

SMG 1119A.2

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 Scientist

Office of Counter-Terrorism and Emerging Threats

Effective Date: December 14, 2018

1. Office of Counter-Terrorism and Emerging Threats (DCPA).

- A. Provides leadership, coordination, and oversight for Food and Drug Administration's (FDA) national and global health security, counterterrorism, and emerging threats portfolios.
- B. Serves as the point of entry to the FDA on matters related to the above portfolios
- C. Develops and coordinates the implementation of comprehensive FDA plans and strategies for the above portfolios in support of, and collaboration with, FDA Centers and Offices, and with external US government and international partners.
- D. Serves as the focal point 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.
- E. Develops, coordinates, and leads the implementation of FDA's Medical Countermeasures Initiative (MCMi) to facilitate the development and production of safe and effective MCMs against chemical, biological, radiological, and nuclear agents and emerging threats, such as pandemic influenza, including implementing the MCM Regulatory Science Program and providing focused training for the Center reviewers to enhance the product review and approval processes for MCMs.
- F. 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.

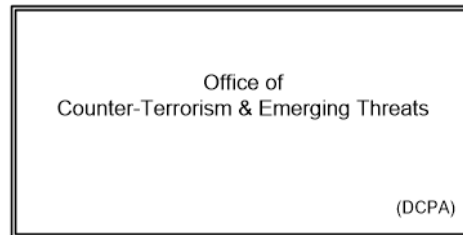
G. Promotes the goals and needs for the above portfolios in the FDA budgeting and priority-setting processes.

H. 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 Counter-Terrorism and Emerging Threats 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 the Commissioner
Office of the Chief Scientist
Office of Counter-Terrorism and Emerging Threats**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist, Office of Counter-Terrorism and Emerging Threats organization structure depicting all the organizational structures reporting to the Director.

Office of Counter-Terrorism and Emerging Threats (DCPA)