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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 97D-0383]

Guidance for Industry on Population Pharmacokinetics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Population Pharmacokinetics." This guidance provides recommendations to pharmaceutical industry scientists, who have long been interested in the application of population pharmacokinetics, during the new drug development, safety and efficacy evaluation, and approval processes.

DATES: Written comments on the guidance may be submitted at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm" or "http://www.fda.gov/cber/guidelines.htm". Submit written requests for single copies of "Population Pharmacokinetics" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. Copies of this guidance may also be obtained by fax from 1-888-CBERFAX or 301-827-3844 or by mail from the Voice Information System at 800-835-4709 or 301-827-1800. Submit written comments on the guidance

to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

He Sun, Center for Drug Evaluation and Research (HFD-880), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2205, or

Martin D. Green, Center for Biologics Evaluation and Research (HFM-579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5349.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled “Population Pharmacokinetics.” Pharmaceutical industry scientists and FDA have long been interested in the application of population pharmacokinetics and pharmacodynamics to the evaluation of drug safety and efficacy. Although several special data collection and analysis methodologies are available for use, this guidance provides recommendations regarding the use of population pharmacokinetics in new drug development and evaluation.

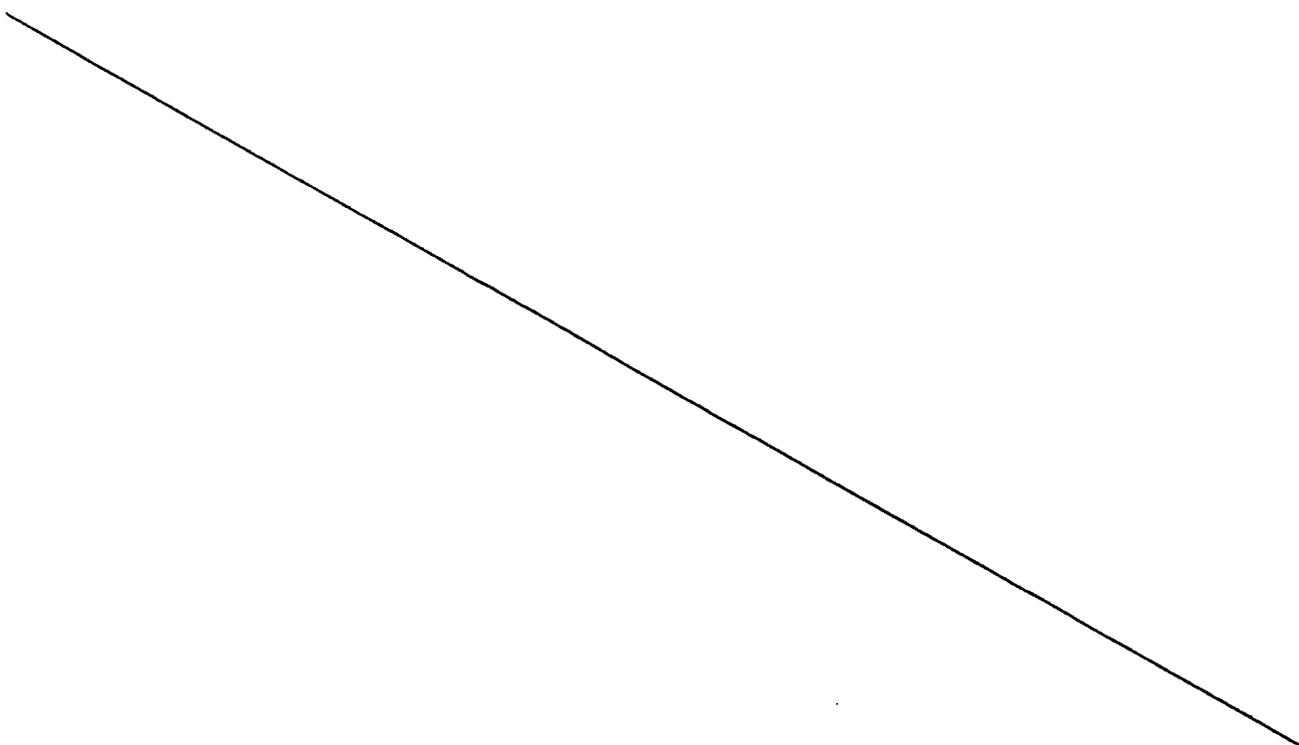
In addition to summarizing the scientific and regulatory issues that should be addressed when conducting population pharmacokinetic studies and analyses, the guidance: (1) Presents an overview of population methods, including when to perform a population study/analysis; (2) discusses how to design and execute a population pharmacokinetic study; (3) describes how to handle and analyze population pharmacokinetic data; (4) summarizes what model validation methods are available; and (5) explains how to provide appropriate documentation for population pharmacokinetic reports intended for submission to FDA. Although the information provided in this document focuses primarily on population pharmacokinetics, the principles discussed are equally applicable to population pharmacodynamic and toxicokinetic studies.

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

In the **Federal Register** of September 18, 1997 (62 FR 49016), FDA announced the availability of a draft version of this guidance entitled “Population Pharmacokinetics.” The September 18, 1997, document gave interested persons an opportunity to submit comments through November 17, 1997. All comments received have been carefully reviewed and incorporated, where appropriate, in this revised guidance.

This guidance is being issued as a Level 1 guidance consistent with FDA’s Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency’s current thinking on population pharmacokinetics. 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.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number



found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 3, 1999
February 3, 1999



William K. Hubbard
Associate Commissioner
for Policy Coordination

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