SMG 1292.1a

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 Bioequivalence

Effective Date: October 9, 2020

1. Office of Bioequivalence (DCDMB).

A. Evaluates in vivo and in vitro bioequivalence data and protocols in Abbreviated New Drug Applications (ANDAs) and their supplements and amendments, as per the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), and section 505(j) of the Federal Food, Drug, and Cosmetic Act.

B. Recommends for approval, disapproval, or new bioequivalence studies ANDAs and/or protocols for all equivalence studies for generic drug products.

C. Identifies bioequivalence problems for generic drugs both pre- and post-approval.

D. Develops new bioequivalence methods and the provision of guidance for conducting bioequivalence studies for all dosage forms as covered in 21CFR 320.24; reviews and evaluates pharmacokinetic, pharmacodynamic and in vitro product performance data to assure bioequivalence of drug products. Also provides subject matter expertise on bioequivalence studies to be recommended within product-specific guidance.

E. Contributes to the pre-ANDA program by providing bioequivalence insight and expertise to inform pre-ANDA consults, internal discussions, and industry meetings for proposed complex generic products and Competitive Generic Therapies.

F. Assists in the evaluation and response to bioequivalence aspects of citizens petitions, suitability petitions, controlled correspondences, dispute resolutions, Congressional inquiries, and other regulatory activities related to generic drugs.

2. Authority and Effective Date.

The functional statements for the Office of Bioequivalence 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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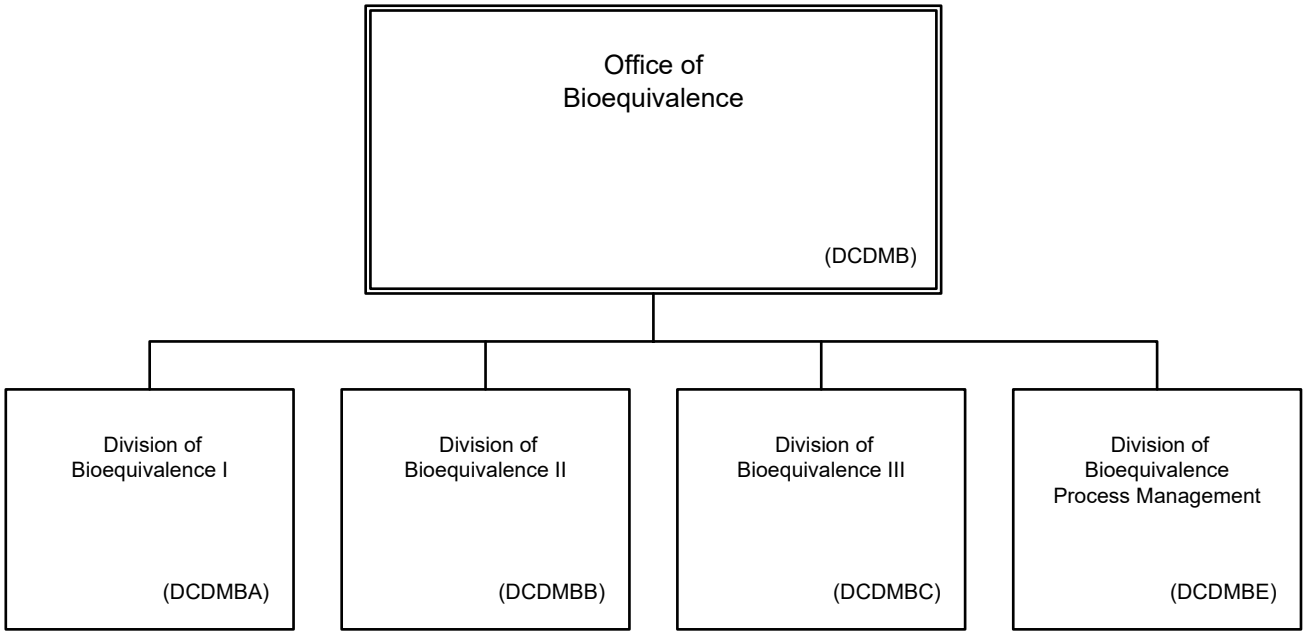

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Bioequivalence, organization structure depicting all the organizational structures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

Office of Bioequivalence (DCDMB).

Division of Bioequivalence I (DCDMBA)

Division of Bioequivalence II (DCDMBB)

Division of Bioequivalence III (DCDMBC)

Division of Bioequivalence Process Management (DCDMBE)