4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0816]

Joint Meeting of the Gastroenterology-Urology Panel and the Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Office of the Commissioner, 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: Gastroenterology-Urology Panel and Radiological Devices Panel of the Medical Devices 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 September 9, 2013, from 8 a.m. to 6 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. 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: Daniel Sigelman, Food and Drug Administration, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, rm. 4254, Silver Spring, MD, 20993-

0002, 301-796-4706, Daniel.Sigelman@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 September 9, 2013, the joint committee, convened by the Office of the Commissioner, will discuss current evidence on the risks and benefits of computed tomography colonography for screening of asymptomatic patients for colorectal cancer. The joint committee will provide advice that will assist FDA's consideration of evolving research on this topic and inform the Agency's continuing regulation of these devices.

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 being discussed at the meeting pending before the committee. Written submissions may be made to the docket on or after [INSERT DATE OF PUBLICATION IN

THE FEDERAL REGISTER]. 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 August 22, 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 29, 2013.

FDA has opened a docket for public comment on this meeting. The docket number is FDA-2013-N-0816. The docket will open for public comment on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received to the docket on or before September 3, 2013, will be provided to the committee before the meeting. Comments received after that date will not be provided to the committee, but will be taken into consideration by the Agency. The docket will remain open for 30 days after the meeting for additional written submissions.

Interested persons may submit either electronic comments regarding this meeting to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. It is only necessary to send one set of comments. Identify comments with the docket number FDA-2013-N-0816. 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.

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 Daniel Sigelman 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 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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