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Draft Guidance for Industry on Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling.''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DATES: Submit written or electronic comments on the draft guidance by April 11, 2005.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes a weight-of-evidence approach to determining whether additional immunotoxicity testing for nonbiological pharmaceuticals is appropriate when the findings from standard toxicity studies indicate signs of immunotoxicity. The draft guidance is intended to provide recommendations on nonclinical testing to identify compounds that have the potential to be immunosuppressive and guidance on a weight-of-evidence decision making approach for immunotoxicity testing.

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 (CDER), 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. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the 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:

Regarding the guidance: Kenneth L. Hastings, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5922.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, the Japanese Pharmaceutical Manufacturers Association, CDER and CBER (FDA), and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations.

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization (WHO), Health Canada, and the European Free Trade Area.

In November 2004, the ICH Steering Committee agreed that a draft guidance entitled ''S8 Immunotoxicity Studies for Human Pharmaceuticals'' should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft guidance will be considered by FDA and the Safety Expert Working Group.

The draft guidance describes a weight-of-evidence approach to determining whether additional immunotoxicity testing for nonbiological pharmaceuticals is appropriate when the findings from standard toxicity studies indicate signs of immunotoxicity. The draft guidance provides the following: (1) Recommendations on nonclinical testing approaches to identify compounds which have the potential to be immunosuppressive and (2) guidance on a weight-of-evidence decision making approach for immunotoxicity testing. The primary data are from routine nonclinical toxicology studies conducted during drug development. Additional causes for concern that can affect the decision for additional immunotoxicity testing include the pharmacology of the drug, intended patient population, known drug class effects, and retention of the drug in cells of the immune system.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This 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 may be seen 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 *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: February 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2418 Filed 2–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: January 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of January 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under