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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of an advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committees: Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 18, 2014, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-

0002, 301-796-9001, Fax: 301-847-8533, email: BRUDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The meeting will be closed to permit discussion of whether FDA should permit further clinical development of an existing investigational drug product, which will include the review of trade secret and/or confidential information.

Procedure: On December 18, 2014, from 8:30 a.m. to 9:45 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before December 4, 2014. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. Those individuals interested in making 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 November 24, 2014. 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 November 25, 2014.

Closed Committee Deliberations: On December 18, 2014, from 9:45 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will review data from an investigational new drug (IND) application. Information regarding pending applications, including active INDs, is generally not publicly available under applicable laws and regulations, including 21 CFR 312.120 and 314.430.

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: November 4, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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