



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Endocrinologic and Metabolic Drugs 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 meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the Federal Register of October 10, 2012 (77 FR 61609). The amendment is being made to reflect a change in the Location and Procedure portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Paul Tran, 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:

[EMDAC@fda.hhs.gov](mailto:EMDAC@fda.hhs.gov), or 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 October 10, 2012, FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on November 8, 2012. On page 61609, in the second column, the Location portion of the document is changed to read as follows:

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 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.

On page 61609, in the third column, the Procedure portion of the document is changed to read as follows:

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 November 2, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 October 25, 2012. 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 October 26, 2012.

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: October 15, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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