draft guidance documents, including the draft guidance for reviewers on ''Evaluation of Human Pregnancy Outcome Data.'' This draft guidance document will be discussed during the June 3, 1999, meeting of the Subcommittee of the Advisory Committee for Reproductive Health Drugs (64 FR 23340, April 30, 1999).

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the evaluation of human pregnancy outcome data. 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Interested persons may submit written comments on the draft guidance to the Dockets Managements Branch (address above). 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–14149 Filed 6-3-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1541]

Draft Guidance for Industry on Establishing Pregnancy Registries; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing the availability of a draft guidance for industry entitled ''Establishing Pregnancy Registries.'' Pregnancy registries are recognized as one method of obtaining meaningful information on the risks associated with exposure to drugs or biologics during pregnancy. The draft guidance is intended to provide sponsors with guidance on establishing pregnancy registries that help ensure the quality and integrity of registry data and adequately document registry research methods. The draft guidance will be discussed during the June 3, 1999, meeting of the Subcommittee of the Advisory Committee for Reproductive Health Drugs.

DATES: Written comments may be submitted on the draft guidance document by September 2, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; or Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; http://www.fda.gov/cber/guidelines.htm; Fax: 1–888–CBERFAX or 301–827–3844, Mail: the Voice Information System at 800–835–4709 or 301–827–1800.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5468; or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via e-mail at ''stifano@cber.fda.gov''.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Establishing Pregnancy Registries.''

As part of its evaluation of pregnancy labeling, in September 1997 the agency held a part 15 (21 CFR part 15) hearing on the current category requirements for pregnancy labeling (see 62 FR 41061, July 31, 1997). The agency sought comment on the practical utility, effects, and limitations of the pregnancy categories. The agency also sought input on ways to address problems, including possible alternatives to the categories for communicating information on reproductive and developmental toxicity.

Subsequently, the agency has been working on the development of various draft guidance documents, including the draft guidance for industry entitled ''Establishing Pregnancy Registries.'' At the time of marketing approval, FDA may request sponsors to conduct certain post-marketing studies (phase 4) to provide data on the potential risks of the product in human pregnancy. Pregnancy registries are recognized as one method of obtaining information on risks associated with exposure to drugs or biologics during pregnancy.

The draft guidance is intended to provide sponsors with guidance on establishing pregnancy registries that help ensure the quality and integrity of registry data and adequately document registry research methods. The draft guidance focuses on registries designed to assess products for suspected or unknown risks to pregnancy outcomes. The registry design is not appropriate for products (e.g., tretinoin or thalidomide) where the goal is to monitor and evaluate programs intended to prevent pregnancy exposures.

The draft guidance will be discussed during the June 3, 1999, meeting of the Subcommittee of the Advisory Committee for Reproductive Health Drugs (64 FR 23340, April 30, 1999).

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on establishing pregnancy registries. 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 submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

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