

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

Effective Date: December 14, 2018

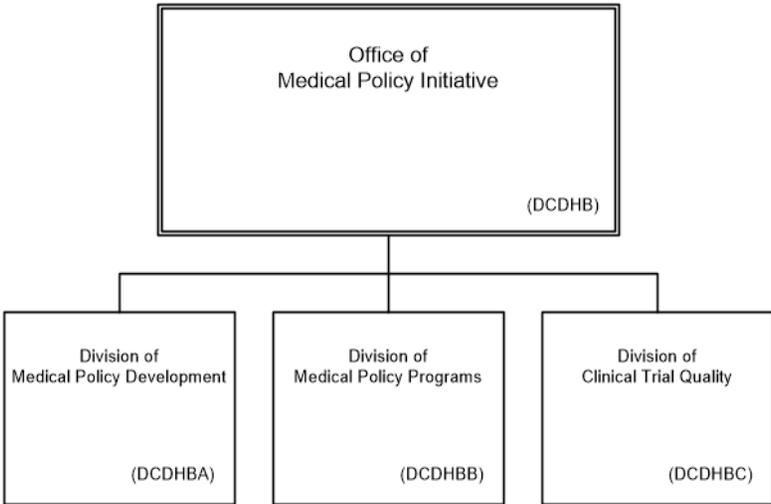
1. Office of Medical Policy Initiatives (DCDHB).

- A. Directly responsible for the development of medical policy pertaining to the drug development, drug approval, bioresearch monitoring, human subject protection and post market surveillance processes in collaboration with appropriate program areas and coordinating committees. Develops issue papers, guidances, regulations, and operating procedures
- B. Provides advice and assistance to FDA staff and external constituents concerning implementation or application of new and existing medical policies and procedures
- C. Collaborates with the Office of Regulatory Policy to ensure timely and efficient clearance and dissemination of new and revised policy documents.

2. Authority and Effective Date.

The functional statements for the Office of Medical Policy Initiatives 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
Center for Drug Evaluation and Research
Office of Medical Policy
Office of Medical Policy Initiative**



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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 Initiative organization structure depicting all the organizational structures reporting to the Director.

Office of Medical Policy Initiative (DCDHB)

These organizations report to the Office of Medical Policy Initiative:
Division of Medical Policy Development (DCDHBA)
Division of Medical Policy Programs (DCDHBB)
Division of Clinical Trial Quality (DCDHBC)