Guidance for Industry
Population Pharmacokinetics

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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CP 1

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I.   INTRODUCTION

This guidance makes recommendations on the use of population pharmacokinetics in the drug development process to help identify differences in drug safety and efficacy among population subgroups. It summarizes scientific and regulatory issues that should be addressed using population pharmacokinetics. The guidance discusses when to perform a population pharmacokinetic study and/or analysis; how to design and execute a population pharmacokinetic study; how to handle and analyze population pharmacokinetic data; what model validation methods are available; and how to provide appropriate documentation for population pharmacokinetic reports intended for submission to the FDA. Although the information in this guidance for industry focuses on population pharmacokinetics, the principles discussed here are equally applicable to population pharmacodynamic and toxicokinetic studies.[2]

Because the analysis of drug safety and efficacy among population subgroups is a rapidly evolving area of drug development and regulation, frequent communication between the sponsor and the FDA review staff is encouraged throughout the drug development process.

Pharmaceutical industry scientists and the FDA have long been interested in the use of population pharmacokinetics/pharmacodynamics in the analysis of drug safety and efficacy among population subgroups (1). Reference is made to this subject in other FDA guidance documents, including *General Considerations for the Clinical Evaluation of Drugs* (FDA 77-3040) and in International Conference on Harmonisation (ICH) guidances, including *E4 Dose-Response Information to Support Drug Registration*, and *E7 Studies in Support of Special Populations: Geriatrics*.[3] These guidance documents support the use of special data collection and analysis methodologies, such as the population pharmacokinetic approach (population PK approach), as part of the

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[1] This guidance has been prepared by the Population Pharmacokinetic Working Group of the Clinical Pharmacology Section of the Medical Policy Coordinating Committee in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on population pharmacokinetics in drug evaluation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] A separate guidance on pharmacokinetic and pharmacodynamic modeling is in preparation.

[3] A guidance for industry on general considerations for pediatric pharmacokinetic studies is in preparation.

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