4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the joint meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the Federal Register of March 14, 2013 (78 FR 16271-16272). The amendment is being made to reflect a change in the Agenda portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: 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, ACRHD@fda.hhs.gov, or use the FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 14, 2013, FDA announced that a joint meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee would be held on April 18, 2013.

On page 16272, in the first column, the Agenda portion of the document is changed to read as follows:

Agenda: The committee will discuss the efficacy and safety of new drug application (NDA) 22219, AVEED (testosterone undecanoate) intramuscular injection, submitted by Endo Pharmaceutical Solutions, Inc., for the proposed indication of replacement therapy in adult males for conditions associated with a deficiency or absence of testosterone. The safety discussion will focus on postmarketing reports of oil microembolism in the lungs and potential anaphylactic reactions**.** In addition to AVEED, other approved testosterone injectable products will be referenced, especially in regard to oil microembolism and potential anaphylactic reactions reported for those products.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 27, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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