

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2009-N-0664]

**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 August 13, 2009, from 8 a.m. to 4:30 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD. The hotel phone number is 301-977-8900.

*Contact:* Kalyani Bhatt, 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:

*Kalyani.Bhatt@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in Washington, DC area), code 3014512537. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss new biologics license applications (BLAs) 125-320, 125-331, 125-332, and 125-333, proposed trade name PROLIA (denosumab) subcutaneous injection, 60 milligrams (mg), Amgen Inc., for the proposed indications of the treatment and prevention of osteoporosis in postmenopausal women, and the treatment and prevention of bone loss in patients undergoing hormone ablation for prostate or breast cancer. Hormone ablation is a term used to encompass

therapies for hormone sensitive breast or prostate cancer administered to decrease sex hormone (estrogen or testosterone) levels. These therapies can result in increased bone loss.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>, click on the year 2009 and scroll down to the appropriate advisory committee link.

*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 July 30, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 July 22, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 23, 2009.

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 Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on

public conduct during advisory committee meetings.

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

Dated: June 11, 2009.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E9-14638 Filed 6-22-09; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; ARRA P30 Faculty Recruitment.

*Date:* July 13, 2009.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Christine A. Livingston, PhD, Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd., MSC 7180, Bethesda, MD 20892, (301) 496-8683, *livingsc@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: June 16, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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