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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). 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 July 22 and 23, 1999, 8 a.m. to 5:30 p.m.

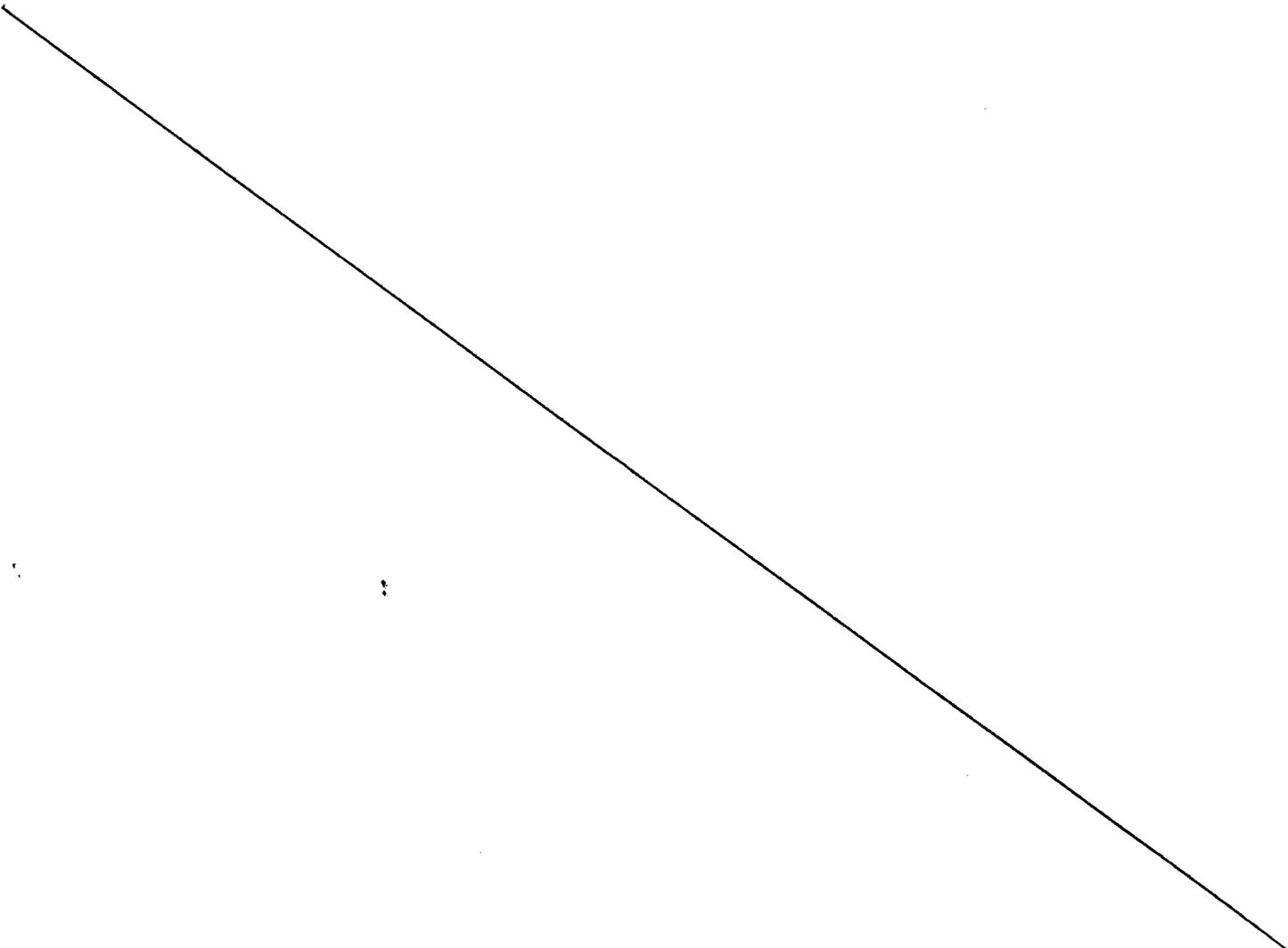
Location: Hilton Hotel, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 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 July 22, 1999, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for the correction of myopia with and without astigmatism using laser in-situ keratomileusis (LASIK). The committee will also discuss, make recommendations, and vote on a holmium laser for the correction of hyperopia using laser thermal keratomileusis. On July 23, 1999, the committee will discuss, make recommendations, and vote on a soft acrylic intraocular lens for the visual correction of aphakia after cataract extraction. The

committee will also discuss, make recommendations, and vote on a PMA for the correction of myopia with and without astigmatism using LASIK.

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 by July 12, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. on July 22 and 23, 1999. Near the end of the committee deliberations on each PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission 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 12, 1999, 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.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: June 9, 1999



Michael A. Friedman
Deputy Commissioner for Operations

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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