Meeting Announcement: June 27, 2013 Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

U.S. Food & Drug Administration

Holiday Inn
Ballroom
2 Montgomery Village Ave.
Gaithersburg, MD 20879
301-948-8900

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-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.

Contact Person: Shanika Craig, Shanika.Craig@fda.hhs.gov [1], Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6639, 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 [2] 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 June 27, 2013, during session I, the committee will discuss and make

recommendations regarding the proposed classification of sorbent hemoperfusion systems, one of the remaining preamendments class III devices. The class III sorbent hemoperfusion system is a device intended for the treatment of poisoning, drug overdose, hepatic coma, and metabolic disturbances. It consists of an extracorporeal blood system and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated carbon or resins, which may be coated or immobilized to prevent fine particles from entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. Sorbent hemoperfusion systems may also include the machine or instrument used to drive and manage blood and fluid flow within the extracorporeal circuit, as well as any accompanying controllers, monitors, or sensors.

On April 4, 2013 (78 FR 20268), FDA issued a proposed order which, if made final, would reclassify sorbent hemoperfusion systems labeled for the treatment of poisoning and drug overdose class II subject to premarket notification [510(k)] and special controls, while sorbent hemoperfusion systems labeled for the treatment of hepatic coma and metabolic disturbances would remain class III requiring premarket approval (PMA) applications. The committee’s discussion will involve making recommendations regarding the regulatory classifications noted above. The committee will also discuss whether the proposed special controls are adequate to reasonably ensure the safety and effectiveness of sorbent hemoperfusion devices labeled for the treatment of poisoning and drug overdose. The regulatory history of sorbent hemoperfusion has been discussed as part of a previously published proposed rule (77 FR 9610).

During session II on June 27, 2013, the committee will discuss and make recommendations regarding the proposed classification of implanted blood access devices for hemodialysis from class III to class II. The class III implanted blood access devices for hemodialysis include various flexible or rigid tubes, such as catheters, cannulae or hollow needles. Chronic hemodialysis catheters are soft, blunt-tipped plastic catheters that have a subcutaneous “cuff”' for tissue ingrowth. They are placed in a central vein to allow blood access. Chronic hemodialysis catheters serve as conduits for the removal of blood from the patient, delivery to a hemodialysis machine for filtering, and return of filtered blood to the patient. They have no moving parts, consisting, essentially, of flexible tubing terminating in rigid Luer lock connectors for attachment to a dialysis machine. Subcutaneous catheters are totally implanted below the skin surface with no external communication. Arteriovenous shunts and vessel tips are tubing with tapered tips that are inserted into the artery and vein. The tubing is attached to the roughened or etched outer surface of the tip. The tubing is external to the skin and can be accessed with needles. They are similar to subcutaneous catheters.

On June 20, 2012 (77 FR 36951), FDA issued a proposed rule which, if made final, would make the class III implanted blood access devices class II subject to premarket notification [510(k)] and special controls. The regulatory history of implanted blood access devices has been discussed as part of the proposed rule (77 FR 36951).

The committee's discussion will involve making recommendations regarding regulatory classification to either reaffirm class III or reclassify these devices into class II and comment on whether special controls are adequate to reasonably ensure the safety and effectiveness of this device.

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/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm [3]. 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 11, 2013. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. for session I and session II will start immediately after lunch between approximately 1:30 p.m. and 2:30 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 June 3, 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 June 4, 2013.

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, Committee Management Staff, at james.clark@fda.hhs.gov [4], 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 [5] 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: April 26, 2013.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

Links:
[1] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:Shanika.Craig@fda.hhs.gov
[2] http://www.fda.gov/AdvisoryCommittees/default.htm
[3] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm
[4] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:james.clark@fda.hhs.gov
[5] http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm