

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 June 27, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4179, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application, sponsored by CryoCor Inc., for the CryoCor Cryoablation System, which is intended for the treatment of isthmus-dependent atrial flutter in patients 18 years or older.

FDA intends to make background material available to the public no later than 1 business day 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/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and 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 June 13, 2007. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of committee deliberations. Those desiring to make 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 5, 2007. 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 6, 2007.

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 240-276-8932, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 3, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Vaccines and Related Biological Products

Advisory Committee. This meeting was originally announced in the **Federal Register** of April 16, 2007 (72 FR 19003). The amendment is being made to reflect a change in the *Date and Time*, *Agenda*, and *Procedure* portions of the meeting.

FOR FURTHER INFORMATION CONTACT:

Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 16, 2007, FDA announced that a meeting of the Vaccines and Related Biological Products Advisory Committee would be held on May 16, 2007, from 9 a.m. to 4:30 p.m. and May 17, 2007, from 8 a.m. to 1 p.m. Changes to the meeting times, agenda, and procedure are as follows:

- The meeting will be held on May 16, 2007, from 8:30 a.m. to 4:45 p.m. and on May 17, 2007, from 9 a.m. to 3:30 p.m.
- In addition to the agenda items listed in the April 16, 2007, meeting notice, on May 16, 2007, in the afternoon session, the committee will hear an update on the influenza strain selection for the 2007 to 2008 influenza season. As stated in the April 16, 2007, meeting notice, FDA intends to make background material available to the public no later than 1 business day 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/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

- On May 16, 2007, from 8:30 a.m. to 4:05 p.m. and on May 17, 2007, from 9 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled between approximately 11:25 a.m. and 11:55 a.m. and between 3:35 p.m. and 4:05 p.m. on May 16, 2007, and between approximately 12:45 p.m. and 1:15 a.m. on May 17, 2007.

- On May 16, 2007, from 4:05 p.m. to 4:45 p.m., the meeting will be closed to