

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Field Operations and Response

Office of Emergency Response

Division of Emergency Preparedness and Support

Effective Date: May 13, 2024

1. Division of Emergency Preparedness and Support (DCSHBB).

- A. Serves as the Food and Drug Administration (FDA) focal point for coordination of response to emergencies involving FDA-regulated products, including natural and technological disasters.
- B. Provides oversight through the development and management of emergency preparedness and response policies, procedures, systems, and programs needed to respond rapidly to emergency situations. Coordinates the FDA's 24-hour emergency response system.
- C. Serves as FDA Emergency Coordinator and primary point of contact with the Department of Health and Human Services (HHS) and other external organizations for emergency management matters.
- D. Participates in international initiatives to ensure capability and readiness with foreign counterparts in responding to international emergencies involving or impacting FDA-regulated products and shares information with international counterparts during such emergencies.
- E. Serves as the FDA coordinator for intake and review of Committee on Foreign Investment in the United States (CFIUS) cases. Assesses joint voluntary notices and determines appropriate action offices within FDA to provide subject matter expert review. Consolidates responses and adjudicates internal comments, as needed. Serves as the FDA interface with HHS and Committee staff related to CFIUS case reviews.

2. Emergency Planning, Exercises, and Evaluation Branch (DCSHBB2).

- A. Develops and updates the FDA's Emergency Operations Plan (EOP), incident-specific annexes to it, and other FDA emergency planning and preparedness documents ensuring their alignment and compliance with the National Response Framework (NRF) and its Emergency Support Functions (ESFs) and the National Incident Management System (NIMS).
- B. Plans and conducts exercises and training to test emergency operations plans at the FDA level, and in partnership with HHS and other Departments and Agencies, including national and international-level exercises.
- C. Provides staffing and other support during Incident Management Group (IMG) activations.
- D. Serves as the FDA lead for NIMS coordination to ensure its incident management programs and activities, including plan development, training, and implementation status reporting.
- E. Conducts evaluations of exercises, special events, and the agency's response to actual incidents to improve and strengthen FDA preparedness for future emergencies.
- F. Responsible for the timely and accurate handling and management of all complaints received, including routine complaints, as well as those characterized as Whistleblower and Confidential Source complaints.

3. Program Operations and Coordination Branch (DCSHBB3).

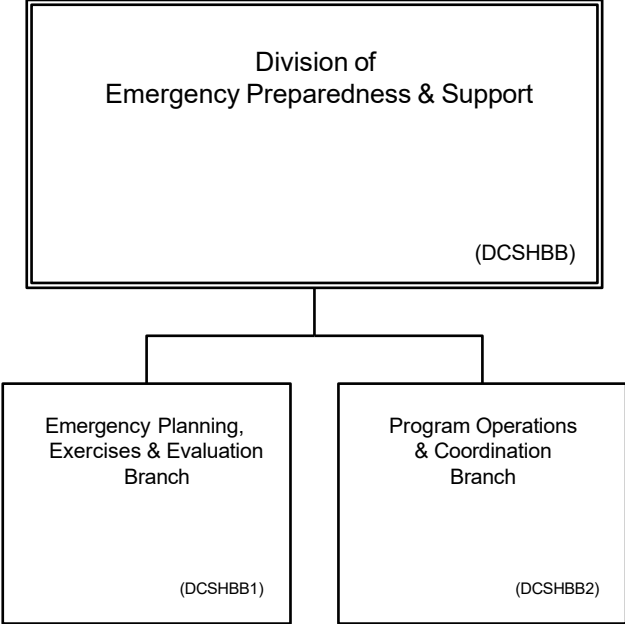
- A. Provides and manages administrative, financial, project management, and logistical support in response to emergency situations that involve public health and/or impact FDA-regulated products.
- B. Provides mapping capabilities that strengthen the FDA's overall immediate response efforts and its ability to analyze data effectively.
- C. Manages the enterprise-wide Geographic Information System and FDA GeoWeb.
- D. Manages the FDA Emergency Call Center to provide 24-hour call taking service and surge capacity capabilities for responding to public inquiries and reports related to FDA-regulated products.
- E. Provides support for FDA's Emergency Operations Center (EOC) facilities, equipment, and communications maintenance.

- F. Provides logistics, finance, and administrative support to Incident Management Groups activated to respond to emergencies and events involving FDA-regulated products.
- G. Manages the FDA Emergency Operations Network Incident Management System (EON IMS), a system for capturing real-time information about emergencies related to FDA-regulated products.
- H. Provides budget execution and formulation, human resources, website management, project management, and other administrative support.

4. Authority and Effective Date.

The functional statements for the Division of Emergency Preparedness and Support 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
Office of Inspections and Investigations
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Field Operations and Response, Office of Emergency Response, Division of Emergency Preparedness and Support organization structure depicting all the organizational structures reporting to the Director:

Emergency Planning, Exercises and Evaluation Branch (DCSHBB1)

Program Operations and Coordination Branch (DCSHBB2)