Dated: June 9, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–15755 Filed 6–21–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee, Ophthalmic Drugs Subcommittee; 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: Dermatologic and Ophthalmic Drugs Advisory Committee, Ophthalmic Drugs Subcommittee.

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 July 21, 1999, 8:30 a.m. to 5 p.m.

Location: Hilton Hotel, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at the FDA Website ''www.FDA.GOV''.

Agenda: The subcommittee will discuss new drug application (NDA) 21–023 (cyclosporine ophthalmic emulsion, 0.05%, Allergan, Inc.), for treatment of moderate to severe keratoconjunctivitis sicca.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 16, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before July 16, 1999, 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: June 16, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–15752 Filed 6–21–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions; Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting concerning the public availability of information on clinical trials for investigational devices intended to treat serious or life-threatening conditions and the availability of this information in a publicly available data bank. This meeting is being held to assist the agency in preparing a report to Congress required under the FDA Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is inviting written comments and information that may assist FDA in this endeavor.

DATES: The meeting will be held on July 8, 1999, from 1:30 p.m. to 4:30 p.m.; registration will begin at 1 p.m.

ADDRESSES: The meeting will be held at 9200 Corporate Blvd., conference room 020B, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Robert R. Gatling, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 140, FAX 301–594–2977, or e-mail ''rrg@cdrh.fda.gov''.

Those persons interested in attending the meeting should fax or e-mail their registration including name, title, firm name, address, telephone, and fax number to Linda J. Lyons at 301–594–1190, ext. 108 or by fax at 301–594–2977. There is no charge to attend this meeting, but advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Linda J. Lyons at least 7 days in advance. Comments at the meeting may be limited in time depending on the number of presenters. Presenters should contact Linda J. Lyons by July 5, 1999.

SUPPLEMENTARY INFORMATION: FDAMA (Pub. L. 105–115) was enacted on November 21, 1997. Section 113(a) of FDAMA amends section 402 of the Public Health Service Act (PHS Act) (42 U.S.C. 282) by adding a new section 402(j). This new section directs the Secretary of Health and Human Services (the Secretary), acting through the Director of the National Institutes of Health (NIH), to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions.

Section 113(b) of FDAMA (collaboration and report) directs the Secretary, the Director of NIH, and the Commissioner of Food and Drugs to collaborate to determine the feasibility of including device investigations within the scope of the data bank under new section 402(j) of the PHS Act. In addition, section 113(b) of FDAMA directs the Secretary to prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report on the following:

1. The public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the PHS Act;

2. The adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed; and,

3. Such other issues relating to section 402(j) of the PHS Act as the Secretary determines to be appropriate.

Elsewhere in this issue of the **Federal Register**, FDA is inviting written comments and information that may assist FDA in preparing their report to Congress. Those questions should also be considered by those making presentations at the public meeting.

Dated: June 14, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–15758 Filed 6–21–99; 8:45 am]

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