

SMG 1266.12

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

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

Effective Date: March 23, 2015

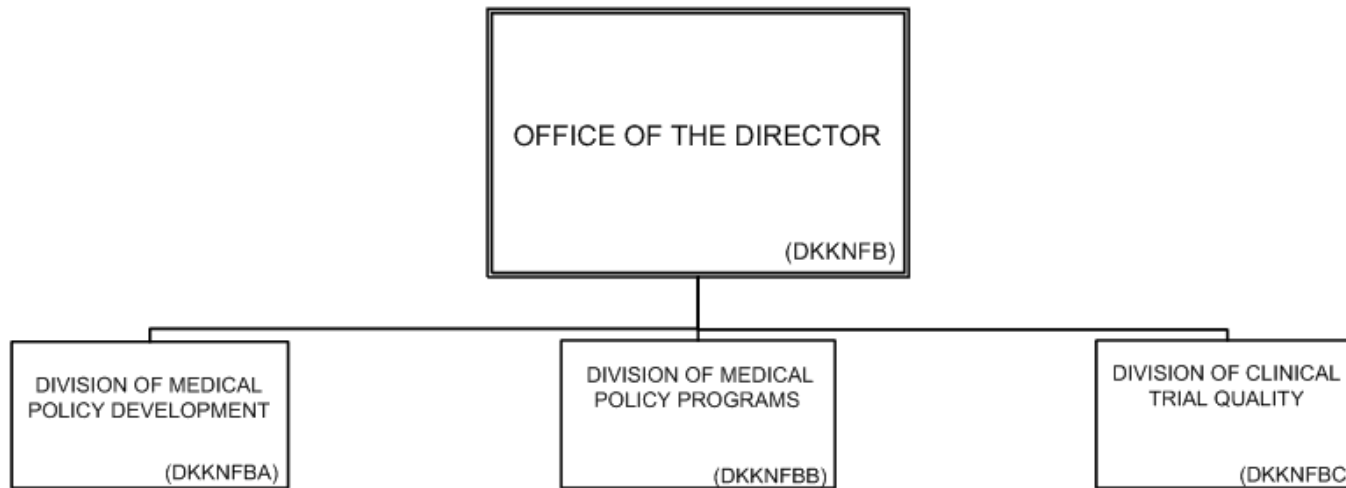
1. OFFICE OF MEDICAL POLICY INITIATIVES (DKKNFB).

- A. Provides oversight and direction for development of medical policies and procedures pertaining to the drug development, drug approval, and post market surveillance processes.
- B. Provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas, including initiatives to develop active safety monitoring of marketed products, improve the science and efficiency of clinical trials, and collaboratively enhance professional and patient labeling.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner for Food and Drug, and effective on March 23, 2015.

FOOD AND DRUG ADMINISTRATION
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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, 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 Office Director.

OFFICE OF THE DIRECTOR (DKKNFB)

- DIVISION OF MEDICAL POLICY DEVELOPMENT (DKKNFBA)
- DIVISION OF MEDICAL POLICY PROGRAMS (DKKNFBB)
- DIVISION OF CLINICAL TRIAL QUALITY (DKKNFBC)