

**SMG 1293.1a**

**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 GENERIC DRUGS**

**OFFICE OF GENERIC DRUG POLICY**

Effective Date: 01/24/2014

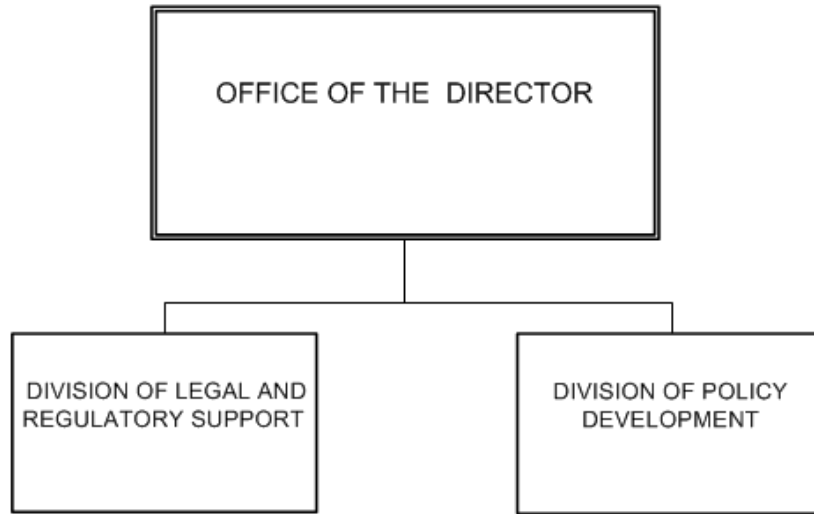
**1. OFFICE OF GENERIC DRUG POLICY (DKKNUC).**

- A. Coordinates the development of policy within the Office of Generic Drugs; conducts other functions with respect to the review of ANDAs and other administrative matters affecting generic drugs.
- B. Coordinates the policy initiatives developed by OGD and other offices within CDER/FDA.
- C. Ensures consistent policies in assessing ANDAs in the context of active citizen's petitions, and communication with OND and other relevant offices in CDER.

**2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services and effective on January 24, 2014.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF PHARMACEUTICAL SCIENCE  
OFFICE OF GENERIC DRUGS  
OFFICE OF GENERIC DRUG POLICY**



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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 Generic Drugs, Office of Generic Drug Policy organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF LEGAL AND REGULATORY SUPPORT
- DIVISION OF POLICY DEVELOPMENT