during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Any persons requiring special accommodations to attend the hearing should contact Nancy L. Stanisic (see *Contacts*).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see *Addresses*) written or electronic notices of participation and comments for consideration at the hearing. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions to which they refer (see section III of this document). Two copies of any 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Transcripts of the hearing also will be available for review at the Division of Dockets Management.

VI. Transcripts

The hearing will be transcribed as stipulated in § 15.30(b). The transcript of the hearing will be available 30 days after the hearing on the Internet at *http://www.fda.gov/ohrms/dockets*, and orders for copies of the transcript can be placed at the meeting or through the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, at a cost of 10 cents per page.

Dated: February 2, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2300 Filed 2–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0422]

Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act; 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 (#173) entitled ''Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA).'' This guidance describes how FDA intends to implement the Federal Food, Drug, and Cosmetic Act (the act) as it relates to animal drug sponsor fees.

DATES: Comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance via the Internet at *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: David Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *dnewkirk@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry (#173) entitled ''Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act.'' ADUFA requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. This guidance represents FDA's current thinking on how it intends to implement the animal drug sponsor fee provision of ADUFA.

In the **Federal Register** of September 28, 2004 (69 FR 57941), FDA published a notice of availability for a draft of the guidance, giving interested persons until October 28, 2004, to comment. FDA received one comment on the draft guidance. No substantive changes were made in finalizing this guidance document.

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on the 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any substantive amendments through a document in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document 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.

V. Electronic Access

Copies of the guidance document entitled ''Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act'' may be obtained from the CVM home page (*http://www.fda.gov/cvm*) and from the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: January 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2417 Filed 2–7–05; 8:45 am]

BILLING CODE 4160–01–S

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 April 11, 2005. 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 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.

[FR Doc. 05–2416 Filed 2–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0022]

International Conference on Harmonisation; Draft Guidance on S8 Immunotoxicity Studies for Human Pharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.