

SMG 1293.12

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 GENERIC DRUGS

OFFICE OF GENERIC DRUG POLICY

DIVISION OF POLICY DEVELOPMENT

Effective Date: 01/24/2014

1. DIVISION OF POLICY DEVELOPMENT (DKKNUCB).

- A. Develops guidances, MaPPs, and other statements of policy with respect to generic drugs.
- B. Coordinates with Center for Drug Evaluation and Research (CDRH) with respect to drug/device combinations and develops Office of Generic Drugs (OGD) policy with respect to these products; monitors and coordinates the development of OGD policy with respect to emerging therapies.
- C. Manages generic drug withdrawals, represents OGD in drug shortage matters, and provides coordination with external organizations on international issues regarding generic drugs.
- D. Publishes and maintains the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book); coordinates the resolution of policy issues related to what goes into the Orange Book, including but not limited to 3- and 5-year exclusivity, Therapeutic Equivalence codes, dosage forms, patent listing and patent usage codes

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.