

agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0511. The approval expires on August 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 18, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Arthritis Advisory Committee; 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). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Arthritis Advisory Committee.

*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, 2003, from 8 a.m. to 5 p.m.; and on September 30, 2003, from 8 a.m. to 1 p.m.

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

*Contact Person:* Kimberly Topper, 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, or e-mail: [topperk@cder.fda.gov](mailto:topperk@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On both days, the committee will discuss the proposed systemic lupus erythematosus (SLE) concept paper, a preliminary discussion for creating a guidance document for the development of drugs, biologics, and devices for the treatment of SLE.

On September 29, 2003, the committee will discuss the proposed sections regarding the current state of the art, the claims for treatments, and clinical markers. On September 30, 2003, the meeting will be open to the public from 8 a.m. to 11 a.m., and the committee will discuss the section concerning clinical trial design. From 11 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

*Procedure:* On September 29, 2003, from 8 a.m. to 5 p.m.; and on September 30, 2003, from 8 a.m. to 11 a.m., the meeting will be open to the public. 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 19, 2003. Oral presentations from the public will be scheduled on September 29, 2003, between approximately 12:30 p.m. and 1 p.m., on the topic of claims; between approximately 2:45 p.m. and 3:15 p.m., on the topic of clinical markers; and on September 30, 2003, between approximately 9 a.m. and 9:30 a.m., on the topic of trial design. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 19, 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 desiring to speak who have not registered in advance may be recognized from the floor by the Chair.

*Closed Committee Deliberations:* On September 30, 2003, from 11 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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 Trevelin Prysock at 301-827-7001 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: August 18, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

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## 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 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](mailto: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](http://www.fda.gov/ohrms/dockets/ac/acmenu.htm).

*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