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.

[FR Doc. E7–9054 Filed 5–9–07; 8:45 am]

BILLING CODE 4160–01–S

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

permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

There are no other changes to the meeting.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: May 7, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–9053 Filed 5–9–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0440]

Guidance for Industry on Computerized Systems Used in Clinical Investigations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Computerized Systems Used in Clinical Investigations,'' dated May 2007. This document provides to sponsors, contract research organizations, data management centers, clinical investigators, and institutional review boards, recommendations regarding the use of computerized systems in clinical investigations. Because the source data in source documentation are necessary for the reconstruction and evaluation of the trial to determine the safety and effectiveness of new human and animal drugs, and medical devices, this guidance is intended to assist in ensuring confidence in the reliability, quality, and integrity of electronic source data and source documentation, i.e., electronic records. This guidance supersedes the guidance entitled ''Computerized Systems Used in Clinical Trials,'' dated April 1999; finalizes the draft guidance of the same title dated September 2004; and supplements the guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' dated August 2003, and FDA's international harmonization efforts when applying guidance to source data generated at clinical study sites.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Computerized Systems Used in Clinical Investigations.'' This document provides to sponsors, contract research organizations, data management centers, clinical investigators, and institutional review boards, recommendations regarding the use of computerized systems in clinical investigations. There is an increasing use of computerized systems in clinical trials to generate and maintain source data and source documentation on each clinical trial subject. Such source data and source documentation must meet certain fundamental elements of data quality, e.g., attributable, legible, contemporaneous, original, and accurate, that are expected of paper records. FDA's acceptance of data from clinical trials for decisionmaking purposes depends on FDA's ability to verify the quality and integrity of the data during FDA onsite inspections and audits.

In the **Federal Register** of October 4, 2004 (69 FR 59239), FDA announced the availability of the draft guidance entitled ''Computerized Systems Used in Clinical Trials,'' dated September 2004. FDA considered the comments submitted to the docket in revising this guidance. This guidance supersedes the guidance of the same title dated April 1999; finalizes the draft guidance dated September 2004; and supplements the guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' dated August 2003, and FDA's international harmonization efforts when applying guidance to source data generated at clinical study sites.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on computerized systems used in clinical investigations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 11 have been approved under OMB Control No. 0910–0303. The collections of information in 21 CFR 312.62 have been approved under OMB Control No. 0910–0014. The collections of information in 21 CFR 511.1(b)(7)(ii) have been approved under OMB Control No. 0910–0117. The collections of information in 21 CFR 812.140 have been approved under OMB Control No. 0910–0078.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/gcp* or *http://www.fda.gov/ohrms/dockets/default.htm*.