

SMG 1121.852

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Human and Animal Food Operations

Office of Human and Animal Food Operations East

Division of Human and Animal Food Operations East I

Effective Date: December 14, 2018

1. Division of Human and Animal Food Operations East I (DCIEBB).

- A. Manages field inspection and compliance operations within the associated division for human and animal food (HAF) and other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM).
- B. Manages and evaluates resource use in support of the human and animal food program.
- C. Conducts investigations and inspections related to human and animal food and other products for which CFSAN and CVM have regulatory responsibility.
- D. Recommends legal action and assists in implementing approved action.
- E. Manages and evaluates human and animal food program activities and manages a quality assurance program.
- F. Develops short and long-range work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program.
- G. Advises the HAF Program Director- East of emerging problems, trends, program needs and any local or state issues.
- H. Manages program and operational activities, including all phases of personnel management, financial management, property and supplies for the Division.

2. Human and Animal Food Investigations Branch (DCIEBB1)

- A. Inspects human and animal food establishments for which CFSAN and CVM have regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports.
- B. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up.
- C. Evaluates corrective actions taken by human and animal food establishments and provides feedback.
- D. Prepares and provides evidence of investigational findings.
- E. Performs special investigations, including foodborne outbreaks.
- F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
- G. Provides inspectional and investigational support to the Office of Regulatory Affairs (ORA) headquarters, CFSAN, CVM, and other divisions, as needed.
- H. Plans, schedules and controls human and animal food inspectional operations.
- I. Supports the development and implementation of domestic and foreign inspectional work plans.
- J. Provides counsel and training regarding inspectional techniques and technical developments to other Federal, State, local agencies and foreign counterpart agencies and to industry, as appropriate.
- K. Assists in managing, evaluating and auditing the program aspects of federal-state contracts.

3. Human and Animal Food Compliance Branch (DCIEBB2)

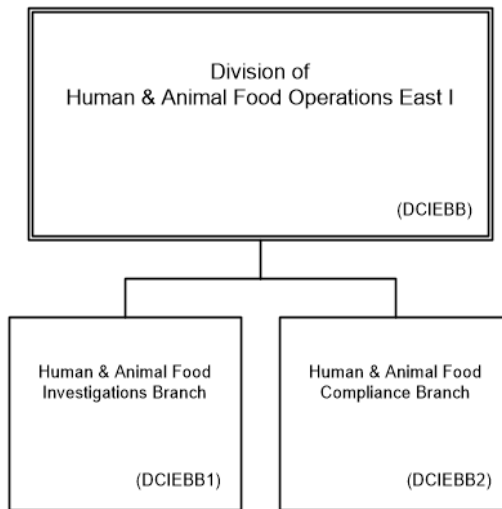
- A. Reviews and evaluates inspectional and analytical findings to assess compliance with the Food and Drug Administration (FDA)-enforced laws and regulations; determines the most suitable course of action and, if appropriate, recommends legal action.
- B. Liaises with the United States (U.S.) attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

- C. Ensures court-ordered actions are completed on time and in total fulfillment of the Court's order.
- D. Issues deficiency, untitled, or warning letters to regulated industry.
- E. Answers inquiries from other Federal agencies, foreign missions and industry regarding interpretations of FDA-enforced laws and regulations, case status and enforcement policies, as appropriate.
- F. Works with State and local officials to develop uniform legislation, codes and regulations; advises state and local officials on interpretation of federal laws, regulations and enforcement policies and provides consultation relative to joint regulatory approaches.
- G. Plans, organizes and implements comprehensive industry education, training and technical assistance programs designed to promote voluntary compliance and self-regulation in cooperation with other field and Headquarters components.
- H. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Maintains cooperative relationships with State and local counterpart agencies, and develops work and information sharing agreements. Presents public education and information programs to various external stakeholders and organizations.

4. Authority and Effective Date.

The functional statements for the Division of Human and Animal Food Operations East I were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Human and Animal Food Operations
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Human and Animal Food Operations, Office of Human and Animal Food Operations East, Division of Human and Animal Food Operations East I organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Human & Animal Food Operations East I (DCIEBB):

Human & Animal Food Investigations Branch (DCIEBB1)

Human & Animal Food Compliance Branch (DCIEBB2)