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Draft Guidance for Industry on Arsenic in Apple Juice: Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; A Quantitative Assessment of Inorganic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SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the draft guidance for industry entitled ''Arsenic in Apple Juice: Action Level'' that appeared in the **Federal Register** of July 15, 2013 (78 FR 42086). The draft guidance identifies for the industry an action level for inorganic arsenic in apple juice that FDA considers protective of human health and achievable with the use of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 In the notice, we requested comments on the draft guidance.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DATES: FDA is extending the comment period on the draft guidance.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ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.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,

1000 H St. NW., Washington, DC 20001, 202–582–1234.

Contact Person: Herbert Lerner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G114, Silver Spring, MD 20993–0002, 301–796–6511, email: *herbert.lerner@fda.hhs.gov.*

Registration: Registration is limited and is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EDT), October 10, 2013. Onsite registration will be available after this date. To register for the public workshop, please visit AGA's Web site at *http://www.gastro.org/education-meetings/live-meetings/aga-fda-regulation-and-reimbursement-workshop.* For more information on the workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

The AGA will collect a registration fee to cover its share of the expenses associated with the public workshop, which is included in the registration information on the AGA Web site.

If you need special accommodations due to a disability, please contact Herbert Lerner (see ''*Contact Person''*) at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public workshop is to facilitate discussion between FDA, the AGA and other interested parties on the issues of device development, public and private payer reimbursement, venture capital, and regulatory pathways for device innovation and marketing. The workshop will provide a forum for discussing new approaches for the treatment of morbid obesity and other metabolic diseases as well as evolving approaches for the regulation and reimbursement of minimally invasive procedures.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Challenges to MedTech Innovation in the United States;
- Evolving Approaches for the Regulation of Minimally Invasive Procedures: The FDA Benefit/Risk Paradigm;
- Evolving Approaches for the Reimbursement of Minimally Invasive Procedures: How to Put a Price on Value;
- Obesity as a Disease: Redefining the Regulatory and Reimbursement Context; and
- The ''Process''—Investigational Device Exemption Review.

Dated: September 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22311 Filed 9–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Aortic Access From Vena Cava for Large Caliber Transcatheter Cardiovascular Interventions

Description of Technology: The invention pertains to a device and method for transcatheter correction of cardiovascular abnormalities, such as the delivery of prosthetic valves to the heart. Featured is a device implant for closing a caval-aortic iatrogenic fistula created by the introduction of a transcatheter device from the inferior vena cava into the abdominal aorta. The occlusion device includes an expandable transvascular implant with an elastomeric surface capable of extending between a vein and artery which conforms to the boundaries of an arteriovenous fistula tract between the artery and vein. A guidewire channel is disposed within the occlusion device where the channel also has elastomeric wall surfaces that conform or can be expanded to the area so that it occludes the channel when the guidewire is not present. The implant is resiliently deformable into a radially compressed configuration for delivery through the catheter. When not deformed into the radially compressed configuration, the distal end of the device is radially enlarged, relative to the intermediate neck, whereby the distal end forms an enlarged distal skirt, such as a disk or button shaped member. A polymer coating on the radially enlarged distal end conforms to the endoluminal aortic wall for deployment against an internal wall of the artery.

Potential Commercial Applications:

- cardiovascular surgery.
- heart valve implantation.
- valve-repair.

Competitive Advantages:

- closure of the caval-aortic iatrogenic fistula.
- vascular access.

Development Stage:

- Prototype.
- In vivo data available (animal).
- In vivo data available (human).

Inventors: Robert Lederman and Ozgur Kocaturk (NHLBI).

Publications:

1. Kodali SK, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med. 2012 May 3;366(18):1686–95. [PMID 22443479]
2. Makkar RR, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med. 2012 May 3;366(18):1696–704. [PMID 22443478]
3. Smith CR, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011 Jun 9;364(23):2187–98. [PMID 21639811]

Intellectual Property: HHS Reference No. E–553–2013/0—U.S. Provisional Patent Application 61/863,071 filed August 7, 2013.

Related Technologies:

- HHS Reference No. E–115–2013/0—U.S. Provisional Patent Application No. 61/834,357 filed June 12, 2013.
- HHS Reference No. E–027–2013/0—U.S. Provisional Patent Application No. 61/785,652 filed March 14, 2013.

Licensing Contact: Michael Shmilovich; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Heart Lung & Blood