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 either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances* or *http://www.regulations.gov.*

Dated: September 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22309 Filed 9–12–13; 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Draft Guidance for Industry on Arsenic in Apple Juice: Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; A Quantitative Assessment of Inorganic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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the draft guidance for industry entitled ''Arsenic in Apple Juice: Action Level'' that appeared in the **Federal Register** of July 15, 2013 (78 FR 42086). The draft guidance identifies for the industry an action level for inorganic arsenic in apple juice that FDA considers protective of human health and achievable with the use of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. In the notice, we requested comments on the draft guidance. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance. Submit either electronic or written comments by November 12, 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ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.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

In the **Federal Register** of July 15, 2013 (78 FR 42086), we published a notice announcing the availability of three documents, a draft guidance for industry entitled ''Arsenic in Apple Juice: Action Level,'' 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. The notice invited comments on the draft guidance by September 13, 2013.

As of August 28, 2013, we have received two requests for an extension of the comment period. The requests, from the Arsenic Science Task Force and the Juice Products Association, explained that they needed more time to complete their analyses of the supporting documents.

We have considered the request and are extending the comment period for the notice for 60 days, until November 12, 2013. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance.

II. Request for 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.*

Dated: September 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22313 Filed 9–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Challenging Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Metabolic Diseases: How to Estimate and Reward True Patient-Centric Value in Innovation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Metabolic Diseases: How to Estimate and Reward True Patient-Centric Value in Innovation.'' FDA is cosponsoring the workshop with the American Gastroenterological Association (AGA). The purpose of the workshop is to facilitate discussion between FDA, AGA, and other interested parties of the development of medical devices for the treatment of morbid obesity and other metabolic diseases and evolving approaches for the regulation and reimbursement of minimally invasive procedures.

Dates and Times: The public workshop will be held on October 17, 2013, from 8:30 a.m. to 5 p.m. and October 18, 2013, from 8:30 a.m. to 12:15 p.m.

Location: The public workshop will be held at the Grand Hyatt Washington,