SMG 1292.12

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 II

Effective Date: December 14, 2018

1. Division of Bioequivalence II (DCDMBB).

A. Evaluates in vivo and in vitro bioequivalence data and protocols in Abbreviated New Drug Applications and their supplements and amendments.

B. Recommends approval, disapproval, or new bioequivalence studies and/or protocols.

C. Identifies potential bioequivalence problems and provides guidance for conducting bioequivalence studies for all dosage forms.

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

2. Authority and Effective Date.

The functional statements for the Division of Bioequivalence II 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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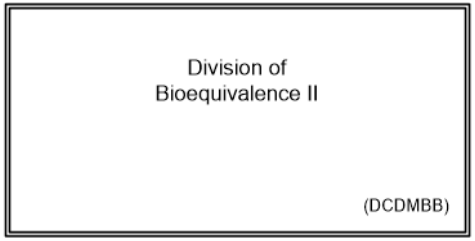

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Bioequivalence, Division of Bioequivalence II organizational structures depicting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

Division of Bioequivalence II (DCDMBB)

Back to Organizations and Functions, Volume I (1000-1300)