

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

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of Medical Policy**

**Office of Medical Policy Initiatives**

**Division of Medical Policy Programs**

Effective Date: December 14, 2018

**1. Division of Medical Policy Programs (DCDHBB).**

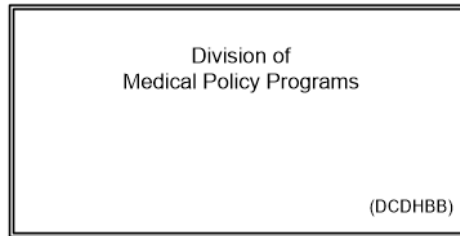
- A. Spearheads implementation of the Sentinel Initiative, an innovative safety monitoring program for marketed medical products that employs active surveillance of automated healthcare databases.
- B. Coordinates with Food and Drug Administration Centers, external partners and stakeholders to ensure efficient implementation of quality science and technology and effective privacy and security strategies.
- C. Manages and coordinates policy development related to the biosimilars legislation and resulting programs.
- D. Manages and coordinates the clinical trial modernization policy and programs including coordinating public-private partnerships dedicated to removing barriers to clinical trials participation, enhancing evidence derived from clinical trials, and optimizing the use of clinical trial resources.
- E. Manages and coordinates policy and program initiatives to improve quality and utility, and broaden dissemination, of consumer-directed medical information.
- F. Manages and coordinates efforts to ensure that professional labeling is compliant with applicable regulations and is optimized as a tool for communicating about the safety and efficacy of drugs.
- G. Coordinates and collaborates with relevant program areas to ensure optimal FDA scientific and technical input for ongoing policy initiatives.

H. Develops and manages new science and technology policy initiatives pertaining to the drug development, drug approval, and post market surveillance processes.

**2. Authority and Effective Date.**

The functional statements for the Division of Medical Policy Programs 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  
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Office of Medical Policy Initiative  
Division of Medical Policy Programs**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Medical Policy, Office of Medical Policy Initiatives, Division of Medical Policy Programs organization structure depicting all the organizational structures reporting to the Director.

Division of Medical Policy Programs (DCDHBB).