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4. U.S. Food and Drug Administration, "Analytical Results from Inorganic Arsenic in Rice Cereals for Infants, Non-rice Infant Cereal and Other Foods Commonly Eaten by Infants and Toddlers," 2016, (<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm>).

5. U.S. Food and Drug Administration, "Arsenic in Rice and Rice Products Risk Assessment: Report," 2016, (<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm>).

6. U.S. Food and Drug Administration, "External Peer Review Report. Arsenic in Rice and Rice Products Risk Assessment: Draft Report, Addendum, and Model," 2015, (<http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM486544.pdf>).

7. U.S. Food and Drug Administration, "FDA's Response to External Peer Review on FDA's Arsenic in Rice and Rice Products Risk Assessment: Draft Report (July 2015), Addendum to FDA's Arsenic in Rice and Rice Products Risk Assessment, and Arsenic in Rice and Rice Products Risk Assessment Cancer Model," 2016, (<http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM487230.pdf>).

Dated: April 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of March 17, 2016. The amendment is being made to reflect a change in the *Date and Time* portion of the document. The *Date* of the meeting is changed to May 24, 2016. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** LaToya Bonner, 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,

[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). Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 17, 2016 (81 FR 14448), FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on May 25, 2016. On page 14449, in the first column, the *Date and Time* portion of the document is changed to read as follows:

*Date and Time:* The meeting will be held on May 24, 2016, from 8 a.m. to 5 p.m.

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: April 1, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Advisory Committee; Bone, Reproductive and Urologic Drugs Advisory Committee, Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Bone, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until March 23, 2018.

**DATES:** Authority for the Bone, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2018, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Kalyani Bhatt, Division of Advisory Committee and Consultant Management, 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, email: [BRUDAC@fda.hhs.gov](mailto:BRUDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Bone, Reproductive and Urologic Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm107572.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION**