

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 Process Management

Effective Date: October 9, 2020

1. Division of Bioequivalence Process Management (DCDMBE).

- A. Leads and manages all processes associated with the bioequivalence review throughout the drug product lifecycle for all Abbreviated New Drug Applications (ANDAs), 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, and 21 CFR 314, Subpart C – Abbreviated Applications.
- B. Coordinates and manages the bioequivalence workload, timelines, meetings, and activities of internal division review teams associated with bioequivalence reviews.
- C. Acts as internal liaison for all bioequivalence-related questions within the Office of Generic Drugs (OGD), as well as offices/centers outside of OGD, who are associated with the ANDA review process.
- D. Coordinates and conducts bioequivalence communications with generic sponsors.
- E. Coordinates and reports the overall bioequivalence performance trends of the office and provides recommendations for continual improvement of the process to support work quality.

2. Authority and Effective Date.

The functional statements for the Division of Bioequivalence Process Management 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
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Office of Biostatistics
Division of Bioequivalence Process Management**

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(DCDMBE)

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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 Process Management, organization structure depicting all the organizational structures reporting to the Director:

Division of Bioequivalence Process Management (DCDMBE).