Proposed Project

National Program of Cancer Registries Cancer Surveillance System (NPCR CSS, OMB No. 0920–0469, exp. 5/31/2016)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2012, the most recent year for which complete information is available, more than 580,000 people died of cancer and more than 1.5 million were diagnosed with cancer. It is estimated that 13.8 million Americans are currently alive with a history of cancer (2). In the U.S., state-based cancer registries are the only method for systematically collecting and reporting population based information about cancer incidence and outcomes such as survival. These data are used to measure the changing incidence and burden of each cancer; identify populations at increased or increasing risk; target preventive measures; and measure the success or failure of cancer control efforts in the U.S.

In 1992, Congress passed the Cancer Registries Amendment Act which established the National Program of Cancer Registries (NPCR). The NPCR provides support for state-based cancer registries that collect, manage and analyze data about cancer cases. The state-based cancer registries report information to CDC through the National Program of Cancer Registries Cancer Surveillance System (NPCR CSS), (OMB No. 0920–0469 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).

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Central Cancer Registries in States, Territories and the District of Columbia.	Standard NPCR CSS Report	38	2	2
	Enhanced NPCR CSS Report	10	2	2

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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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, 301–796–9001, 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]

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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