4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

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 July 30 and 31, 2014, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring MD 20993-0002, Sara.Anderson@fda.hhs.gov, 301-796-7047, 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 July 30, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Ablatherm Integrated Imaging device sponsored by EDAP Technomed, Inc. The proposed Indication for Use for the Ablatherm Integrated Imaging device, as stated in the PMA, is as follows:

The Ablatherm Integrated Imaging device is intended for the primary treatment of prostate cancer in subjects with low risk, localized prostate cancer.

On July 31, 2014, the committee will discuss and make recommendations regarding the classification of Penile Tumescence Monitors, Nephrostomy Catheters, Stimulators for Electrical Sperm Collection, Erectile Dysfunction Devices, and Alloplastic Spermatoceles. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Penile Tumescence Monitors are currently regulated under the heading, "Monitor, Penile Tumescence," Product Code LIL, as unclassified under the 510(k) premarket notification authority. Nephrostomy Catheters are currently regulated under the heading, "Catheter, Nephrostomy," Product Code LJE, as unclassified under the 510(k) premarket notification authority. Stimulators for Electrical Sperm Collection are currently regulated under the heading, "Stimulator, Electrical for Sperm Collection," Product Code LNL, as unclassified under the 510(k) premarket notification authority. Erectile Dysfunction Devices are currently regulated under the heading, "Device, Erectile Dysfunction," Product Code LST, as unclassified under the 510(k) premarket

notification authority. Alloplastic Spermatoceles are currently regulated under the heading, "Spermatocele, Alloplastic," Product Code LQS, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the safety and effectiveness and the regulatory classification of Penile Tumescence Monitors, Nephrostomy Catheters, Stimulators for Electrical Sperm Collection, Erectile Dysfunction Devices, and Alloplastic Spermatoceles.

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 pending before the committee. Written submissions may be made to the contact person on or before June 24, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 30, 2014, and between approximately 8:50 a.m. and 9:50 a.m. on July 31, 2014. 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 June 16, 2014. 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 June 17, 2014.

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 James Clark at James.Clark@fda.hhs.gov, or 301-796-5293 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: June 6, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-13650 Filed 06/11/2014 at 8:45 am; Publication Date: 06/12/2014]