

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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D. Hawkins

Food and Drug Administration

**Medical Devices Dispute Resolution 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: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on April 19, 2007, from 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Nancy Collazo-Braier, Center for Devices and Radiological Health (HFZ-1), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3959, e-mail: nancy.braier@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014510232. Please call the Information Line for up-to-date information on this meeting.

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Agenda: The committee will discuss, make recommendations, and vote regarding a scientific dispute between the agency and Cardima Inc. related to the not-approvable determination for the premarket approval application (PMA) for the REVELATION Tx Microcatheter with NavAblator Ablation System, indicated for the treatment of drug refractory paroxysmal atrial fibrillation.

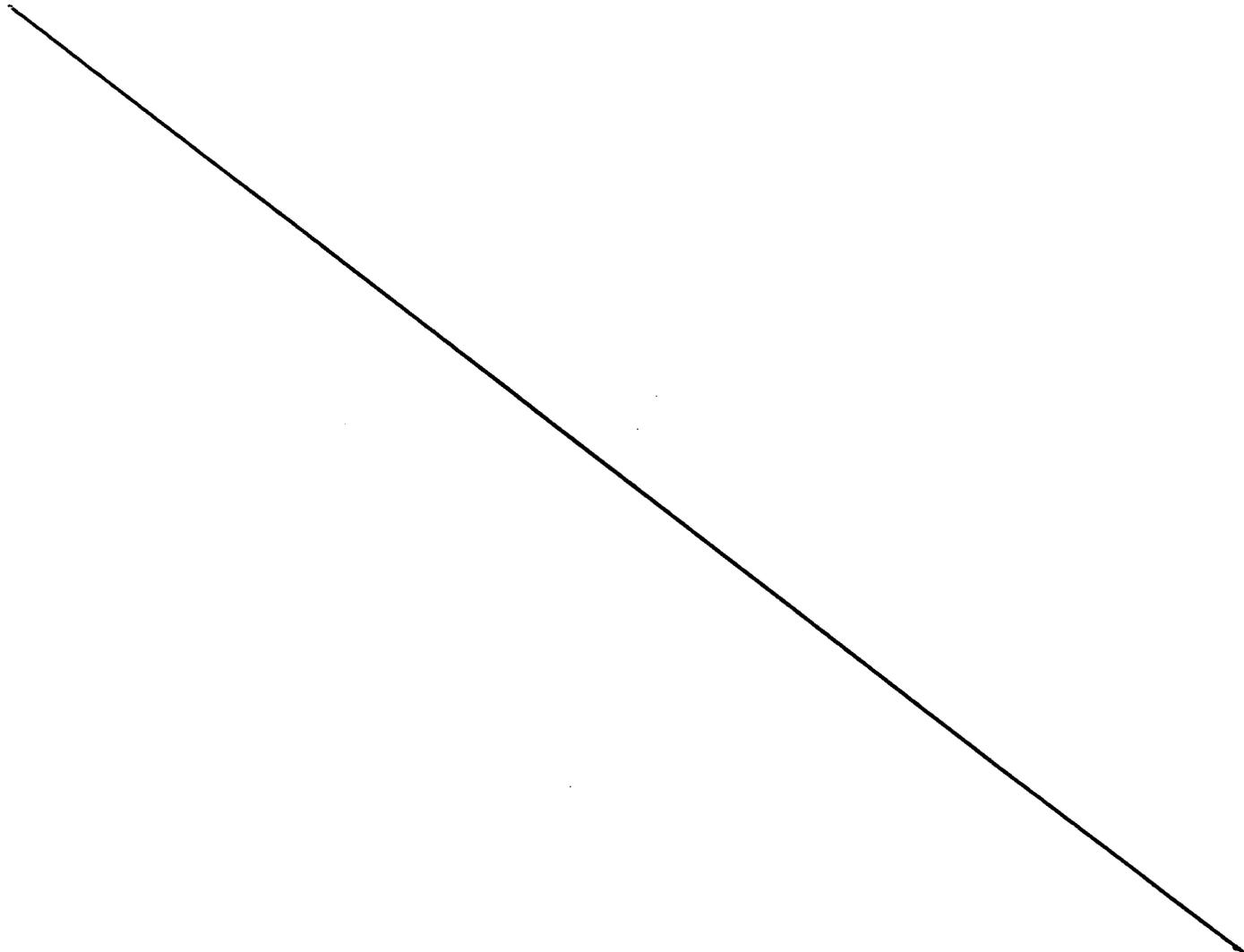
FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, 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 April 5, 2007. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and between approximately 1:30 p.m. and 2 p.m. 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 March 28, 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 March 29, 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 Ann Marie Williams, Conference Management Staff, at 301-827-7291, 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: 3/14/07
~~March 14, 2007.~~



Randall W. Lutter
Associate Commissioner for Policy and Planning.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Dawn P. Hawkins