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Contractor	Jen Windt

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: 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 October 18, 1999, 9 a.m. to 5 p.m.

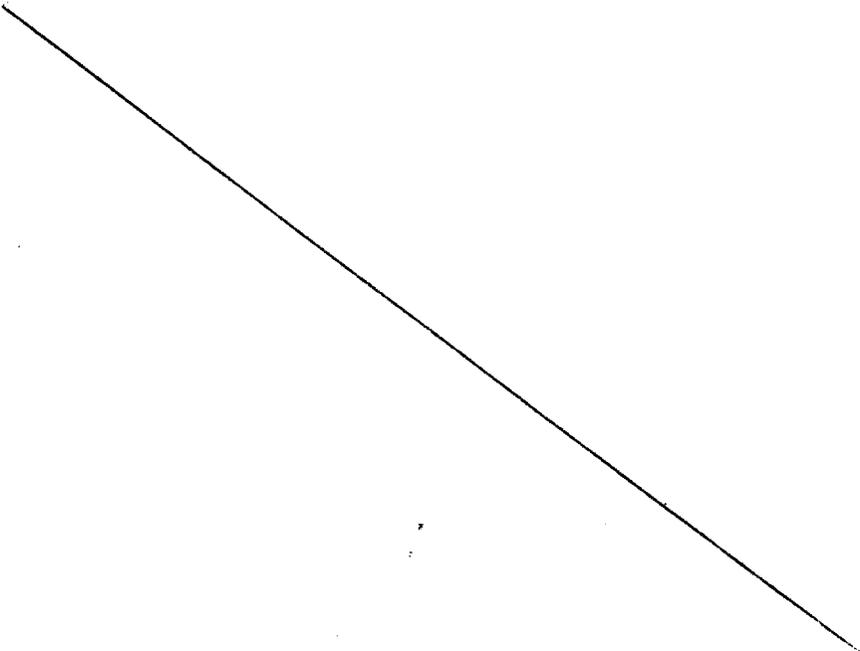
Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: 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, or by e-mail at PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at FDA's website <http://www.fda.gov/cder/coe.htm>.

Agenda: Presentations and committee discussions will address the following draft FDA guidance documents: (1) Draft guidance for reviewers entitled "Evaluation of Human Pregnancy Outcome Data" (see 64 FR 30040, June 4, 1999, including solicitation for comments [Docket No. 99D-1540]), and (2) draft guidance for industry entitled "Guidance for Industry, Establishing Pregnancy Registries Data" (see 64 FR 30041, June 4, 1999, including solicitation for comments [Docket No. 99D-1541]). The application and impact of these guidances on drugs reviewed by

the Division of Reproductive and Urologic Drug Products will be considered with specific emphasis on drugs used in assisted reproductive technology (infertility treatment regimens). In addition, if revised guidances are available at the time of the meeting, the topics of labeling for non-contraceptive estrogen drug products and the clinical evaluation of estrogen and estrogen/progestin-containing drugs used for hormone replacement therapy in postmenopausal women will be discussed. Any revised draft guidances will be made available to the public near the time of the October 18, 1999, advisory committee meeting.

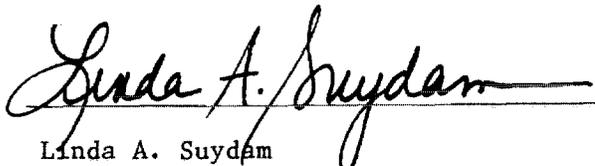
Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the committee. Written submissions may be made to the contact person by October 13, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and 1 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 October 13, 1999, 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.

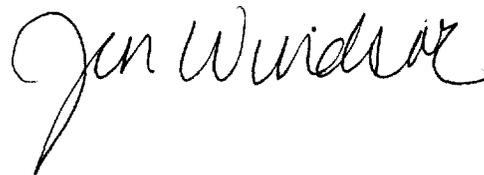
2).

Dated: September 22, 1999



Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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