
Guidance for Industry

Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
December 2013
Biopharmaceutics

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**U.S. Department of Health and Human Services
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Center for Drug Evaluation and Research (CDER)
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Contains Nonbinding Recommendations

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I. INTRODUCTION

This guidance provides recommendations to applicants planning to include bioequivalence (BE) information in abbreviated new drug applications (ANDAs) and ANDA supplements. The guidance describes how to meet the BE requirements set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations. The guidance is generally applicable to dosage forms intended for oral administration and to non-orally administered drug products in which reliance on systemic exposure measures is suitable for documenting BE (e.g., transdermal delivery systems and certain rectal and nasal drug products). We believe that the guidance will also be useful when planning BE studies intended to be conducted during the postapproval period for certain changes in an ANDA.

This guidance revises and replaces parts of two FDA guidances for industry,² relating to BE and fed BE studies to be submitted in ANDAs. This guidance does not address bioavailability (BA), BE, and food effect studies in investigational new drug applications (INDs) and new drug applications (NDAs). A separate guidance will soon be available that will address BA and BE studies for INDs, NDAs, and NDA supplements.³ FDA has determined that separating guidances according to application type will be beneficial to applicants.

¹ This guidance was prepared by the Division of Bioequivalence in the Office of Generic Drugs, Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

² *Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations* and *Food-Effect Bioavailability and Fed Bioequivalence Studies*.

³ Many guidances are referenced throughout this document, and they can be found on the Internet at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. We update guidances periodically. To make sure you have the most recent version of a guidance, check this CDER guidance Web site.

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