

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

Effective Date: May 13, 2024

1. Office of Emergency Response (DCSHB).

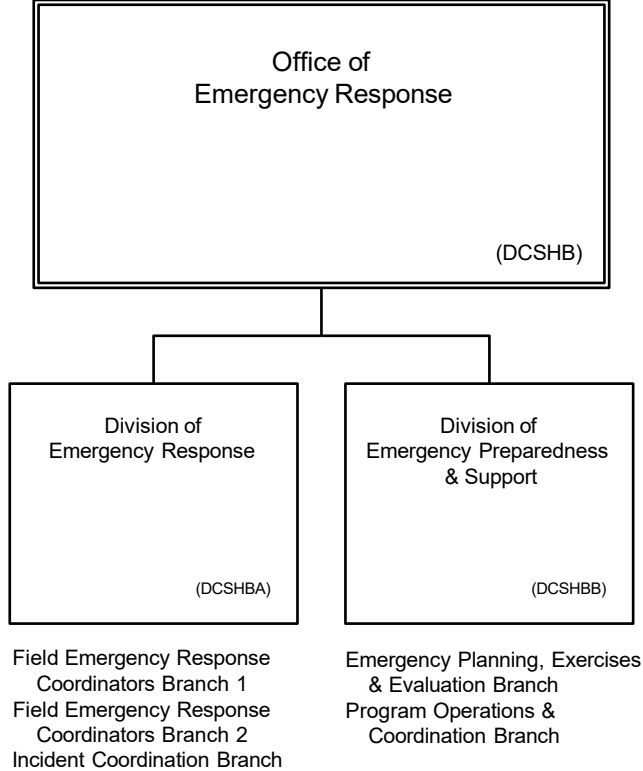
- A. Provides leadership, oversight, and collaboration of the Food and Drug Administration (FDA) emergency management and response programs by developing and implementing policies in coordination with internal service providers, Department of Health and Human Service (HHS) service providers, and other Federal Agency components.
- B. Provides management oversight by developing and implementing FDA-wide emergency response and management inspectorate policy, programs and initiatives and coordinates with HHS and FDA components.
- C. Provides oversight and leadership for coordination of response to emergencies involving FDA-regulated products, including natural and technological disasters.
- D. Provides oversight and leadership for the development and management of emergency preparedness and response policies, procedures, and program needs to respond rapidly to emergency situations.
- E. Develops and provides oversight for strategic plans and the implementation of emergency management, quality, and safety initiatives and requirements.
- 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 consistent with FDA-wide complaint handling.

- G. Provides direction and leadership for all internal Office of Emergency Response (OER) administrative programs such as human resources, budget, and travel.
- H. Manages and initiates all FDA financial requirements for budget execution and formulation for OER.
- I. Provides quality support, monitoring, and evaluation of policies and procedures in the Office of Inspections and Investigations' (OII's) Quality Management System.
- J. Provides overall safety support to OII Offices, Districts, and Resident posts including respirator fit testing program for investigators, liaise with the Office of Safety and Occupational Health, and responds to all safety issues and complaints from OII.

2. Authority and Effective Date.

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



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

Division of Emergency Response (DCSHBA)

Division of Emergency Preparedness and Support (DCSHBB)

These organizations report to the Division of Emergency Response (DCSHBA):

Field Emergency Response Coordinators Branch 1

Field Emergency Response Coordinators Branch 2

Incident Coordination Branch

These organizations report to the Division of Emergency Preparedness and Support (DCSHBB): Emergency Planning, Exercises and Evaluation Branch

Program Operations and Coordination Branch