**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: December 14, 2018

## 1. Office of Bioequivalence (DCDMB).

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

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

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

D. Develops bioequivalence methods and the provision of guidance for conducting bioequivalence studies for all dosage forms as covered in 21CFR 320.24.

E. Develops new methods, reviews and evaluates drug disposition data and specialized drug delivery systems to assure bioequivalence of drug products.

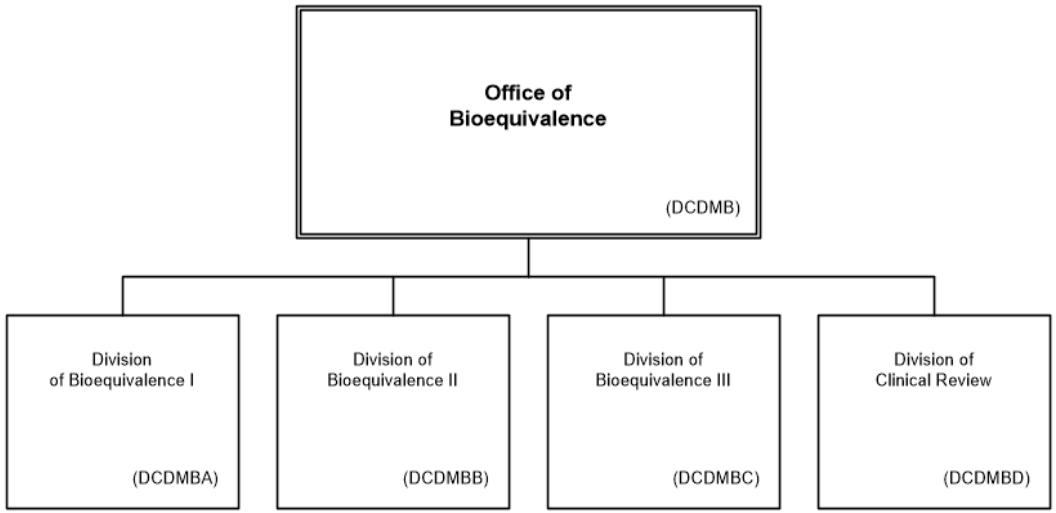
F. Evaluates the safety of inactive ingredients and bioequivalence study designs.

G. Evaluates pre- and post-marketing safety reports for generic drug products.

## 2. Authority and Effective Date.

The functional statements for the Office of Bioequivalence were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Generic Drugs**
**Office of Bioequivalence**



Staff Manual Guide 1292.1a
Organizations and Functions
Effective Date: December 14, 2018

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 organizational structures depicting all the organizational structures reporting to the Director:

Office of Bioequivalence (DCDMB)

These organizations report to the Office of Bioequivalence:
Division of Bioequivalence I (DCDMBA)
Division of Bioequivalence II (DCDMBB)
Division of Bioequivalence III (DCDMBC)
Division of Clinical Review (DCDMBD)

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