

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee;

Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

173 FR 15530
3/24/08

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: Ophthalmic 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 April 24 and 25, 2008, from 8:30 a.m. to 5 p.m.

Location: Gaithersburg Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Karen F. Warburton, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4238, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512396.

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

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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 April 24, 2008, the committee will discuss, make recommendations, and vote on a premarket approval application, sponsored by VisionCare Technologies, Inc., for an implantable miniature telescope (IMT). The IMT, a visual prosthetic device, is indicated for monocular implant in patients with stable, moderate to profound central vision impairment due to bilateral central scotomas associated with end-stage macular degeneration with geographic atrophy or disciform scar, foveal involvement, and cataract. On April 25, 2008, the committee will discuss general issues concerning the post market experience with phakic intraocular lenses and laser-assisted in situ keratomileusis (LASIK).

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 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 15, 2008. Oral presentations from the public will be scheduled on April 24, 2008,

between approximately 9:30 a.m. and 10 a.m. and between approximately 3:30 p.m. and 4 p.m.; and on April 25, 2008, between approximately 10 a.m. and 11:15 a.m. and between approximately 3 p.m. and 4 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 April 7, 2008. 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 April 8, 2008.

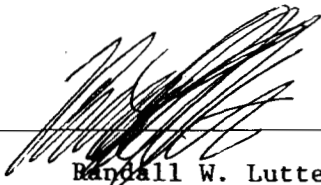
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.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: 3/14/08
March 14, 2008.



Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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**CERTIFIED TO BE A TRUE
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Dawn P. Hawkins