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Guidance for Industry

The FDA published Good Guidance Practices in February 1997. This guidance was developed and issued prior to that date.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

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Center for Drugs and Biologics
Food and Drug Administration
Department of Health and Human Services

GUIDELINE FOR THE FORMAT AND CONTENT OF THE HUMAN PHARMACOKINETICS AND BIOAVAILABILITY SECTION OF AN APPLICATION

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GUIDELINE FOR THE FORMAT AND CONTENT OF THE HUMAN PHARMACOKINETICS AND BIOAVAILABILITY SECTION OF AN APPLICATION

I. INTRODUCTION

Biopharmaceutic studies are required by Part 320, Title 21, and by the Waxman-Hatch Amendments to the Federal Food, Drug and Cosmetic Act (the act). These amendments define bioequivalence and require generic drugs to show bioequivalence to the previously approved dosage form. The regulations define important biopharmaceutic terms and establish acceptable procedures for determining the bioavailability of drug products. The new drug application (NDA) rewrite regulations require a separate biopharmaceutic review section in the NDA (21 CFR 314). This guideline is intended to assist applicants to prepare the biopharmaceutics section of the NDA.

The guideline is issued under 21 CFR 10.90. An applicant may, but is not required to, rely upon the guideline in preparing the biopharmaceutics section of an application. When a different approach is chosen, the applicant is encouraged to discuss the

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matter in advance with FDA to prevent the expenditure of money and effort on preparing a submission that may later be determined to be unacceptable.

II. TYPES OF STUDIES

The particular studies required for a specific drug will depend on many factors. If there is any question concerning the requirements, the Division of Biopharmaceutics should be consulted for NDAs and the Division of Bioequivalence should be consulted for abbreviated new drug applications (ANDAs).

The studies included in the Biopharmaceutics Section are of five general types:

A. Pilot or Background Studies

Pilot studies are carried out in small numbers of subjects/patients to provide a preliminary assessment of the absorption, distribution, metabolism and/or elimination (ADME) of a drug as a guide to the design of early clinical trials and definitive kinetic studies. As analytical methodology for measuring blood levels of the drug and its metabolites is often incomplete at the time such studies are carried out, radioisotope techniques may be used.

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B. Bioavailability/Bioequivalence Studies

Bioavailability studies are intended to measure the rate and extent to which an active drug ingredient or therapeutic moiety is absorbed from a drug product and becomes available at the site of drug action. Several types of studies fall under the classification of bioavailability studies including:

1. Bioavailability studies to define the rate and extent of absorption relative to a reference dosage form (e.g., an intravenous injection, true solution, or suspension).

2. Bioequivalence studies comparing pharmaceutical equivalents/alternatives for the purpose of establishing equivalent extents and (where necessary) equivalent rates of absorption.

3. Dosage strength equivalence studies which show that equivalent doses of different dosage forms deliver the same amount of drug (e.g., 3 X 100 mg vs. 1 X 300 mg tablets).

C. Pharmacokinetic Studies

Pharmacokinetic studies are intended to define the time course of drug and, where appropriate, major metabolite concentrations

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