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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date AUG 22 2003

Publication Date AUG 25 2003

Certifier

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 September 29 and 30, 2003, from 8:30 a.m. to 5 p.m.

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

Contact Person: Shalini Jain, 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: *jains@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. Background materials for this meeting when available will be posted on the Web site 1 business day before the meeting at: *www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

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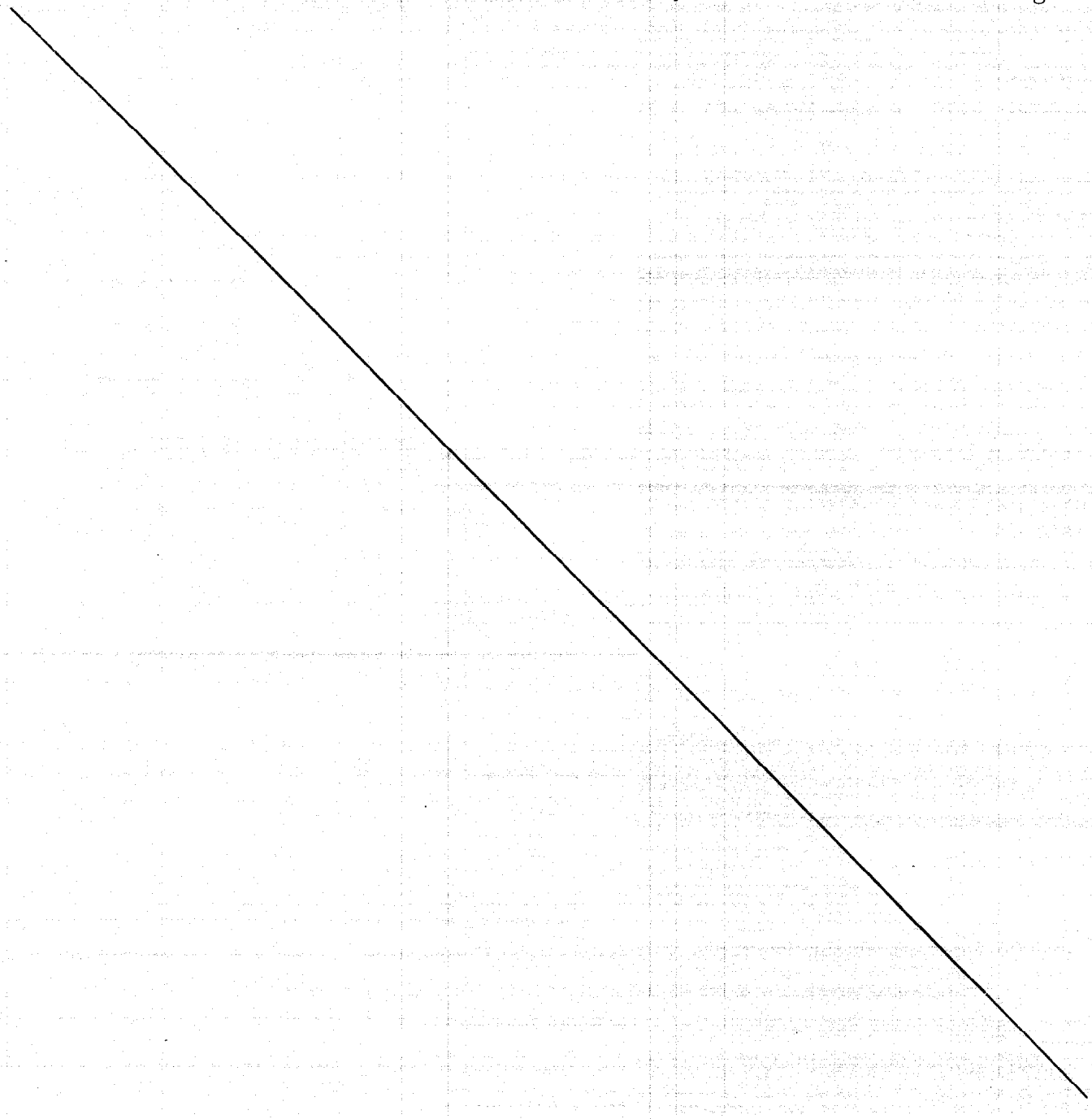
Agenda: On September 29, 2003, the committee will discuss issues relevant to the conduct of clinical trials and outcome measures for consideration of approval of drug products for the indications of induction of ovulation and pregnancy in anovulatory, infertile women and development of multiple follicles, and pregnancy in ovulatory women participating in assisted reproductive technology (ART) programs. On September 30, 2003, the committee will discuss new drug application (NDA) 21–322, Luveris (lutropin alfa for injection) Serono, Inc., a recombinant human luteinizing hormone (r-hLH) drug product, proposed for concomitant administration with recombinant human follicle stimulating hormone (r-hFSH), for the proposed indication of induction of ovulation in infertile women with severe luteinizing hormone and follicle stimulating hormone deficiency.

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 September 22, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on September 29, 2003, and between approximately 1:30 p.m. and 2:30 p.m. on September 30, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 22, 2003, 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 Shalini Jain 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: 8/18/03
August 18, 2003.

Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S