Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *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 16, 2016 (81 FR 14115), FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on May 24, 2016. On page 14115, in the second 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 25, 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.

[FR Doc. 2016–07899 Filed 4–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1099]

Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Inorganic Arsenic in Rice Cereals for Infants: Action Level,'' a supporting document entitled ''Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants'' (the supporting document), and a risk assessment report entitled ''Arsenic in Rice and Rice Products Risk Assessment: Report'' (the risk assessment report). The draft guidance, when finalized, will identify for industry an action level for inorganic arsenic in rice cereals for infants that will help protect public health and is achievable with the use of current good manufacturing practice. It also will describe our intended sampling and enforcement approach. The risk assessment report includes a quantitative component (a mathematical model) that estimates occurrence of lung cancer and bladder cancer from long-term exposure to inorganic arsenic in rice and rice products, and a qualitative component that describes our review and evaluation of the scientific literature of certain non-cancer health risks, in certain susceptible life stages, from inorganic arsenic in rice and rice products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance, the supporting document, or the risk assessment report by July 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1099 for ''Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the

docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance and the supporting document to the Division of Plant Products and Beverages, Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance, supporting document, and risk assessment report.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

Arsenic is present in the environment as a naturally occurring substance or as a result of contamination from human activity. It is found in water, air (*e.g.,* in dust or particulates), soil, and foods. In foods, arsenic may be present as inorganic arsenic (the primary toxic form of arsenic) or organic arsenic. Exposure to inorganic arsenic is associated with many adverse human health effects, including cancer. FDA has been monitoring the levels of total arsenic in foods for decades, as part of our Total Diet Study, an ongoing survey and analysis of the average American diet (Ref. 1), and our Toxic Elements in Food and Foodware and Radionuclides in Food Program (Ref. 2), but only in recent years has methodology been available to FDA laboratories to readily distinguish between inorganic and organic arsenic in a large number and variety of food samples. Arsenic is inadvertently taken up by plants through pathways for essential or beneficial nutrients, and, compared to other cereals, such as oat, wheat, and barley, rice is much more efficient at arsenic accumulation. In 2011, we increased our testing for arsenic in certain foods. In 2012 and 2013, we released analytical results for approximately 1,300 samples of rice and rice products as part of a major effort to understand and manage arsenic-related risks associated with the consumption of these foods in the United States (Ref. 3). More recently, in April 2016 we released the results of our analysis of inorganic arsenic in 526 samples collected in 2014; the samples included rice cereals for infants, as well as non-rice infant cereal and other foods commonly eaten by infants and toddlers (Ref. 4).

We have focused on rice and rice products because evidence from FDA's Total Diet Study revealed that arsenic levels, although varying, tend to be higher in these foods than in others, and rice products are common in the average American diet. Collectively, our sampling indicates that the presence of inorganic arsenic varies widely among and within different categories of rice grain and products made from rice grain, ranging from <1 to 545 parts per billion (ppb) inorganic arsenic.

We are announcing the availability of three documents: (1) A draft guidance for industry entitled ''Inorganic Arsenic in Rice Cereals for Infants: Action Level;'' (2) a supporting document referenced in the draft guidance entitled ''Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants;'' and (3) a risk assessment referenced in the draft guidance entitled ''Arsenic in Rice and Rice Products Risk Assessment: Report.''

In the risk assessment report, we provide quantitative estimates of lung and bladder cancer risk presented by long-term exposure to inorganic arsenic in rice and rice products. We qualitatively address certain non-cancer health risks of exposure to inorganic arsenic in rice and rice products during pregnancy, infancy, and early childhood, periods of high susceptibility to those risks. We also used the mathematical cancer risk model to evaluate the impact of potential mitigation options to reduce the risk. We conducted this risk assessment in consultation with other Federal Agencies, including the National Institute of Environmental Health Science, the FDA National Center for Toxicological Research, and the Environmental Protection Agency. External expert peer review of the risk assessment was conducted; the risk assessment report and peer review documents are available online (Refs. 5, 6, and 7).

The draft guidance identifies an action level for inorganic arsenic in rice cereals for infants of 100 micrograms/kilogram (µg/kg) or 100 parts per billion (ppb), and identifies FDA's intended sampling and enforcement approach. The supporting document reviews data on inorganic arsenic levels in rice cereals for infants, health effects, and achievability, and explains FDA's rationale for identifying an action level for inorganic arsenic in rice cereals for infants of 100 µg/kg.

We conclude that the 100 µg/kg action level will help protect the public health and is achievable with the use of current good manufacturing practice, but we especially welcome comments and information bearing on the achievability and public health benefits and risks of 100 µg/kg, as compared with other potential action levels (including no action level). If the guidance is finalized consistent with the draft, we intend to consider the action level of 100 µg/kg or 100 ppb inorganic arsenic, in addition to other factors, when considering whether to bring enforcement action in a particular case.

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance and the supporting document at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance. Persons with access to the Internet may obtain the risk assessment report at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm.*

III. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. U.S. Food and Drug Administration, ''Total Diet Study,'' 2016, (*http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm2006799.htm*).

2. U.S. Food and Drug Administration, ''Toxic Elements in Food and Foodware and Radionuclides in Food Program,'' 2016, (*http://www.fda.gov/downloads/Food/ComplianceEnforcement/ucm073204.pdf*).

3. U.S. Food and Drug Administration, ''Analytical Results from Inorganic Arsenic in Rice and Rice Products Sampling,'' 2013, (*http://www.fda.gov/downloads/Food/*

FoodborneIllnessContaminants/Metals/UCM352467.pdf).

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.

[FR Doc. 2016–07840 Filed 4–5–16; 8:45 am]

BILLING CODE 4164–01–P

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,* 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.

[FR Doc. 2016–07906 Filed 4–5–16; 8:45 am]

BILLING CODE 4164–01–P

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.*

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**