4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Obesity and 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.

Summary: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Obesity and 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. The public workshop is being rescheduled due to the government shutdown. The title of the workshop has also been changed.

Dates and Times: The public workshop will be held on December 19, 2013, from 8:30 a.m. to 5 p.m. and on December 20, 2013, from 8:30 a.m. to 12:15 p.m.

Location: The public workshop will be held at the Grand Hyatt Washington, DC, 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 pm (EDT), December 10, 2013. Onsite registration will be available after this date. To register for the public workshop, please visit the American Gastroenterological Association (AGA) Web site: http://www.gastro.org/education-meetings/live-meetings/aga-fda-regulation-and-reimbursement-workshop. For more information on the workshop, please see the 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: November 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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