PMB

Display Date 10-22-01
Publication Date 10-23-01
Certifier A Federow

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 November 30, 2001, from 9:45 a.m. to 4:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, 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, l-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 conductive keratoplasty' (CK) refractive surgical device for the reduction of previously untreated spherical hyperopia in patients 40 years of age or greater, who have 0.75 diopter (D) to 3.25 D of cycloplegic spherical hyperopia, with less than or equal to

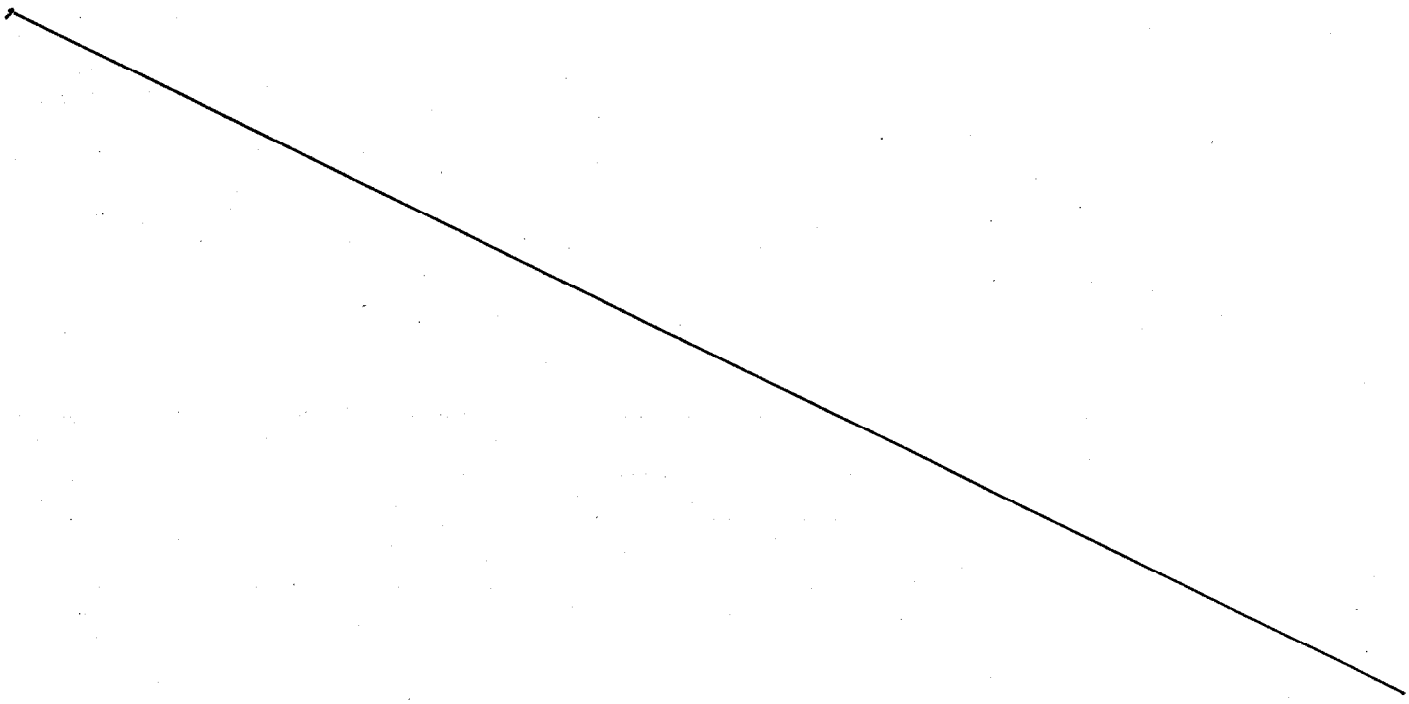
oc01256

3806

NM I

0.75 D of refractive astigmatism (minus cylinder format), a cycloplegic spherical equivalent of 0.75 D to 3.00 D, and no more than 0.50 D difference between preoperative manifest refraction spherical equivalent (MRSE) and cycloplegic refraction spherical equivalent (CRSE) which shows some regression of the initial effect over time. Background information, including the agenda and questions for the committee, will be available to the public on November 29, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

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 16, 2001. Formal oral presentations from the public will be scheduled between approximately 9:50 a.m. and 10:20 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. Those desiring to make formal oral presentations should notify the contact person before November 16, 2001, 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: 10/16/01
October 16, 2001.

Linda A. Suydam
Linda A. Suydam,
Senior Associate Commissioner.

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

BILLING CODE 4160-01-S