experts or advisors.
- B. Leads development of compliance and enforcement cases and manages the development of scientifically and legally supportable advisory, administrative and judicial actions.
- C. Issues Untitled Letters, Warning Letters and other types of compliance and enforcement correspondence to regulated industry.
- 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.

7. Authority and Effective Date.

The functional statements for the Division of Food Compliance were approved by the Commissioner of Food and Drugs on, 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
Center for Veterinary Medicine
Office of Surveillance and Compliance
Division of Food Compliance**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Surveillance and Compliance, Division of Food Compliance organization structure depicting all the organizational structures reporting to the Director of Food Compliance:

Division of Food Compliance (DCGDE)
Complaints, Emergencies, and Recall Branch (DCGDE1)
Field Operations and Investigations Branch (DCGDE2)
Regulatory Policy and Program Branch (DCGDE3)
Science Policy Branch (DCGDE4)
Compliance Action Branch (DCGDE5).