for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rosemary Addy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–1640; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans.'' The purpose of this draft guidance is to assist sponsors in the submission of an initial PSP and any amendments to the PSP. Specifically, this guidance addresses FDA's current thinking regarding implementation of the requirement for sponsors to submit an initial PSP under section 505B of the FD&C Act as amended by FDASIA (Pub. L. 112–144, 126 Stat. 993 (enacted July 9, 2012)).

This draft guidance addresses topics related to the submission of an initial PSP and any amendments to the PSP, including who must submit an initial PSP, when a PSP must be submitted, what is expected to be included in an initial PSP, and what is expected to be included in a requested amendment to an initial PSP. The guidance also includes a template that should be used for submission of an initial PSP.

This draft guidance does not contain a discussion of general requirements for pediatric drug development under the Pediatric Research Equity Act. That topic is addressed in the draft guidance for industry entitled ''How to Comply With the Pediatric Research Equity Act.'' [1]

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the content of and process for submitting initial PSPs and amended PSPs.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

[1] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

II. The Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information referenced in this draft guidance that are related to the burden on the submission of investigational new drug applications are covered under 21 CFR Part 312, including plans for pediatric studies under 21 CFR 312.47(b)(1)(iv) and waiver requests under 21 CFR 312.10, and have been approved under OMB control number 0910–0014. The collections of information referenced in this draft guidance that are related to the burden on the submission of new drug applications are covered under 21 CFR Part 314, including pediatric use information under 21 CFR 314.50(d)(7) and waiver requests under 21 CFR 314.90, and have been approved under OMB control number 0910–0001. The collections of information referenced in this draft guidance that are related to the burden on the submission of biologic license applications are covered under 21 CFR Part 601, including pediatric use information and waiver requests under 21 CFR 601.27, and have been approved under OMB control number 0910–0338.

Sponsors are already required to submit plans for pediatric studies and often provide the information outlined in this guidance pursuant to the regulations noted above. The new FDASIA provisions primarily serve to establish a more precise timeline for the submission of that information; however, some of the information may be considered a new collection of information. Federal law at 44 U.S.C. 3506(c)(2)(A) requires Federal Agencies to publish a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice of the proposed collection of information in a future issue of the **Federal Register** for any information collections recommended in this guidance that may be considered new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: July 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16825 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–2012–D–0322]

Draft Guidance for Industry on Arsenic in Apple Juice: Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; A Quantitative Assessment of Inorganic Arsenic in Apple Juice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Arsenic in Apple Juice: Action Level'' and two supporting documents entitled ''Supporting Document for Action Level for Arsenic in Apple Juice'' (the draft supporting document) and ''A Quantitative Assessment of Inorganic Arsenic in Apple Juice'' (the risk assessment document). The supporting documents are referenced in the draft guidance. The

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