

**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**

Effective Date: May 13, 2024

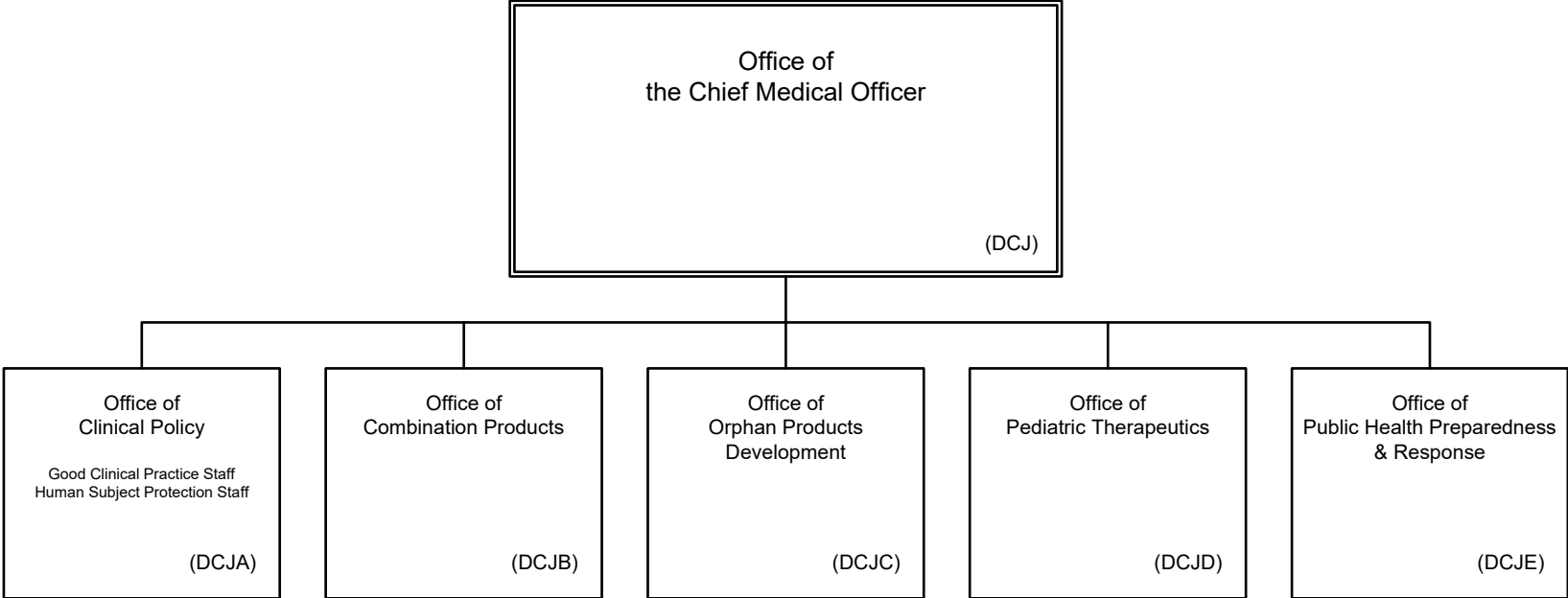
**1. Office of the Chief Medical Officer (DCJ).**

- A. Provides executive leadership, coordination, and oversight for Food and Drug Administration (FDA) cross-cutting clinical and regulatory policy matters and public health preparedness and response activities on behalf of the Commissioner.
- B. Promotes the development of safe, effective and innovative medical products for patients through FDA-wide collaboration on combination products, improvement of evidence generation practices, ethical conduct of clinical research, orphan product development, and pediatric therapeutics.
- C. Serves as a central coordination point for preparedness and response to public health threats, including medical product shortages, outbreaks, and preparedness and response to consumer concerns.
- D. Fosters clinical community of practice and clinical career development across the FDA.
- E. Serves as primary liaison to clinical societies and other clinician stakeholder groups.

**2. Authority and Effective Date.**

The functional statements for the Office of the Chief Medical Officer 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**



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

Office of Clinical Policy (DCJA)  
Office of Combination Products (DCJB)  
Office of Orphan Products Development (DCJC)  
Office of Pediatric Therapeutics (DCJD)  
Office of Public Health Preparedness and Response (DCJE)

These organizations report to the Office of Clinical Policy (DCJA):  
Good Clinical Practice Staff  
Human Subject Protection Staff