

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

Division of Quantitative Methods and Modeling

Effective Date: December 14, 2018

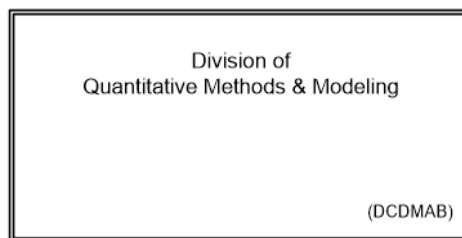
1. Division of Quantitative Methods and Modeling (DCDMAB).

- A. Uses predictive or physiological models of drug product performance, drug absorption, drug pharmacology, or other quantitative methods to ensure generic drug equivalence and develop new policies.
- B. Develops and implements new computational tools for analysis of in vitro, pharmacokinetic, pharmacodynamic and clinical bioequivalence studies.
- C. Establishes in vitro in vivo (IVIVC) correlations for the use in generic drug review and policy development and provides consults for the review of IVIVC's submitted in Abbreviated New Drug Applications.
- D. Performs quantitative data-driven risk assessments to prioritize Office of Generic Drugs (ODG) review and post-approval surveillance activities.
- E. Provides OGD's scientific computing expertise and infrastructure including software access and training for effective use of the Center for Drug Evaluation and Research and Food and Drug Administration scientific computing resources.

2. Authority and Effective Date.

The functional statements for the Division of Quantitative Methods and Modeling were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**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 & Standards, Division of Quantitative Methods & Modeling organizational structures depicting all the organizational structures reporting to the Director:

Division of Quantitative Methods & Modeling (DCDMAB)