

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic 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). At least one portion of the meeting will be closed 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 July 14, 2006, from 8 a.m. to 6 p.m.

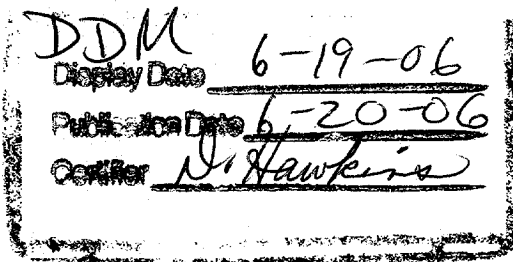
Location: Hilton Washington DC North/Gaithersburg, Montgomery Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053 x 127, 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.

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Agenda: The committee will hear a presentation on FDA's Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics, Center for Devices and Radiological Health, outlining their responsibility for the review of postmarket study design. Subsequently, the committee will discuss, make recommendations, and vote on a premarket approval application for an implantable miniature telescope (IMT). The IMT™ is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto lens and is indicated for use in patients with bilateral, stable macular degeneration and other bilateral, stable untreatable central vision disorders. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panel> (click on "Upcoming CDRH Advisory Committee/Panel Meetings").

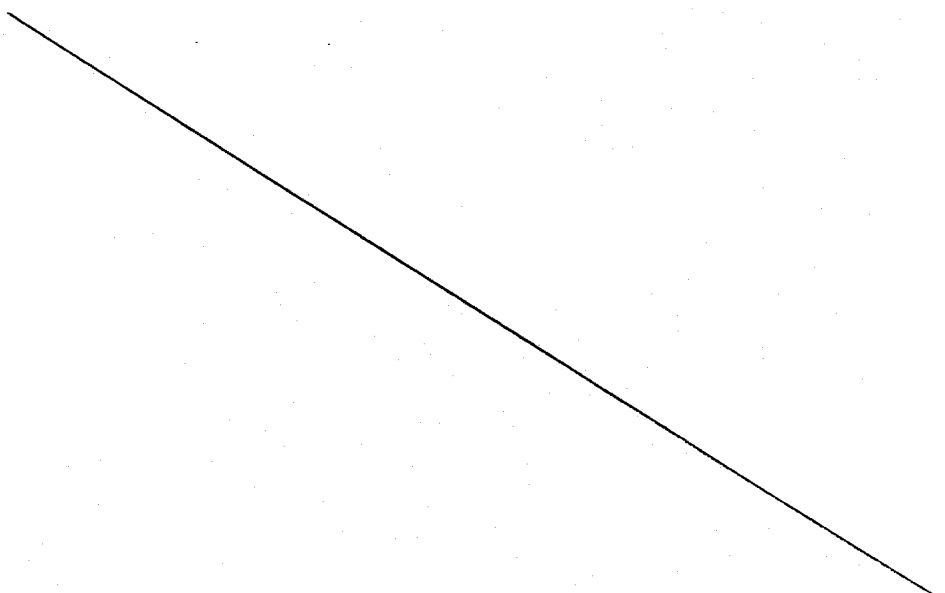
Procedure: On July 14, 2006, from 8:45 a.m. to 6 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 5, 2006. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m., and between approximately 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. 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 July 5, 2006.

Closed Committee Deliberations: On July 14, 2006, from 8 a.m. to 8:45 a.m., the meeting will be closed to permit discussion and review of trade secret

and/or confidential commercial information (5 U.S.C. 552b(c)(4)). This information is relevant to pending and future device submissions for vitreoretinal, surgical and diagnostic devices, intraocular and corneal implants, and contact lenses.

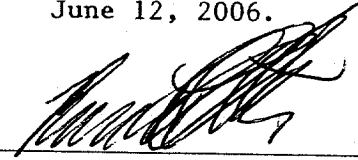
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 301-827-7291 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: June 12, 2006
June 12, 2006.



Randall W. Lutter,
Associate Commissioner for Policy and Planning.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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COPY OF THE ORIGINAL
Dawn P. Hawkins