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Dated: June 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-15601 Filed 6-21-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Circulatory System 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: Circulatory System 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 20 and 21, 2011, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1609, Silver Spring, MD 20993-0002, 301-796-6313, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 20, 2011, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Edwards SAPIEN Transcatheter Heart Valve sponsored by Edwards Lifesciences. The Edwards SAPIEN™ Transcatheter Heart Valve, model 9000TFX, sizes 23 millimeters (mm) and 26 mm and accessories implant system consists of the following:

- The Edwards SAPIEN Transcatheter Heart Valve consists of a heterologous (bovine) pericardium leaflet valve sutured within a stainless steel mesh frame, with a polyester skirt. It is offered in 2 sizes, a 23 mm and a 26 mm.
- The RetroFlex 3 Delivery System is used to advance the bioprosthesis through the RetroFlex sheath over a guidewire and to track the bioprosthesis over the aortic arch and for crossing and positioning in the native valve. The delivery system also comes with a sheath, introducer, loader, dilator, balloon (used to pre-dilate the native annulus) and a crimper.

On July 21, 2011, the committee will discuss, make recommendations, and vote on information related to the humanitarian device exemption for the Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD) sponsored by Berlin Heart, Inc. The Berlin Heart EXCOR Pediatric VAD device is a pneumatically-driven extracorporeal ventricular assist device. It is designed to provide bridge-to-transplant mechanical support to the heart. The system consists of one or two extracorporeal blood pumps (univentricular or biventricular support), cannulae for the connection of the blood pumps to the atria and great arteries, and the IKUS Stationary Driving Unit (electro-pneumatic driving system).

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 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 July 14, 2011. Oral

presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. 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 July 6, 2011. 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 July 8, 2011.

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, Conference Management Staff, at 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: June 15, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-15539 Filed 6-21-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-E-0104 (Formerly Docket No. 2007E-0001)]

Determination of Regulatory Review Period for Purposes of Patent Extension; METVIXIA

AGENCY: Food and Drug Administration, HHS.