

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Ear, Nose, and Throat Devices Panel and the 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: Joint meeting of the Ear, Nose, and Throat Devices Panel and the Dental Products 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 6, 2004, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, 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, ext. 127, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC

area), code 3014512522. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss general issues surrounding the prescription use versus over the counter (OTC) use of devices intended to treat snoring or mild to severe obstructive sleep apnea (OSA). The discussion will include the role of the medical/dental provider in the diagnosis, treatment, and followup of snoring and OSA; the ability of the patient to self diagnose and treat OSA; the types of clinical data that would be needed to support an OTC intended use; and the components of adequate device labeling. The discussion will not include continuous positive airway pressure (CPAP) devices and surgical treatments for OSA. Background information, including the attendee list, agenda, and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: On October 6, 2004, from 8:30 a.m. to 5:30 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 September 17, 2004. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. Near the end of the committee discussion, a second 30-minute open public session will be conducted for interested persons to comment further on the discussion topic. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 17, 2004, 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 6, 2004, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information relevant to pending and future device submissions for ear, nose, and throat devices. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

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

Dated: August 11, 2004.

William K. Hubbard,

Associate Commissioner Policy and Planning.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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