DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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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 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 keratomeileusis. 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).


Linda A. Suydam, Senior Associate Commissioner.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Technology Assessment Conference on Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities

Notice is hereby given of the NIH Technology Assessment Conference on “Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities,” which will be held January 10–12, 2000, in the Natcher Conference Center of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:00 a.m. on January 10, at 8:00 a.m. on January 11, and at 9:00 a.m. on January 12.

Various medical implant devices have been widely used since the 1960s, and it is estimated that eight to ten percent of the American population currently has a permanent medical implant. Yet, there has not been any systematic effort developed in the United States for
implant retrieval analysis or data banking, even though medical implant retrieval research provides the only true long-term data on the host response to and the final condition of the implant. Thorough reporting on the performance of implants would allow physicians to evaluate devices, understand the clinical benefit and risks associated with medical implant treatment and prevention of disease, and advance the development of better devices and materials. This will ultimately benefit patients through superior implant technology.

While most medical implants function very well, significant challenges remain associated especially with their intended long-term duration of use. The advance of medical implant science is hampered by a lack of study of implants retrieved after surgery or at autopsy. Much can be learned of clinical end points, implant performance, and design theory, and this information will again lead to superior medical implants that benefit U.S. patients.

The objective of the conference is to assess the opportunities and challenges to developing a framework for independent research of explanted natural and synthetic implants, with the ultimate objective to provide benefits to patients through implant retrieval and analysis. For the purpose of this conference, implants are defined as having a minimum life span of three months; as penetrating living tissue; as having a physiologic interaction; and of being retrievable. This conference will bring together specialists in surgery, pathology, engineering, biomaterials, information systems, and other related disciplines, as well as representatives from the public, legal, ethical, and industrial communities.

After 1 1/2 days of presentations and audience discussion, an independent, non-Federal technology assessment panel will weigh the scientific evidence and write a draft statement that it will present to the audience on the third day. The technology assessment panel’s statement will address the following key questions:

- What is the lifetime costs, risks, and benefits of medical implants?
- What can the role of information data systems be in educating the public, medical community, and policymakers about medical implants and retrieval?
- What are the legal, ethical, religious, cultural, public policy, and economic barriers to implant retrieval and reporting, and how can they be overcome?
- What information is necessary to evaluate and improve implant and material performance and device design?
- What future research and institutional support is necessary to ensure continuing advances in implantable devices?

The primary sponsors of this conference are the National Heart, Lung, and Blood Institute (NHLBI) and the NIH Office of Medical Applications of Research (OMAR). Additional sponsors are the NIH Biomaterials and Medical Implant Science Coordinating Committee, which represents all of the NIH Institutes and Centers, the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Dental and Craniofacial Research; the National Institute of Neurological Disorders and Stroke; the National Library of Medicine; and the National Institute of Standards and Technology. This is the 19th Technology Assessment Conference held by the NIH in the 23-year history of the Consensus Development Program.

Advance information on the conference program and conference registration materials may be obtained from Louise Harkavy, Prospect Associates, 10720 Columbia Pike, Suite 500, Silver Spring, Maryland 20901–4437, (301) 592–3320, mirr@prospectassoc.com. The consensus statement will be submitted for publication in professional journals and other publications. In addition, the statement will be available beginning January 12, 2000 from the NIH Consensus Program Information Center, P. O. Box 2577, Kensington, Maryland 20891, phone 1-888-644-2667 and from the NIH Consensus Program site on the World Wide Web at http://consensus.nih.gov.


Ruth L. Kirschstein,
Deputy Director, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discuss could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–7, J2 P.

Date: December 15–17, 1999.

Time: 7:30 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Omni Charlottesville Hotel, 235 W. Main St., Charlottesville, VA 22902.

Contact Person: Lakshmanan Sankaran, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building Room 6AS2SF. National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–7799.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)


LaVerne Y. Stringfield,
Director, Office of Federal Advisory Committee Policy.

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