

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATION AND  
FUNCTIONS**

**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: 07/26/2011

**1. DIVISION OF MEDICAL POLICY PROGRAMS (DNFBB).**

- 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 FDA 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 this Division were approved by the Secretary, Health and Human Services on July 26, 2011.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	07/26/2011	N/a	CDER/OM	Secretary, Health and Human Services

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF MEDICAL POLICY  
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Staff Manual Guide 1266.122  
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The following is the 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 Office of the Director.

OFFICE OF THE DIRECTOR