draft guidance identifies for the industry an action level for inorganic arsenic in apple juice that FDA considers protective of human health and achievable with the use of good manufacturing practices. It also describes FDA's intended sampling and enforcement approach.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 13, 2013.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1639.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three documents, a draft guidance for industry entitled ''Arsenic in Apple Juice: Action Level'' and supporting documents referenced in the draft guidance, including a draft supporting document entitled ''Supporting Document for Action Level for Arsenic in Apple Juice'' and a risk assessment document entitled ''A Quantitative Assessment of Inorganic Arsenic in Apple Juice.'' The draft guidance identifies an action level for inorganic arsenic in apple juice of 10 micrograms/kilogram (µg/kg) or 10 parts per billion (ppb), and identifies FDA's intended sampling and enforcement approach. The draft supporting document reviews data on arsenic levels, health effects, and achievability, and explains FDA's rationale for identifying an action level for inorganic arsenic in apple juice of 10 µg/kg. The risk assessment document provides estimates of arsenic exposure and risk to humans at different hypothetical limits for inorganic arsenic in apple juice.

FDA considers the 10 µg/kg action level to be protective of human health and to be achievable with the use of good manufacturing practices, but FDA especially welcomes comments and information bearing on the achievability of 10 µg/kg, as compared with other potential action levels. Consistent with 21 CFR 109.6, FDA intends to consider the action level of 10 ug/kg or 10 ppb inorganic arsenic, in addition to other factors, when considering whether to bring enforcement action in a particular case.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on arsenic in apple juice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic or written comments regarding this document according to the instructions in the **ADDRESSES** section of this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance, the draft supporting document, and the risk assessment document at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: July 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16719 Filed 7–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Risk Communications Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communications Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 16, 2013, from 9 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Luis G. Bravo, Risk Communication Staff, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3274, Silver Spring, MD 20993–0002, 240–402–5274, FAX: 301–847–8609, email: *RCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On August 16, 2013, the Committee will discuss how FDA can communicate more effectively with

health care professionals and other stakeholders about the public health risks posed by counterfeit and unapproved drugs, in addition to safe purchasing practices, and how FDA can evaluate that communication and its impact.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 8, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 31, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 1, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Luis G. Bravo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16831 Filed 7–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Anesthetic and Analgesic Drug Products Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Anesthetic and Analgesic Drug Products Advisory Committee scheduled for July 17, 2013, is cancelled. This meeting was announced in the **Federal Register** of May 17, 2013 (78 FR 29142 to 29143). This meeting has been canceled due to new information submitted to the application. The Agency intends to continue evaluating the application and, as needed, will announce future meeting dates in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Caleb Briggs, 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, email: *AADPAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: July 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16823 Filed 7–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: National Hospital Organ Donation Campaign's Activity Scorecard. OMB No. 0915-xxxx—New.

Need and Proposed Use of the Information: HRSA's Healthcare Systems Bureau, Division of Transplantation administers the Workplace Partnership for Life program under the authority of Section 377A(a) of the Public Health Service (PHS) Act, (42 U.S.C. 274f-1). The Workplace Partnership for Life program seeks to increase the number of registered organ, eye, and tissue donors and to increase awareness about organ donation. HRSA launched a challenge to hospitals nationwide to assist in this effort by conducting donor education and donor