Proposed Project

National Program of Cancer Registries Cancer Surveillance System (NPCR CSS), (OMB No. 0922–0469 5/31/2016). CDC plans to request OMB approval to continue collecting this information for three years. Data definitions will be updated to reflect changes in national standards for cancer diagnosis and coding, but the number of respondents and the burden per respondent will not change.

The NPCR CSS allows CDC to collect, aggregate, evaluate and disseminate cancer incidence data at the national level. The NPCR CSS is the primary source of information for United States Cancer Statistics (USCS), which CDC has published annually since 2002. The latest USCS report published in 2015 provided cancer statistics for 99% of the United States population from all cancer registries whose data met national data standards. Prior to the publication of USCS, cancer incidence data at the national level were available for only 14% of the population of the United States.

The NPCR CSS also allows CDC to monitor cancer trends over time, describe geographic variation in cancer incidence throughout the country, and provide incidence data on racial/ethnic populations and rare cancers. These activities and analyses further support CDC’s planning and evaluation efforts for state and national cancer control and prevention. In addition, datasets can be made available for secondary analysis.

Respondents are NPCR-supported central cancer registries (CCR) in 45 U.S. states, 2 territories, and the District of Columbia. Thirty-eight CCR submit data elements specified for the Standard NPCR CSS Report. Ten specialized CCR submit data elements specified for the Enhanced NPCR CSS Report, which includes additional information about treatment and follow-up for cases of breast, colorectal, and chronic myeloid leukemia cases diagnosed in 2011. Each CCR is asked to transmit two data files to CDC per year. The first file, submitted in January, is a preliminary report consisting of one year of data for the most recent year of available data. CDC evaluates the preliminary data for completeness and quality and provides a report back to the CCR. The second file, submitted by November, contains cumulative cancer incidence data from the first diagnosis year for which the cancer registry collected data with the assistance of NPCR funds (e.g., 1995) through 12 months past the close of the most recent diagnosis year (e.g., 2014). The cumulative file is used for analysis and reporting. The burden for each file transmission is estimated at two hours per response. Because cancer incidence data are already collected and aggregated at the state level the additional burden of reporting the information to CDC is small.

All information is transmitted to CDC electronically. Participation is required as a condition of the cooperative agreement with CDC. There are no costs to respondents except their time.

The total estimated annualized burden hours are 192 (152 for the Standard NPCR CSS Report, and 40 for the Enhanced NPCR CSS Report).

<table>
<thead>
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<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
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<td>Enhanced NPCR CSS Report</td>
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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 16, 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 25, 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, 301–796–0001, 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.

DIRECTIONS: 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 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