

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0459]

Display Date 10-29-04

Publication Date 11-1-04

Certifier R. LEDESMA

DDM

Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling.” This guidance discusses agency recommendations on issues to consider when designing and conducting pharmacokinetic (PK) studies in pregnant women and, specifically, on how to assess the influence of pregnancy on the PKs, and where appropriate, the pharmacodynamics (PD) of drugs or biologic products. The goals of this guidance are to recommend a framework for designing and conducting PK studies in pregnant women and stimulate further study and research to assist in rational therapeutics for pregnant patients.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

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20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kathleen Uhl, Center for Drug Evaluation and Research (HFD-020), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301-443-5157.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling.” This guidance is intended to provide recommendations to sponsors and investigators on how to design, conduct, and assess studies investigating the influence of pregnancy on the pharmacokinetics, and where appropriate, the pharmacodynamics of drugs or biologic products. During the clinical development of most products, pregnant women are actively excluded from trials, and, if pregnancy does occur during a trial, the usual procedure is to discontinue treatment and drop the patient from the study. Consequently, at the time of a drug’s initial marketing, except for products developed to treat conditions specific to pregnancy, there are seldom meaningful human data on the appropriate dosage

and frequency of administration during pregnancy. Even after years of marketing, data in product labels regarding PK and dose adjustments during pregnancy rarely provide more information for appropriate prescribing in pregnancy than what was available at the time of initial marketing.

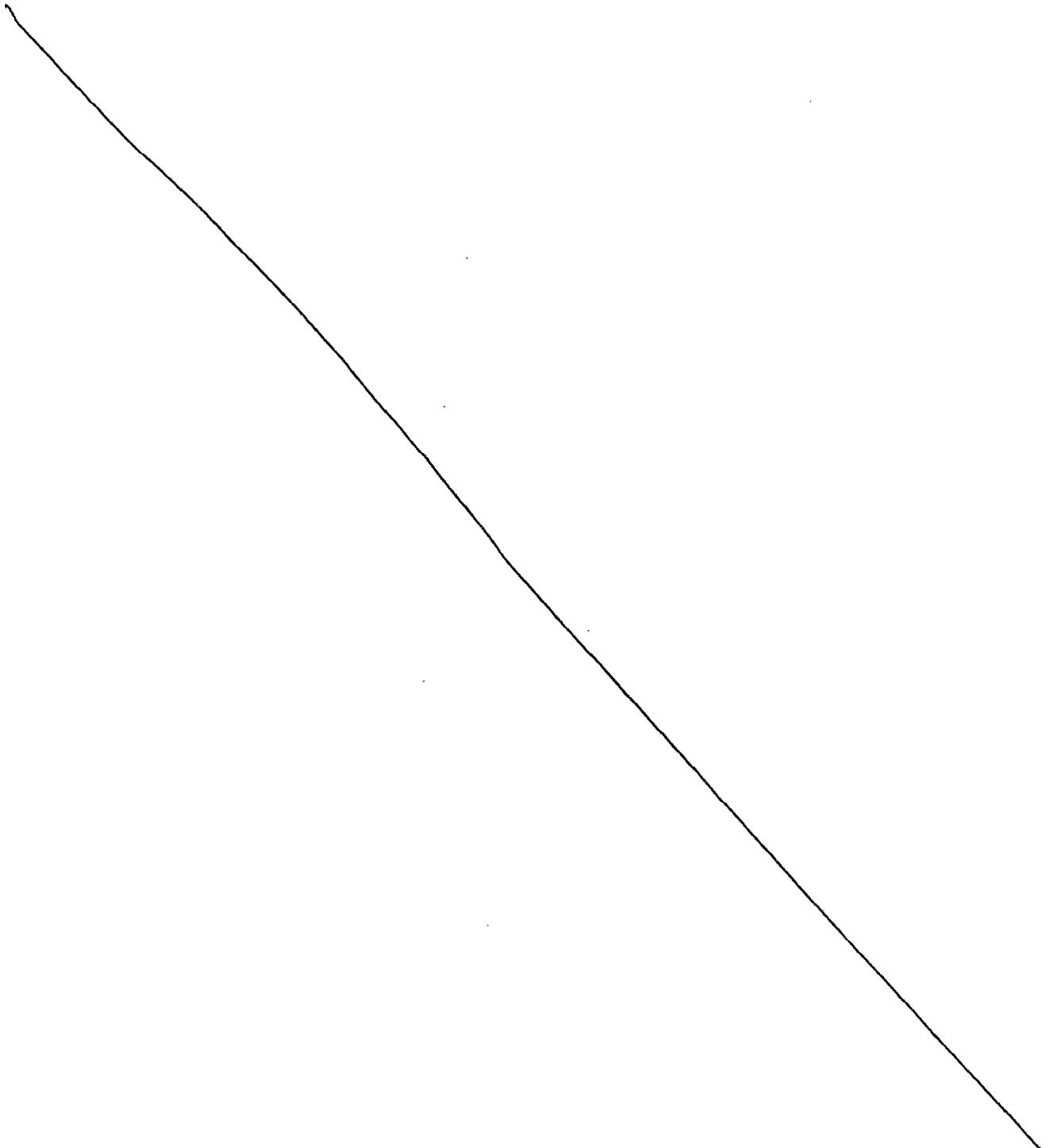
The information in this guidance is intended to promote an increase in the amount of useful data concerning how drug kinetics are affected by pregnancy and to further encourage the development of appropriate therapeutic treatments for pregnant women. Topics covered include ethical considerations associated with conducting PK studies in pregnant women, study design, data analysis, labeling, and considerations for future research. The agency recommends using this guidance in conjunction with other pharmacological and clinical literature on the design, conduct, and interpretation of PK studies. Because the conduct of studies in pregnant women requires specialized knowledge in a variety of areas, investigators designing such studies are encouraged to obtain advice from experts in fields such as obstetrics, pediatrics, pharmacology, clinical pharmacology, pharmacometrics, statistics, and other applicable disciplines.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies

of mailed 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 draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 10/21/04
October 21, 2004



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[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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