Silver Spring, MD 20993–0002, 301–796–0001, 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Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: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SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Inorganic Arsenic in Rice Cereals for Infants: Action Level,” a supporting document entitled “Supporting Document for Action Level for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 The draft guidance, when finalized, will identify for industry an action level for inorganic arsenic in rice cereals for infants that will help protect public health and is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 made public. Your comment may be searched, read, and commented upon by anyone. The docket may be found at the http://www.regulations.gov. Please follow the instructions on that site, enter Docket No. FDA–2016–D–1099 in the search box, and click “Search.”

• If you want to submit a comment with confidential information that you do not wish 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” and will not be disclosed except in accordance with 21 CFR 10.20.

• 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.

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.”

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...
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 address as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

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 (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 Haltzer Warner, Associate Commissioner for Special Medical Programs.

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

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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; renewal of advisory committee.

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.

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

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Dated: April 1, 2016.

Jill Haltzer Warner, Associate Commissioner for Special Medical Programs.

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

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