

February 4, 2004

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Dockets 2003-P-0362, 2003-P-0363

1. **FDA docket #2003-P-0362** "Petition to Create a New OTC Hearing Aid Classification that Grants OTC Sales, Distribution and Use Status to One-Size-Fits-Most Hearing Aid Devices," proposed by mead Killion, President, Etymotic Research, Inc.

2. **FDA docket number 2003-P-0363** "Professional and Patient Labeling for Hearing Aid Devices" proposed by Gail Gudmundsen, GudHear Inc.

To whom it may concern:

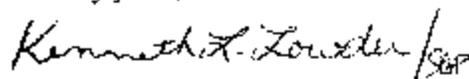
Audiology is currently transitioning its educational requirements for entry into the profession from the masters degree to the professional doctorate - the Doctor of Audiology (Au.D.) degree. The reason for the change is that the scope of audiology practice has expanded dramatically over the years. In addition, new technologies are now in widespread use that require additional preparation time in order to diagnose and treat hearing impaired patients. At this point, approximately 15% of our audiology practitioners have acquired the new training and have earned the Au.D. degree. Another 10% of the profession is engaged in upgrading their education currently. Approximately 40% of our educational programs have already made the switch to providing doctoral education as the entry- level requirement. The upgrade in requirements will be complete within a decade.

The proposal for allowing the sale of over-the- counter (OTC) hearing aids obviates the need for any professional intervention. In reality, the fitting of hearing aids is only one component of total hearing care. Patient care normally includes a hearing evaluation, referral for any medical problems found, prescription of hearing aids and/or other assistive listening devices, training in their use, patient follow-up, as well as counseling the patient and the patient's family on successful strategies to improve communication and other interventions.

The proposal to remove the skills and capabilities of audiologists from the hearing care process runs counter to reason, and certainly counter to the sense of the audiology profession which has determined that more skill and education is needed to provide quality care to American consumers. Hard of hearing consumers, who generally tend to show significant isolation and depression should not be allowed to choose poor quality, poor fitting devices that are likely to cause further problems for them.

We ask you to deny these petitions and help American consumers utilize properly educated providers to assist them with their hearing health care.

Sincerely yours,



Kenneth L. Lowder, Au.D.
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