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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

9785 '00 JUN 30 A9-46

**Food and Drug Administration**

**Ear, Nose, and Throat 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:* Ear, Nose, and Throat 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 July 20, 2000, 9:45 a.m. to 5 p.m., and July 21, 2000, 8:30 a.m. to 5 p.m.

*Location:* Holiday Inn, Goshen Room, Two Montgomery Village Ave., 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, SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12522. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On July 20, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a direct-drive implantable middle ear hearing device intended to provide a useful level of sound perception via mechanical stimulation of the ossicles. On July 21, 2000, the committee will discuss, make recommendations and vote on a PMA for

an implant intended to restore useful hearing to individuals with Neurofibromatosis Type II who have become deaf as a result of surgery to remove bilateral auditory nerve tumors.

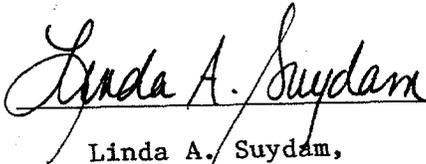
*Procedure:* On July 20, 2000, from 9:45 a.m. to 5 p.m., and on July 21, 2000, from 9:15 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 13, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. on July 20, 2000, and between approximately 9:30 a.m. and 10 a.m. on July 21, 2000. On both days, 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. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 13, 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 July 21, 2000, from 8:30 a.m. to 9:15 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending issues and applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

2).

Dated: 6/26/00  
June 26, 2000

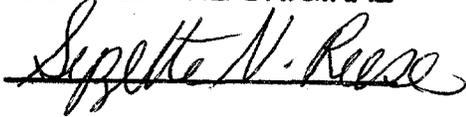
  
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Linda A. Suydam,  
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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