

**SMG 1260.2**

**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 REGULATORY POLICY**

Effective Date: May 27, 2016

**1. OFFICE OF REGULATORY POLICY (DKKNAA).**

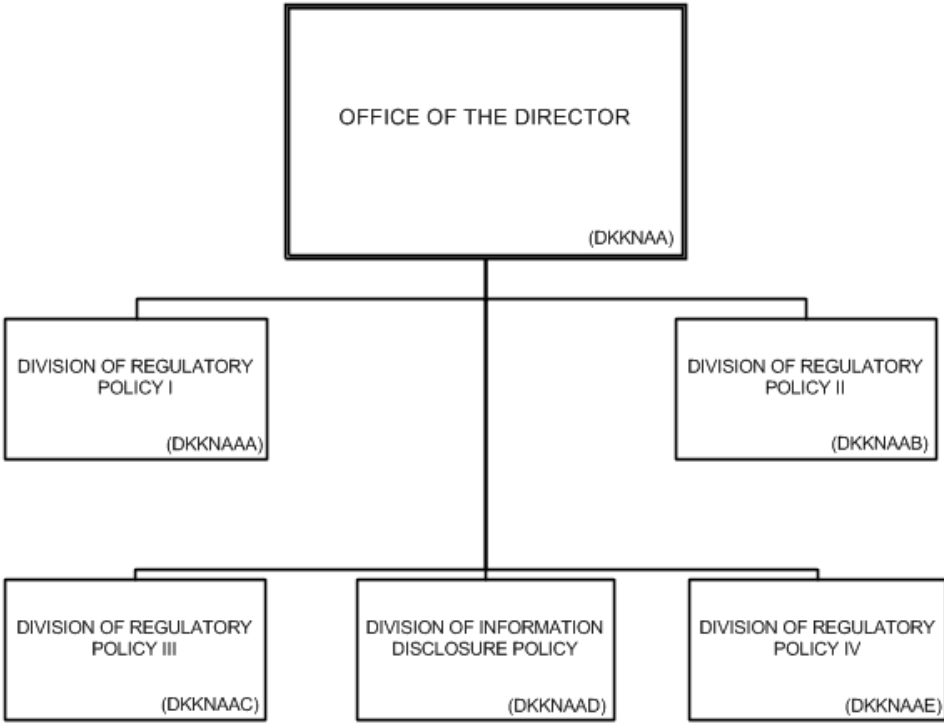
- A. Provides Center oversight and leadership in the development of regulations, policies, procedures and guidances that affect the drug approval process, and in the development of new legislation.
- B. Provides Center oversight and leadership in the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and FDA's public disclosure regulations.

**2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Office were approved by the Director, Center for Drug Evaluation and Research on December 7, 2015 and effective on May 27, 2016.

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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 Regulatory Policy organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKNAA):

- DIVISION OF REGULATORY POLICY I (DKKNAAA)
- DIVISION OF REGULATORY POLICY II (DKKNAAB)
- DIVISION OF REGULATORY POLICY III (DKKNAAC)
- DIVISION OF INFORMATION DISCLOSURE POLICY (DKKNAAD)
- DIVISION OF REGULATORY POLICY IV (DKKNAAE)