

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Security and Emergency Management

Office of Emergency Management

Office of Emergency Operations

Effective Date: December 14, 2018

1. Office of Emergency Operations (DCNHBA).

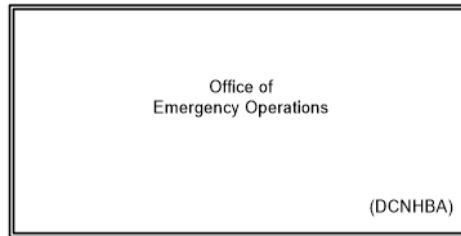
- A. Serves as the Food and Drug Administration (FDA) focal point for emergency preparedness and response operating the 24-hour, seven-day-a-week emergency response system.
- B. Coordinates FDA responses to emergency incidents and situations involving FDA-regulated products and disasters, in conformance with NIMS/ICS principles and practices.
- C. Assists in the development and coordination of the FDA's emergency preparedness and response activities by providing analysis of preliminary information about threats and hazards, and assists in the early recognition of emergencies, outbreaks, natural disasters, and terrorism or other criminal acts.
- D. Manages FDA's Emergency Operations Center (EOC) to ensure responses to emergencies or events involving FDA-regulated products are in compliance with National Incident Management System (NIMS)/Incident Command Structure (ICS) principles.
- E. Coordinates FDA emergency activities with other federal agencies, state, local, tribal, territorial and foreign government officials and industry associations.
- F. Represents the FDA at interagency, intra-agency, state, local and foreign government and industry association meetings and conferences on emergency preparedness and response.

- G. Manages the National Consumer Complaint System which monitors reports of potential problems with FDA-regulated products for potential emergencies.
- H. Recommends activation of an Incident Management Group to coordinate FDA response to disasters and emergencies involving FDA-regulated products. Responsible for coordinating staffing and operations of Incident Management Groups during emergencies.
- I. Monitors international disasters, both natural and manmade, and coordinates with internal FDA and external groups to determine and report the status of staff on official travel in impacted areas.
- J. Monitors and coordinates FDA response to international inquiries directed to FDA from International Food Safety Authority Network (INFOSAN), the European Union's Rapid Alert System for Food and Feed (RASFF), International Health Regulations (IHR) authorities, the Departmental IHR contacts, and other international groups.
- K. Provides alert and notification support for the interagency Advisory Team for the Environment, Food and Health (A-Team), as required, during activation or potential activation.
- L. Represents the FDA at interagency, intra-agency, state, local and foreign government and industry association meetings and conferences on emergency preparedness and response.
- M. Participates in National Biosurveillance Integration Center conference calls sponsored by Department of Homeland Security for interagency information sharing on early recognition of biological events of national concern, both natural and manmade.

2. Authority and Effective Date.

The functional statements for the Office of Emergency Operations 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 Operations
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Office of Emergency Operations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Security and Emergency Management, Office of Emergency Management, Office of Emergency Operations organization structure depicting all the organizational structures reporting to the Director.

Office of Emergency Operations (DCNHBA)