SMG 1121.85

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

Effective Date: December 14, 2018

1. Office of Human and Animal Food Operations East (DCIEB).

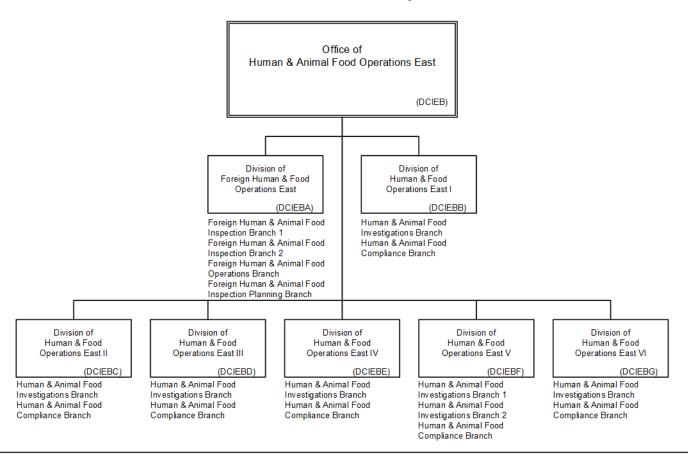
- A. Oversees all field inspection and compliance operations related to human and animal food and other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) in the Divisions of Human and Animal Food Operations- East.
- B. Provides direction and counsel to the Assistant Commissioner for Human and Animal Food Operations (ACHAFO) and other Food and Drug Administration (FDA) leaders relative to human and animal food field operations including emergency response activities.
- C. Coordinates, directs and assists with human and animal food investigative activities.
- D. Supports the development of policy and guidance for investigations and compliance for human and animal food.
- E. Serves as an operational liaison for human and animal food inspection programs to FDA's foreign offices.
- F. Inspects and conducts investigations of human and animal food establishments for which CFSAN and CVM have regulatory responsibilities, collects samples for analysis, performs field examinations and prepares reports.
- G. As needed, participates in system recognition efforts with other FDA components and national and international governments.

- H. Participates as subject matter experts in the design, implementation and presentation of human and animal food training programs.
- I. Monitors emerging issues and advancements in technology and recommends program improvements as necessary.
- J. Serves as subject matter expert on field operations relative to human and animal food on external and internal cross-FDA committees, workgroups and task forces.
- K. Directs and coordinates he Office of Regulatory Affairs (ORA) response to foodborne outbreaks relative to human and animal food in collaboration with Coordinated Outbreak Response and Evaluation (CORE) and the Centers.
- L. Creates, reviews, and/or facilitates issuance of field assignments with Centers for human and animal food programs. Monitors and serves as technical point of contact for these assignments.
- M. Develops and maintains cooperative relationships with State, local and other Federal agencies; serves on interagency councils, encourages improved State and local consumer protection programs pertinent to FDA-enforced laws and regulations.
- N. Plans and evaluates program activities and manages a Quality Assurance Program.
- O. Coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency.
- P. Provides technical assistance regarding food and animal food investigational operations.
- Q. Manages the foreign human and animal food inspection cadre.
- R. Detains human and animal food and in cooperation with the United States Department of Agriculture (USDA), detains meat, poultry or egg products that may be violative.
- S. Conducts administrative hearings for detentions of human and animal food products and other CFSAN and CVM-regulated commodities.

2. Authority and Effective Date.

The functional statements for the Office of Human and Animal Food Operations East 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 Regulatory Affairs Office of Human and Animal Food Operations Office of Human and Animal Food Operations East



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

Division of Foreign Human and Animal Food Operations East (DCIEBA)

Division of Human and Animal Operations East I (DCIEBB)

Division of Human and Animal Operations East II (DCIEBC)

Division of Human and Animal Operations East III (DCIEBD)

Division of Human and Animal Operations East IV (DCIEBE)

Division of Human and Animal Operations East V (DCIEBF)

Division of Human and Animal Operations East VI (DCIEBG)

These organizations report to the Division of Foreign Human and Animal Food Operations:

Foreign Human and Animal Food Inspection Branch 1 (DCIEBA1)

Foreign Human and Animal Food Inspection Branch 2 (DCIEBA2)

Foreign Human and Animal Food Operations Branch (DCIEBA3)

Foreign Human and Animal Food Inspections Planning Branch (DCIEBA4)

These organizations report to the Division of Human and Animal Operations East I:

Human and Animal Food Investigations Branch (DCIEBB1)

Human and Animal Food Compliance Branch (DCIEBB2)

These organizations report to the Division of Human and Animal Operations East II:

Human and Animal Food Investigations Branch (DCIEBC1)

Human and Animal Food Compliance Branch (DCIEBC2)

These organizations report to the Division of Human and Animal Operations East III:

Human and Animal Investigations Branch (DCIEBD1)

Human and Animal Food Compliance Branch (DCIEBD2)

These organizations report to the Division of Human and Animal Operations East IV:

Human and Animal Food Investigations Branch (DCIEBE1)

Human and Animal Food Compliance Branch (DCIEBE2)

These organizations report to the Division of Human and Animal Operations East V:

Human and Animal Food Investigations Branch 1 (DCIEBF1)

Human and Animal Food Investigations Branch 2 (DCIEBF2)

Human and Animal Food Compliance Branch (DCIEBF3)

These organizations report to the Division of Human and Animal Operations East VI:

Human and Animal Food Investigations Branch (DCIEBG1)

Human and Animal Food Compliance Branch (DCIEBG2)