

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Women's Health Initiative 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: Women's Health Initiative 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 November 12, 2002, from 8 a.m. to 6 p.m. and on November 13, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: 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 the FDA Docket Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>.

Agenda: On both days, presentations and subcommittee discussions will address the following issues related to the study results from the estrogen plus progestin component of the Women's

Health Initiative (WHI): (1) Assessment of the known benefits for the approved indications and risk management considerations, (2) the extent to which these new data might be extrapolated to other combination estrogen/progestin products and doses, and (3) the WHI's implications for future clinical trials of hormonal therapy.

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 November 1, 2002. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on November 12, 2002, and between approximately 1 p.m. and 2 p.m. on November 13, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 1, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne Peterson (see *Contact Person*) at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 11, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

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