

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.

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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 August 29, 2006, from 8 a.m. to 5:30 p.m.

Location: Hilton Hotel, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Teresa Watkins, 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, FAX: 301-827-6776, e-mail: Teresa.Watkins@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512537. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day prior to the meeting on the FDA Website at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. Click on

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the year 2006 and scroll down to the Advisory Committee for Reproductive Health Drugs.)

Agenda: The committee will discuss new drug application (NDA) 21-945, proposed trade name Gestiva, 17 alpha-hydroxyprogesterone caproate injection, 250 mg/mL, Adeza Biomedical, for the proposed indication prevention of preterm delivery in women with a history of a prior preterm delivery.

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 on or before August 15, 2006. Oral presentations from the public will be scheduled between approximately 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 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 on or before August 15, 2006.

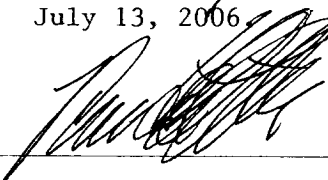
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Teresa Watkins 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: July 13, 2006
July 13, 2006



Randall W. Lutter,
Associate Commissioner for Policy and Planning.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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