DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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: Circulatory System 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 October 27, 1998, 8 a.m. to 5 p.m.

Location: Hilton Hotel, Salons C, D, and E, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. 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 for a transmyocardial revascularization device.

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 October 16, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. Near the end of committee deliberations, a 30-minute open public hearing will be conducted for interested persons to address issues specific to the topics before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 16, 1998, 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: September 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–26571 Filed 10–2–98; 8:45 am]

BILLING CODE 4160–01–F

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). 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 October 22, 1998, 10:30 a.m. to 5:30 p.m., and October 23, 1998, 9 a.m. to 5 p.m.

Location: Holiday Inn Silver Spring, Lincoln Ballroom, 8777 Georgia Ave., Silver Spring, 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, 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 October 22, 1998, the committee will discuss issues related to the development of extensions to the guidance document for refractive surgical lasers, entitled ''Discussion Points for Expansion of the Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers'' to include the clinical criteria for the determination of safety and effectiveness for photorefractive keratectomy (PRK) and laser in-situ keratomileusis (LASIK) for myopia and hyperopia with and without astigmatism, presbyopia, and other refractive indications. Single copies of the guidance document are available to the public by contacting the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1–800–638–2041 or 301–443–6597 and requesting the document by shelf number 093, or by FAX 1–800–899–0381 or 301–827–0111 and requesting facts-on-demand number 2093, or on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cdrh/ode/ed__op.html). On October 23, 1998, the committee will discuss issues related to the preliminary development of guidance for refractive implants (phakic intraocular lenses and corneal implants) to include clinical protocol design and development.

Procedure: On October 22, 1998, from 1:30 p.m. to 5:30 p.m., and on October 23, 1998, from 9 a.m. to 5 p.m., the meeting will be 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 October 15, 1998. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m. on October 22, 1998 and between approximately 9 a.m. and 9:30 a.m. on October 23, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 15, 1998, 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 October 22, 1998, from 10:30 a.m. to 1:30 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: September 24, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

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