

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

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 August 1, 2002, from 8:30 a.m. to 4:30 p.m., and on August 2, 2002, from 8:30 a.m. to 3 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 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, ext. 127, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 1, 2002, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an excimer laser system for use in wavefront guided laser in situ keratomileusis correction for the reduction or elimination of myopia up to -7 diopters (D) with less than -0.50D of astigmatism at the spectacle plane in subjects who are 21 years of

age or older. On August 2, 2002, the committee will discuss issues related to the development of an FDA guidance, an American National Standards Institute standard, and an International Standards Organization standard for intraocular lenses for the treatment of myopia or hyperopia in phakic patients. The committee will address questions on clinical study design, specular microscopy (endothelial cell counts), lens opacity, and contrast sensitivity. Background information for each day's topic, including the attendee list, 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/panelmtg.html>. Material for the August 1, 2002, session will be posted on July 31, 2002; material for the August 2, 2002, session will be posted on August 1, 2002.

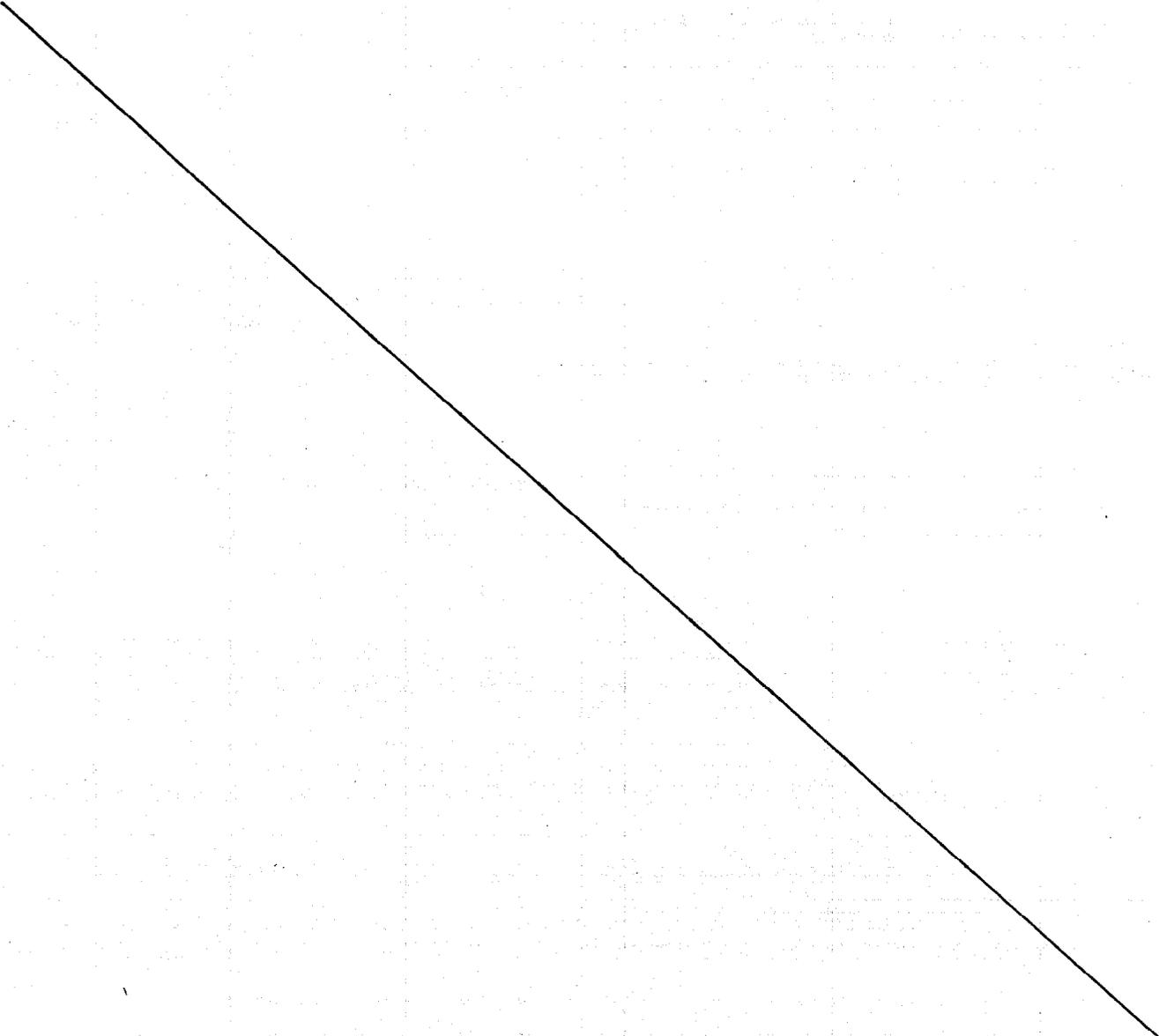
Procedure: On both days from 8:30 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 26, 2002. On August 1, 2002, formal oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. On August 2, 2002, oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of committee deliberations on the agenda topics, a 30-minute open public session will be conducted for interested persons to address issues specific to the topics before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 26, 2002, 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.

Closed Committee Deliberations. On August 1, 2002, from 3 p.m. to 4:30 p.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information relevant to pending and future device submissions for vitreoretinal, surgical

and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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 301-594-1283, ext. 113, 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 26, 2002

June 26, 2002.



William K. Hubbard,
Senior Associate Commissioner for Policy,
Planning, and Legislation.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins