

SMG 1266.1

**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

Effective Date: April 17, 2016

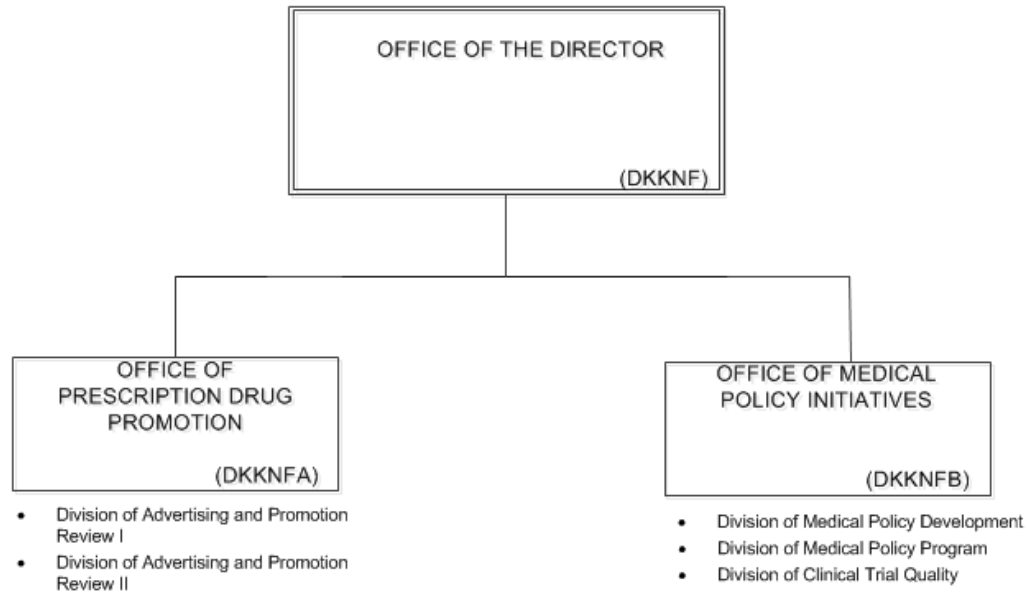
1. OFFICE OF MEDICAL POLICY (DKKNF).

- A. Provides Center oversight (scientific and regulatory) and leadership in the development of medical policy, procedures, and policy initiatives pertaining to drug development, drug approval, bioresearch monitoring, human subject protection, post market surveillance processes, and the science and efficiency of clinical trials.
- B. Provides scientific and regulatory leadership in ensuring accurate and effective communication of medical information to healthcare professionals and patients in compliance with applicable regulations.
- C. Foster an interdisciplinary approach to medical policy development, implementation, and coordination through collaboration with other disciplines, program areas, FDA Centers, and stakeholders in a manner that enhances integration of evolving science and policy into drug development, regulatory review, and post-market surveillance processes.
- D. Provides guidance and policy development regarding prescription promotion and reviews prescription drug advertising and promotional labeling to ensure that the information contained in these materials is not false or misleading.

2. AUTHORITY AND EFFECTIVE DATE.

- A. The functional statements for this Office were approved by the Secretary of Health and Human Services, and effective on July 26, 2011.
- B. The organizational chart for this Office was approved by the Secretary of Health and Human Services on December 15, 2015, and effective on April 17, 2016.

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The following is the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Medical Policy organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR (DKKNF):

- OFFICE OF PRESCRIPTION DRUG PROMOTION (DKKNFA)
 - Division of Advertising and Promotion Review I (DKKNFAB)
 - Division of Advertising and Promotion Review II (DKKNFAA)
- OFFICE OF MEDICAL POLICY INITIATIVES (DKKNFB)
 - Division of Medical Policy Development (DKKNFBA)
 - Division of Medical Policy Program (DKKNFBB)
 - Division of Clinical Trial Quality (DKKNFBC)