

journals and presentation at professional conferences; (10) collaborates with partners to develop new and combined vaccines that can be integrated into national and international immunization programs; (11) participates in trials of new and combined vaccines; (12) participates in international as well as domestic vaccine safety research activities; and (13) conducts research and evaluates alternative approaches for administering vaccines to enhance safety.

Dated: September 12, 2002.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02-24034 Filed 9-20-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0388]

Guidance for Industry on Establishing Pregnancy Exposure Registries; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing the availability of a final guidance entitled "Establishing Pregnancy Exposure Registries." The guidance is intended to provide sponsors with guidance on how to establish pregnancy exposure registries to monitor the outcomes of pregnancies exposed to specific medical products.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office Drug Information (HFD-240), Center for Drug Evaluation and Research, 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, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD-970), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2364, kennedyd@cder.fda.gov; or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM-600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6190, stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Establishing Pregnancy Exposure Registries." Pregnancy exposure registries are recognized as one method of obtaining information on risks associated with exposure to medical products during pregnancy. The guidance is intended to provide sponsors with recommendations on how to establish pregnancy exposure registries, to help ensure the quality and integrity of registry data, and to help ensure the adequacy of document registry research methods.

In June 1999, FDA announced the availability of a draft guidance entitled "Establishing Pregnancy Registries" (64 FR 30041, June 4, 1999). Comments received on the draft guidance revealed that several general areas of the guidance needed revision and/or clarification.

Based on the comments received and on discussions with FDA's Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs on June 3, 1999 (64 FR 23340) and March 28 to 29, 2000 (65 FR 10811), the agency revised and/or clarified several sections of the guidance, including (1) When it is recommended that a registry be conducted, (2) use of comparison groups, (3) promotion of a registry and (4) regulatory reporting requirements. In addition, the name of the guidance was changed from "Pregnancy Registries" to "Pregnancy Exposure Registries" to more accurately reflect the nature of these types of studies and to differentiate them from more classic retrospective registries (e.g., cancer registries and birth defect registries).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on pregnancy exposure

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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the 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 guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>. To obtain the guidance document by fax call the FAX Information System at 1-888-CBER-FAX or 301-827-3844.

Dated: September 16, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-24037 Filed 9-20-02; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Park Service

Information Collection; Request for Extension

AGENCY: National Park Service, Interior

ACTION: Notice of request for extension of a currently approved information collection.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the National Park Service's intention to request an extension for a currently approved information collection in support of its Concession Management Program.

DATES: Comments in this notice must be received no later than November 22, 2002.

ADDITIONAL INFORMATION OR COMMENTS:

Contact Cynthia Orlando, Concession Program Manager, National Park Service, 1849 C Street, NW., (2410), Washington, DC 20240 or 202/513-7144.