SMG 1291.1a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drugs Evaluation and Research

Office of Generic Drugs

Office of Research and Standards

Effective Date: December 14, 2018

1. Office of Research and Standards (DCDMA).

A. Implements the Office of Generic Drugs' (OGD) Generic Drug User Fee Amendments (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.

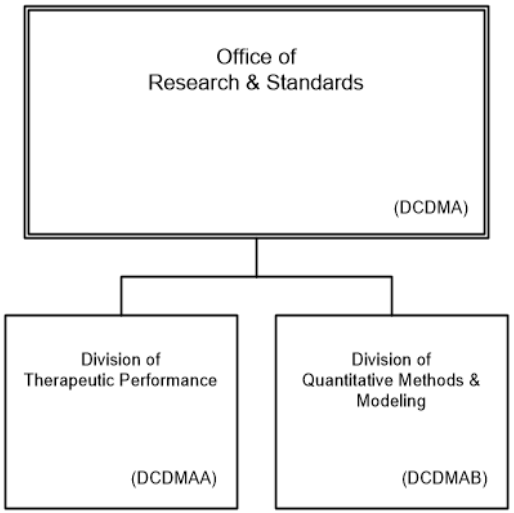
C. Provides consults and reviews of complex scientific issues identified in ANDAs or citizen petitions.

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 the Office of Research and Standards were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Office of Research and Standards



Staff Manual Guide 1291.1a
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Research & Standards organizational structures depicting all the organizational structures reporting to the Director:

Office of Research & Standards (DCDMA)

These organizations report to the Office of Research & Standards:
Division of Therapeutic Performance (DCDMAA)
Division of Quantitative Methods & Modeling (DCDMAB)

Back to Organizations and Functions, Volume I (1000-1300)