100 milligram (mg) tablets, by Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed indication of the treatment of hypoactive sexual desire disorder in premenopausal women.

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. 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 June 3, 2010. 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 May 25, 2010. 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 May 26, 2010.

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/ucm11462.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: April 12, 2010.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council will meet on May 11–12 at SAMHSA, Rockville, Maryland. The meeting is open to the public.

The SAMHSA National Advisory Council was established to advise the Secretary, Department of Health and Human Services (HHS), and the Administrator, SAMHSA, to reduce the impact of substance abuse and mental illnesses in American communities. The Agenda will include a report from the new SAMHSA Administrator and presentations and discussions related to SAMHSA’s 10 strategic initiatives that will focus the Agency’s work on improving lives and capitalizing on emerging opportunities that advance and protect the Nation’s health.

Attendance by the public will be limited to space available. Public comments are welcome. The meeting can also be accessed via webstream. To obtain the call-in numbers and access codes, to submit written or brief oral comments, or to request special accommodations for persons with disabilities, please register on-line at https://nac.samhsa.gov/Registration/meetingsRegistration.aspx. You may also communicate with the SAMHSA National Advisory Council Designated Federal Officer, Ms. Toian Vaughn (see contact information below).

Substantive program information and a roster of Council members may be obtained either by accessing the SAMHSA Committee Web site, https://nac.samhsa.gov/NACouncil/index.aspx or by contacting Ms. Vaughn. The transcript for the meeting will be available on the SAMHSA Committee Web site within three weeks after the meeting.

Committee Name: SAMHSA National Advisory Council.