

DMB

Display Date	12.13.99
Display Date	12.14.99
Control	HH/WH/ST

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 13 19 52

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). 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 January 13, 2000, 9:30 a.m. to 5 p.m., and January 14, 2000, 9:30 a.m. to 2 p.m.

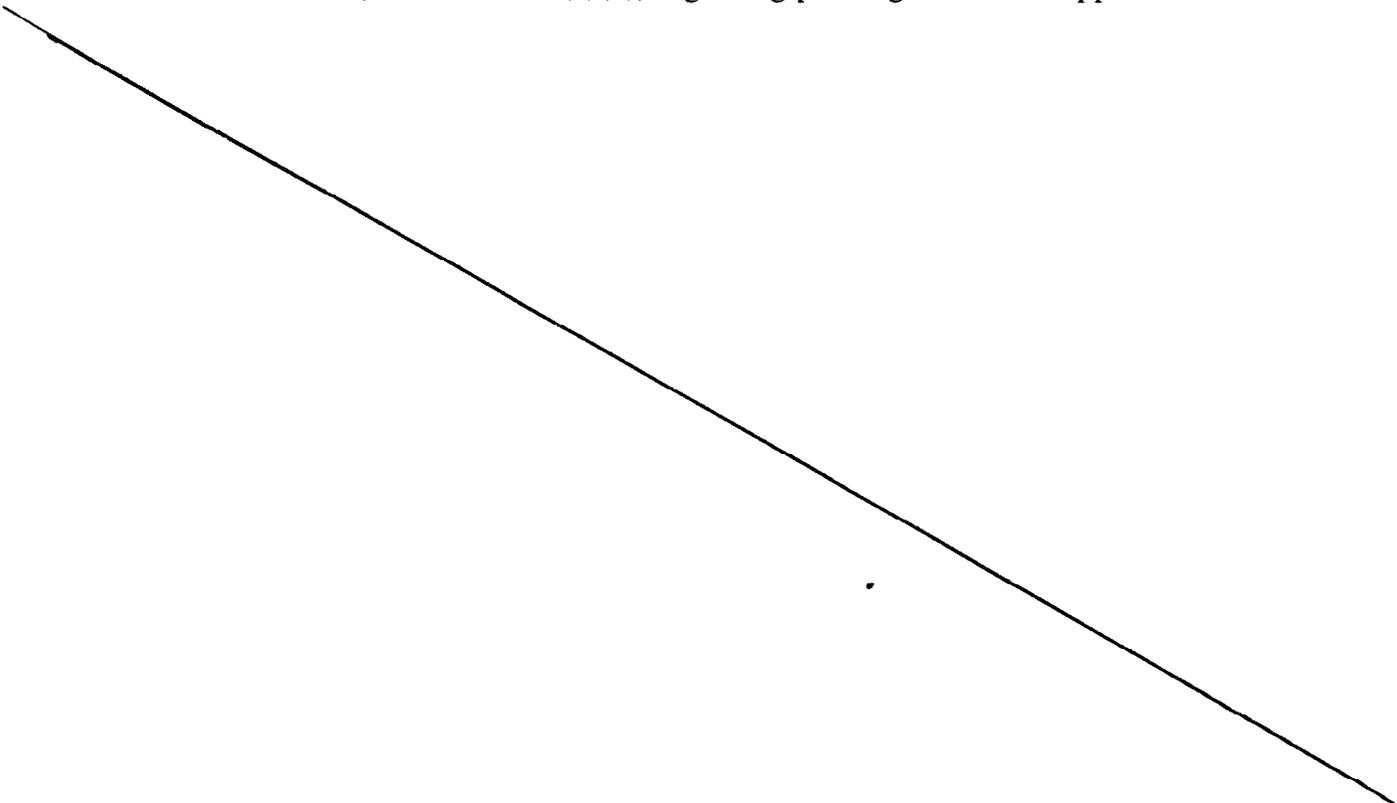
Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact: 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 13, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a holmium laser for the correction of hyperopia using laser thermal keratomileusis. On January 14, 2000, the committee will discuss and make recommendations on: (1) The reclassification of an artificial eye lubricating solution, and (2) the classification status for currently unclassified eyelid weight devices.

Procedure: On January 13, 2000, from 9:30 a.m. to 3 p.m., and on January 14, 2000, from 9:30 to 2 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 January 6, 2000. On January 13, 2000, formal oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 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 January 14, 2000, oral presentations from the public regarding the reclassification of the artificial eye lubricating solution and the classification of the eyelid weight devices will be scheduled between approximately 9:45 a.m. to 10:45 a.m. Those desiring to make formal oral presentations should notify the contact person by January 6, 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.

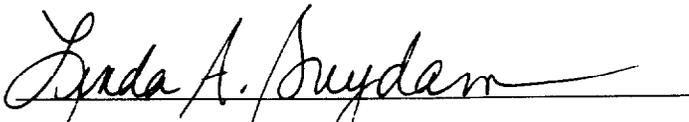
Closed Committee Deliberations: On January 13, 2000, from 3 p.m. to 5 p.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues and applications.



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

2).

Dated: December 7, 1999


Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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

BILLING CODE 4160-01-F