DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0722]

# Gastroenterology and Urology Devices Panel of the Medical Devices 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: Gastroenterology and Urology 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 May 14 and 15, 2015, from 8 a.m. to 6 p.m.

Addresses: FDA is opening a docket for interested persons to submit electronic or written comments regarding this meeting. The Docket No. is FDA-2015-N-0722. Please see the Procedure section of the notice for further information.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability,

visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1552, Silver Spring, MD 20993-0002, 301-796-5290, Natasha.Facey@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 May 14 and 15, 2015, the committee will discuss recent reports and epidemiologic investigations of transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures in hospitals in the United States.

FDA is convening this committee to seek expert scientific and clinical opinion related to reprocessing of duodenoscopes and other endoscopes, as well as automated endoscope reprocessors, based on available scientific information. The committee will make recommendations on: (1) The effectiveness of cleaning, high level disinfection, and sterilization methods; (2) the amount and type of premarket validation data and information needed to support labeling claims and technical instructions; (3) the appropriate use of other risk mitigations, such as surveillance cultures; (4) best practices and guidelines for

reprocessing duodenoscopes and endoscopes at user facilities to minimize the transmission of infections; and (5) recommended approaches for ensuring patient safety during ERCP procedures, including a discussion of appropriate patient selection.

Recommendations on these issues will assist FDA in minimizing patient exposure to infectious agents that may result from reprocessed duodenoscopes and endoscopes.

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.

CDRH plans to provide a live Webcast of the May 14 and 15, 2015, meeting of the Gastroenterology and Urology Devices Panel. While CDRH is working to make Webcasts available to the public for all advisory committee meetings held at the White Oak campus, there are instances where the Webcast transmission is not successful; staff will work to re-establish the transmission as soon as possible. The link for the Webcast is available at: https://collaboration.fda.gov/gudpm052015/. Further information regarding the Webcast, including the Web address for the Webcast, will be made available at least 2 days in advance of the meeting at the following Web site: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/default.htm. Select the link for 2015 Meeting Materials.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 30, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 14 and between approximately 9 a.m. and 10 a.m. on May 15. 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 April 15, 2015. 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 April 20, 2015.

FDA is opening a docket for public comment on this document. The Docket No. is FDA-2015-N-0722. The docket will close on May 28, 2015. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Comments received on or before April 30, 2015, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document.

Received comments may be seen in the Divisions 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.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

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 AnnMarie Williams, at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 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: March 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

4164-01-P

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