

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of the Commissioner**

**Office of the Chief Medical Officer**

**Office of Public Health Preparedness and Response**

Effective Date: May 13, 2024

**1. Office of Public Health Preparedness and Response (DCJE).**

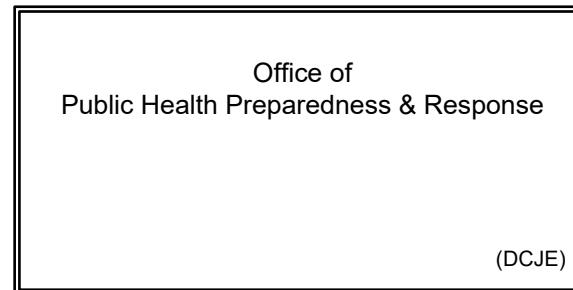
- A. Provides leadership, coordination, and oversight for Food and Drug Administration's (FDA) national and global public health preparedness and response portfolios including consumer safety reporting, health emergencies and product shortages.
- B. Serves as the point of entry to the FDA on matters related to the above portfolios.
- C. Develops and coordinates the implementation of FDA plans and strategies for the above portfolios in support of, and collaboration with, FDA Centers and Offices, and with external United States (US) Government and international partners.
- D. Coordinates FDA-level policy engagement to prevent, detect and respond to drug shortages. Coordinates activities within the FDA, working closely with Center leads; serves as primary focal point for shortage coordination with Health and Human Services (HHS) and the White House.
- E. Oversees central governance structures, protocols, and coordination for consumer and public safety and concern reporting, including, as relevant, assuring that intake systems and triage systems operate efficiently and consistently; coordinating the business process alignment and development for any new consumer safety reporting management technology systems; and coordinating preparedness and response to consumer-related health safety signals that involve multiple Centers or otherwise require an agency preparedness and response.

- F. Serves as the focal point, on behalf of the Commissioner, for the Department of Health and Human Services' Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to protect the civilian population and the Department of Defense medical countermeasure (MCM) programs to support the warfighter.
- G. Coordinates policy and FDA role in research preparedness and response to outbreaks, epidemics and pandemics. This includes interaction with White House, HHS and other entities, in close collaboration with Center subject matter experts (SMEs) and leadership.
- H. Develops and coordinates the implementation of crosscutting FDA policies and procedures to facilitate the availability and assessment of MCMs including efforts to: (1) safeguard MCMs from adulteration or disruption of supplies during public health emergencies; (2) enable access to available MCMs when necessary, through an appropriate mechanism, such as FDA's Emergency Use Authorization (EUA); and (3) assess MCM safety and effectiveness post- administration.
- I. Promotes the goals and needs for the above portfolios in the FDA budgeting and priority-setting processes.
- J. Facilitates communication within FDA and with external partners on matters related to the above portfolios on behalf of the Office of the Commissioner.

## **2. Authority and Effective Date.**

The functional statements for the Office of Public Health Preparedness and 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  
Office of the Chief Medical Officer  
Office of Public Health Preparedness and Response**



Staff Manual Guide 1113B.6  
Organizations and Functions  
Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Medical Officer, Office of Public Health Preparedness and Response organization structure depicting all the organizational structures reporting to the Director: