

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Author SRESE

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 January 17, 2002, from 9:30 a.m. to 5 p.m., and January 18, 2002, from 8:30 a.m. to 3:30 p.m.

*Location:* Hilton 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, 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 January 17, 2002, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) on an endocapsular tension ring for the stabilization of the lens capsular bag. On January 18, 2002, the committee will discuss, make recommendations, and vote on a PMA on an orthokeratology contact lens for corneal refractive therapy with overnight

wear for the temporary reduction of myopia. Background information for each day's topic, including the agenda and questions for the committee, will be available to the public one business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the January 17 session will be posted on January 16, 2002; material for the January 18 session will be posted on January 17, 2002.

*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 January 7, 2002. On January 17, 2002, formal oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m., and on January 18, 2002, between approximately 8:45 and 9:15 a.m. 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. Those desiring to make formal oral presentations should notify the contact person before January 7, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the January 17 and 18, 2002, Ophthalmic Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Ophthalmic Devices Panel' of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

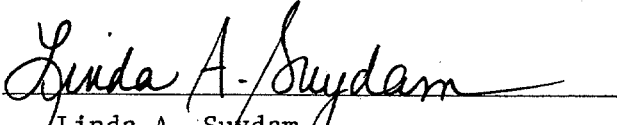
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Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 12-28-01

December 28, 2001.

  
Linda A. Suydam,  
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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