

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	<i>[Signature]</i>

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 November 8, 2000, 8:30 a.m. to 5 p.m.

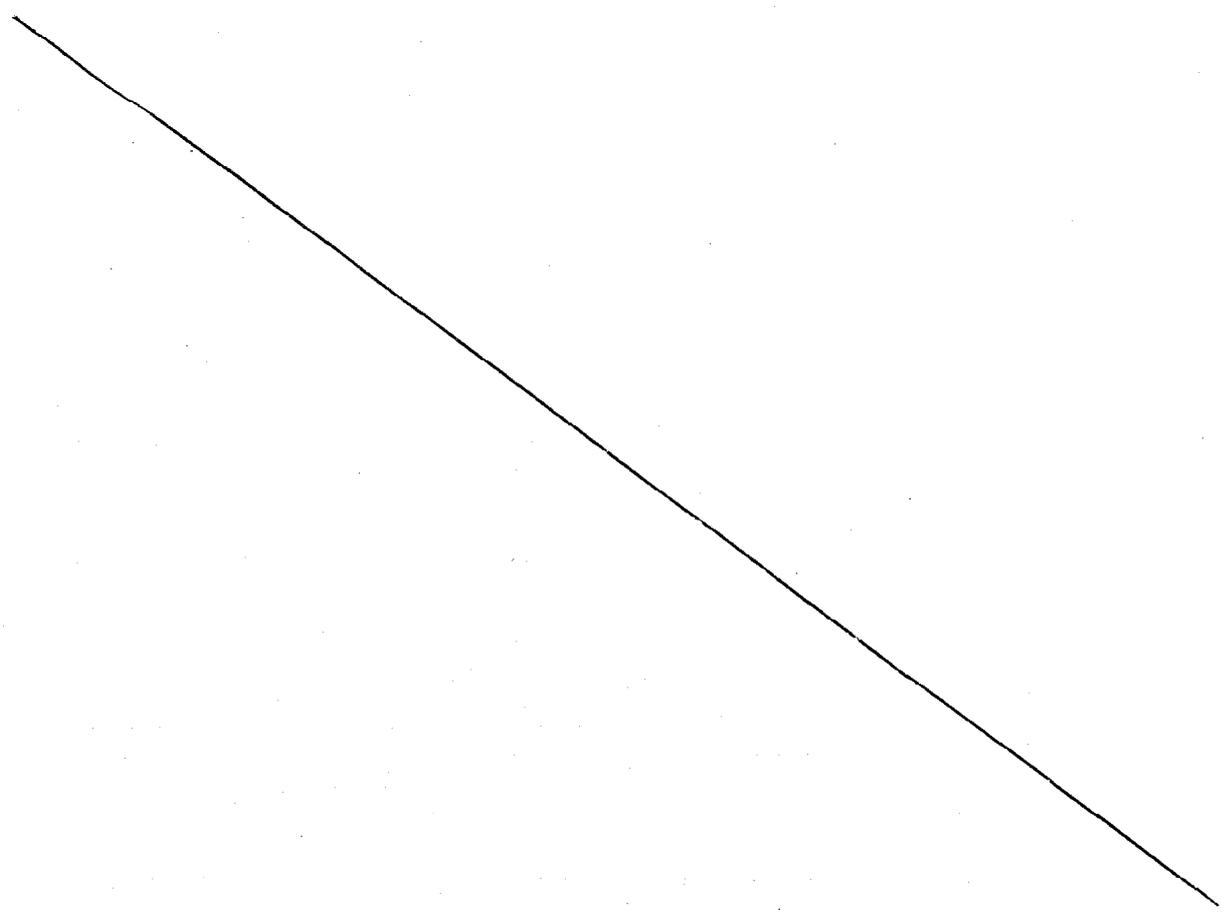
Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

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, e-mail: 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: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a collagen glaucoma drainage device for the reduction of intraocular pressure in patients with open-angle glaucoma uncontrolled on maximum tolerated medical therapy. The committee will also discuss issues related to the development of guidance for the postapproval

study of extended wear contact lenses used beyond 7 days. Study design topics will include the type of study, definition of endpoints, and selection of participating study sites.

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 November 1, 2000. 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, an additional 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 November 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.

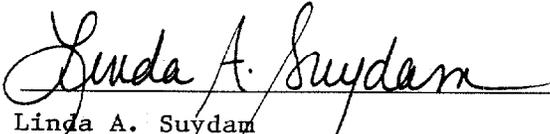


Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

OCT 11 2000

Dated: _____



Linda A. Suydam
Senior Associate Commissioner

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



Jen Windsor

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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