SMG 1295.11

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Generic Drugs

Office of Safety and Clinical Evaluation

Division of Clinical Review

Effective Date: October 9, 2020

1. Division of Clinical Review (DCDMEA).

A. Assesses bioequivalence studies with comparative clinical endpoints and protocols supporting Abbreviated New Drug Applications (ANDAs) and amendments and supplements to ANDAs submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act particularly involving complex generic products. Provides recommendations for approval, or identifies deficiencies or the need for additional data, in the demonstration of bioequivalence in ANDAs, amendments, and supplements.

B. Evaluates substitutability for proposed generic drug-device combination products, including assessment of comparative analyses to address the user interface of combination products, to ensure that the proposed generic products can be used, when substituted for its Reference Listed Drug (RLD), without the intervention of a health care provider and/or without additional training prior to the use of the generic combination product.

C. Assists in the evaluation and response to clinical aspects of citizens petitions, suitability petitions, controlled correspondences, dispute resolutions, Congressional inquiries, and other regulatory activities related to generic drugs.

D. Participates in development of novel bioequivalence studies, including for novel or complex drug delivery systems to assure bioequivalence of generic drug products. Provides subject matter expertise on comparative clinical endpoint bioequivalence studies to be recommended within product-specific guidances.

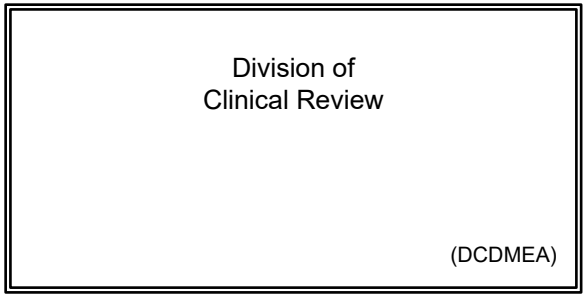
E. Evaluates, in conjunction with the Division of Pharmacology Toxicology Review, the clinical impact of potential differences in excipients and generic drug formulations, as compared to a proposed generic product's RLD.

F. Works in cooperation with the Division of Clinical Safety and Surveillance, in the evaluation of pre- and post-marketing safety information for generic drug products.

2. Authority and Effective Date.

The functional statements for the Division of Clinical Review 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 Safety and Clinical Evaluation
Division of Clinical Review



Staff Manual Guide 1295.11
Organizations and Functions
Effective Date: October 9, 2020

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 Safety and Clinical Evaluation, Division of Clinical Review, organization structure depicting all the organizational structures reporting to the Director:

Division of Clinical Review (DCDMEA)