

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

Effective Date: October 9, 2020

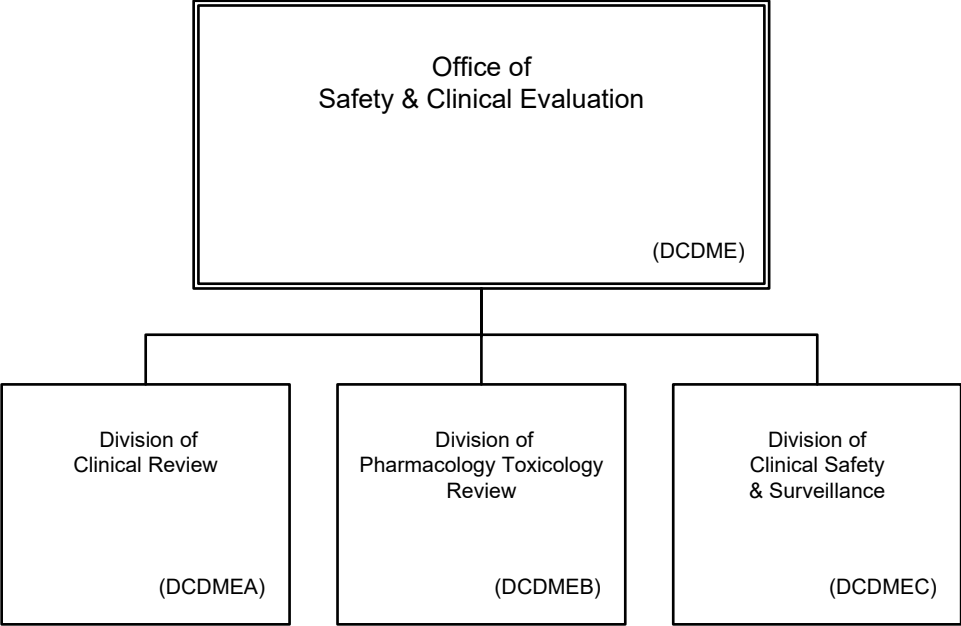
1. Office of Safety and Clinical Evaluation (DCDME)

- A. Supports the timely assessment of Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generics drugs with attention to coordinating complex scientific considerations.
- B. Oversees clinical assessment of formulation differences between the generic drug and its reference listed drug.
- C. Supports development of novel bioequivalence studies, including for novel or complex drug delivery systems to assure bioequivalence of generic drug products and leads assessment of bioequivalence studies with comparative clinical endpoints.
- D. Supports the pre-ANDA program.
- E. Provides subject matter expertise related to generic drug safety assessments.
- F. Supports the development and implementation of safety programs specific to a risk evaluation and mitigation strategy during the generic drug application review, as required by the Food and Drug Administration Amendments Act of 2007.

2. Authority and Effective Date.

The functional statements for the Office of Safety and Clinical Evaluation 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
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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 Safety and Clinical Evaluation, organization structure depicting all the organizational structures reporting to the Director:

Office of Safety and Clinical Evaluation (DCDME)

Division of Clinical Review (DCDMEA)

Division of Pharmacology Toxicology Review (DCDMEB)

Division of Clinical Safety and Surveillance (DCDMEC)