

SMG 1266.121

**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 DEVELOPMENT**

Effective Date: 07/26/2011

**1. DIVISION OF MEDICAL POLICY DEVELOPMENT (DNFBA).**

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

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

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF MEDICAL POLICY  
OFFICE OF MEDICAL POLICY INITIATIVES  
DIVISION OF MEDICAL POLICY DEVELOPMENT**



Staff Manual Guide 1266.121  
Organizations and Functions  
Effective Date: July 26, 2011

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 Development organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR