SMG 1292.11

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

Division of Bioequivalence I

Effective Date: October 9, 2020

1. Division of Bioequivalence I (DCDMBA).

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), section 505(j) of the Federal Food, Drug, and Cosmetic Act.

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

C. Identifies potential bioequivalence problems and provides guidance for conducting bioequivalence studies for all dosage forms as covered in 21 CFR 320.24.

D. Reviews and evaluates drug disposition data and specialized drug delivery systems to assure bioequivalence of drug products.

E. Develops new methods, 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 guidances.

2. Authority and Effective Date.

The functional statements for the Division of Bioequivalence I 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 Bioequivalence, Division of Bioequivalence I organization structure depicting all the organizational structures reporting to the Director:

Division of Bioequivalence I (DCDMBA)