

SMG 1291.1a

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 RESEARCH AND STANDARDS

Effective Date: 01/24/2014

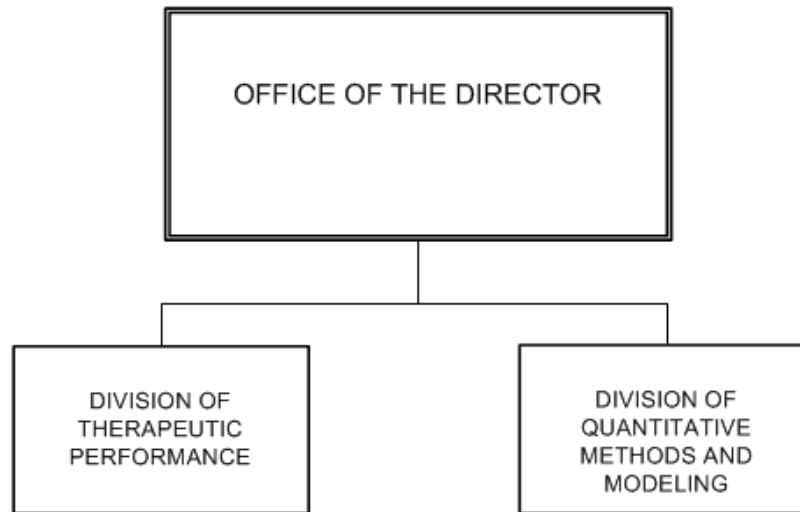
1. OFFICE OF RESEARCH STANDARDS (DKKNUA).

- A. Implements the Office of Generic Drugs GDUFA regulatory science research program
- B. Provides pre-submission scientific advice on equivalence standards to Abbreviated New Drug Applications (ANDA) sponsors through meetings, guidance and correspondence
- C. Provides consults and reviews of complex scientific issues identified in ANDAs or citizen petitions
- D. Ensures the therapeutic equivalence of approved generic drugs through research and investigation informed by OGD's post-approval safety/ surveillance monitoring

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.

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Effective Date: January 24, 2014

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 Research and Standards organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF THERAPEUTIC PERFORMANCE
- DIVISION OF QUANTITATIVE METHODS AND MODELING