

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Dental Products 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: Dental Products Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 3, 1997, 9 a.m. to 5:30 p.m.; November 4, 1997, 8:30 a.m. to 5:30 p.m.; and November 5, 1997, 8 a.m. to 12 m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Pamela D. Scott, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12518. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 3, 1997, the committee will discuss the previously unclassified devices for use in the diagnosis and/or treatment of temporomandibular joint dysfunction and oral-facial pain (e.g., muscle monitor devices, jaw tracking devices, TENS (transcutaneous electrical nerve stimulation) devices, EMG (electromyographic) devices, and ultrasound devices). The committee will provide comments on the types of devices to be included within this category under these indications, which will assist FDA in developing a comprehensive strategy for subsequent classification efforts. This discussion will not include previously classified devices such as temporomandibular joint implants. The proposed listing of devices to be included within this category will be placed on CDRH's Internet website at <http://www.fda.gov/cdrh>. The topical index may be consulted for its specific location. On

November 4, 1997, the committee will discuss and make recommendations to FDA regarding the reclassification of subgroups of endosseous dental implant devices. The following subgroups of endosseous implants will be included: Coated and uncoated hollow cylinder and solid cylinder implants, coated and uncoated screw type implants (other than the commercially pure titanium screw type implant previously proposed for reclassification), coated and uncoated blade type implants, implants with special enhanced retention mechanisms and transitional implants. The coated implants may be further divided into porous coatings (e.g., titanium bead coatings), nonporous coatings (e.g., titanium plasma spray coatings), metallic coatings and ceramic coatings (e.g., hydroxylapatite coatings). The committee will also discuss and make recommendations regarding the classification of oral appliances for the treatment of obstructive sleep apnea and snoring. On November 5, 1997, the committee will continue discussion of the classification of oral appliances for the treatment of obstructive sleep apnea and snoring if time does not permit this issue to be completed on November 4, 1997.

Procedure: On November 3, 1997, from 9 a.m. to 5:30 p.m.; November 4, 1997, from 8:30 a.m. to 4:30 p.m.; and on November 5, 1997, from 8 a.m. to 12 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 October 27, 1997. Oral presentations from the public regarding devices with indications for use involving the diagnosis and/or treatment of temporomandibular joint dysfunction and oral-facial pain will be scheduled between approximately 9:30 a.m. and 10 a.m. on November 3, 1997. Oral presentations from the public regarding the reclassification of subgroups of endosseous dental implant devices will be scheduled between approximately 8:45 a.m. and 9:15 a.m. on November 4, 1997. Oral presentations from the public regarding the classification of oral appliances for the treatment of obstructive sleep apnea and snoring will be scheduled between approximately 3:15 p.m. and 3:45 p.m. on November 4, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 27, 1997, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the November 3, 4, and 5, 1997, Dental Products Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Dental Products Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Closed Committee Deliberations: On November 4, 1997, from 4:30 p.m. to 5:30 p.m., the meeting will be closed to permit discussion of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding dental device issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 8, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

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 Center for Scientific Review Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Clinical Sciences.

Date: October 15-17, 1997.

Time: 8:00 a.m.

Place: Doubletree Hotel, Rockville, Maryland.

Contact Person: Dr. Christine Melchior, Scientific Review Administrator, 6701 Rockledge Drive, Room 4118, Bethesda, Maryland 20892, (301) 435-1713.

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

Name of SEP: Biological and Physiological Sciences.

Date: November 17, 1997.

Time: 11:00 a.m.