SMG 1292.14

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 Clinical Review

Effective Date: December 14, 2018

1. Division of Clinical Review (DCDMBD).

A. Evaluates bioequivalence studies with clinical endpoints and protocols supporting Abbreviated New Drug Applications (ANDAs) and supplements to ANDAs.

B. Recommends approval, disapproval, or new bioequivalence with clinical endpoints and/or protocols.

C. Identifies potential clinical safety or product use issues or bioequivalence problems and provides guidance for resolving the matters.

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

2. Authority and Effective Date.

The functional statements for the Division of Clinical Review 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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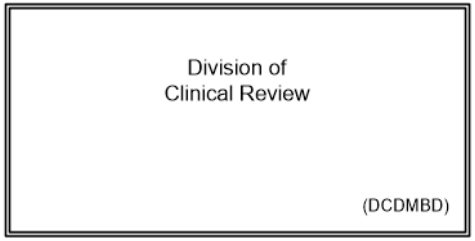

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Bioequivalence, Division of Clinical Review organizational structures depicting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

Division of Clinical Review (DCDMBD)

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