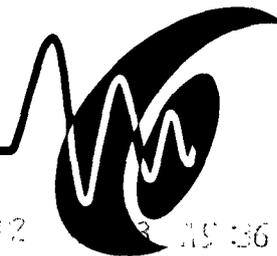


AMERICAN ACADEMY OF AUDIOLOGY

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September 10, 2002

Dockets Management Branch (HFA-305)
Center for Devices and Radiological Health
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RER: Docket No. 02D-0228

Dear FDA Dockets Management Branch:

The American Academy of Audiology, representing over 8,000 audiologists, appreciates this opportunity to comment on the Food and Drug Administration Center for Devices and Radiological Health "Implantable Middle Ear Hearing Device (IMEHD): Draft Guidance for Industry and FDA."

The Academy commends the Ear, Nose and Throat Devices Branch for their hard work in producing this extensive document. The draft guidance provides a thorough description of the procedure for preparing a premarket approval application and of the technical and clinical considerations for a premarket approval application for an IMEHD.

The Academy would like to recommend two editorial changes to the document under Chapter 5, Investigational Device Exemptions:

1. The Academy recommends that the Investigators paragraph read, "...Co-investigators should include **qualified** audiologists, as defined at 42 U.S.C. 1395x(II), who have knowledge and experience with current state-of-the-art air conduction (acoustic) hearing aid technology."
2. The Academy recommends that the first paragraph of the Subject Selection Criteria section read, "...You should describe hearing impairment in each ear as determined by objective hearing tests **conducted by qualified audiologists, as defined at 42 U.S.C. 1395x(II).**"

The Academy looks forward to working with the Food and Drug Administration on future hearing health care issues.

Sincerely,

Angela Loavenbruck, Ed.D.

Angela Loavenbruck, EdD
President

C6

02D-0228

Caring for America's Hearing

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