

SMG 1260.25

**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

DIVISION OF REGULATORY POLICY IV

Effective Date: May 27, 2016

1. DIVISION OF REGULATORY POLICY IV (DKKNAAE).

- A. Initiates, develops, and reviews regulations, policies, procedures and guidance's that affect the regulation of drugs under the Federal Food, Drug, and Cosmetic Act.
- B. Serves as the Center's focal point on regulatory issues providing advice and assistance on such matters as scope, applicability and meaning of the Federal Food, Drug, and Cosmetic Act, other laws, regulations, and policies.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division 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, Division of Regulatory Policy IV organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKNAAE)