

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: October 9, 2020

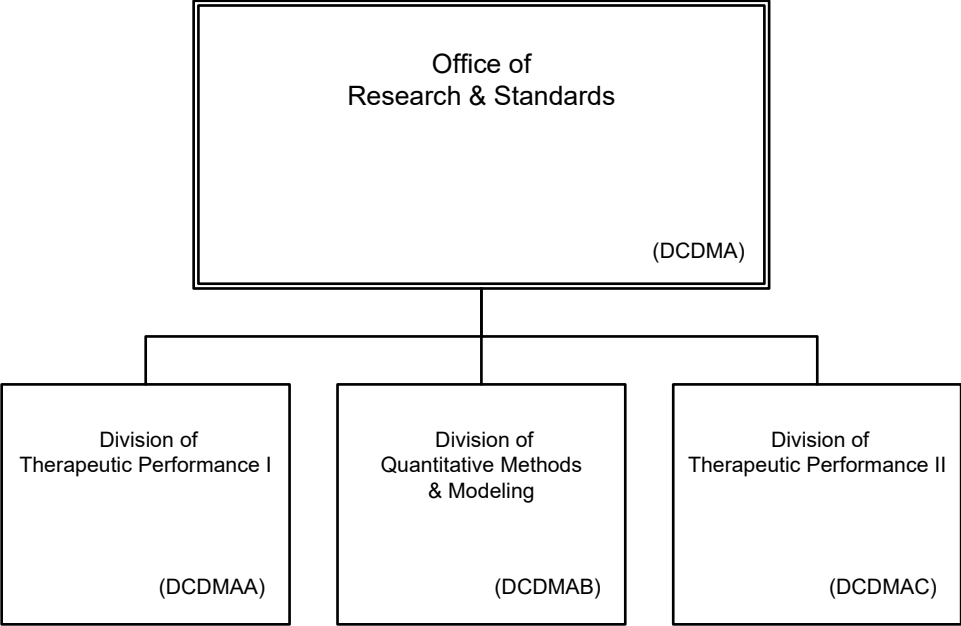
1. Office of Research and Standards (DCDMA).

- A. Implements the Office of Generic Drugs' (OGD) Generic Drug User Fee Amendments regulatory science research program.
- B. Provides pre-submission scientific advice to Abbreviated New Drug Applications (ANDA) sponsors of applications submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act through guidance, pre-ANDA meeting and responses to controlled correspondence.
- C. Provides consults and reviews of complex scientific issues identified in ANDAs, controlled correspondence 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.
- E. Manages the pre-ANDA meeting and product specific guidance processes to provide scientific advice for generic drug development.
- F. Develops product specific guidance that provide timely and clear advice to generic drug developers.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements Office of Research and Standards were approved by the Commissioner of Food and Drugs on September 8, 2020, and effective on October 9, 2020.

Department of Health and Human Services
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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 and Standards, organization structure depicting all the organizational structures reporting to the Director:

Office of Research and Standards (DCDMA)

Division of Therapeutic Performance I (DCDMAA)

Division of Quantitative Methods and Modeling (DCDMAB)

Division of Therapeutic Performance II (DCDMAC)