

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0030]

Draft Guidance for Industry on Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling; Availability

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling.” This guidance discusses agency recommendations on how and when to conduct clinical lactation studies and how to assess the influence of drugs or biologic products on lactation. The goals of this guidance are to provide the basic framework for designing, conducting, and analyzing clinical lactation studies and to stimulate further study and research to assist in rational therapeutics for lactating 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DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the **Federal Register***].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The guidance may also be obtained from CBER by mail by calling 1–800–835–4709 or 301–827–1800. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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, or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling.” This guidance is intended to provide recommendations to sponsors and investigators on how to design, conduct, and assess studies investigating the influence of lactation on maternal pharmacokinetics (PK), and where appropriate, the pharmacodynamics of drugs or biologic products, the extent of drug transfer into breast milk, and the effects of drugs on milk production and composition. Clinical lactation studies are usually not conducted during the development of most products and lactating women are actively excluded from trials. Consequently, at the time of a drug’s initial marketing, there are seldom meaningful human data

on the appropriate dosage and frequency of administration during lactation. Even after years of marketing, data in product labels regarding lactation rarely provide more information for appropriate prescribing in lactation 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 lactation, the extent of drug transfer into breast milk, and the effects of drugs on milk production and composition. Topics covered include 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 lactating women and their breast-fed infants requires specialized knowledge in a variety of areas, investigators designing such studies are encouraged to obtain advice from experts in fields including 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. Submit a single copy of electronic comments or two paper copies of any mailed

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comments, except that individuals may submit one paper 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: February 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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