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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 May 11, 2000, 9:30 a.m. to 5 p.m., and May 12, 2000, 8:30 a.m. to 5 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, SMT@CDRH.FDA.GOV, 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 May 11, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for reduction or elimination of hyperopia (+0.5 to +5.00 diopters of sphere) with astigmatism (+0.5 to +4.0 diopters of cylinder) using photorefractive keratectomy (PRK).

On May 12, 2000, the committee will discuss issues related to the design and development of clinical protocols to support claims of reduced posterior capsular opacification (PCO) for intraocular lenses (IOL's). The topics for discussion will include study, methodology, controls, clinical endpoints, and data analysis. The committee will also discuss issues related to the development of guidance for refractive implants (phakic IOL's and corneal implants). The topics for discussion will include the scope of the proposed guidance, the maintenance of endothelial cell counts, and cataractogenesis due to the presence of an implant. As the materials become available, background information, questions for the panel, a bibliography for the PCO discussion, and an overview of the proposed clinical study section and questions for the panel for the refractive implants discussion will be made available to the public on FDA's website at <http://www.fda.gov/ohrms/dockets/ac/cdrh00.htm#ophthalmicdevices>.

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 May 1, 2000. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. on May 11, 2000, and between approximately 8:45 a.m. and 9:15 a.m. on May 12, 2000. On May 11, 2000, 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. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 1, 2000, 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: 3/30/00
March 30, 2000


Linda A. Suydam
Senior Associate Commissioner

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