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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 28, 2000, 9 a.m. to 5 p.m. and on March 29, 2000, 8 a.m. to 5 p.m.

Location: Hilton Hotel, Crystals Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Jayne E. Peterson or Robin M. Spencer, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-44-30572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 28, 2000, the subcommittee presentations and discussions will include the following topics: (1) The status of proposed pregnancy labeling changes, (2) the status of activities related to preclinical assessment of reproductive toxicity, and (3) FDA draft guidance for industry entitled "Establishing Pregnancy Registries" (see 64 FR 30041, June 4, 1999,

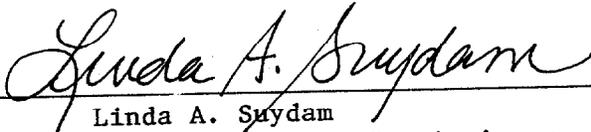
including solicitation for comments [Docket No. 99D-1541], see also the FDA Internet at www.fda.gov/cder/guidance/index.htm under the heading "Clinical/Medical (Draft)". The subcommittee will also address the methodological and operational challenges in developing and running a pregnancy registry. On March 29, 2000, the subcommittee presentations and discussions will address strategies for monitoring drug risks in pregnant women.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the subcommittee. Written submissions may be made to the contact person by March 14, 2000. On March 28, 2000, oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m. and 2:45 p.m. and 3 p.m. On March 29, 2000, oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 14, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

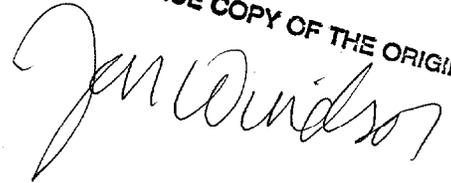
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Dated: February 18, 2000



Linda A. Snyder
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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