AMERICAN ACADEMY OF AUDIOLOGY
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Dr. Eric A. Mann, M.D., Ph.D
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
(HFA-305)
Rockville, MD 20852

Re: Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

Dear Dr. Mann:

I was pleased to have had the opportunity to hear your comments at the recent Hearing Industries Association Annual Meeting in Phoenix, AZ. Your remarks were informative and insightful. It was a pleasure to have had the opportunity to participate in the discussion.

On behalf of the American Academy of Audiology nearly 11,000 members we represent, this letter is in response to the FDA guidance that you mentioned in your comments, issued on February 25, 2009, declaring that over the counter (OTC) devices advertised as "amplifiers" would not be subject to FDA regulation. The Academy believes that this absence of regulation could lead to unsafe, careless, and ill-advised use of such devices, which could result in a detriment to the consumer's overall hearing health. Consumer protection should require consistency with all types of amplification devices, regardless of their classification. Of vital concern are those consumers suffering from hearing loss associated with a medical problem, such as an acoustic neuroma, who may incorrectly and unknowingly believe this type of device will address their hearing concerns and thus further delay their diagnosis, placing them in potential peril.

These personal sound amplification devices are often utilized as a hearing aid substitute, especially for those experiencing mild hearing loss, regardless of the devices "not being intended to compensate for hearing impairment" (www.fda.gov/cdrh/ode/guidance/1696.html). Noise impact studies of several personal sound amplification products have been performed, confirming volume outputs that peak at louder sound pressure levels than what is considered acceptable noise levels per the Occupational

Safety and Health Act (OSHA). This will further damage hearing acuity to an unknowing user.

Other consumer concerns include the following:

- Consumer utilization of these non-regulated, over-the-counter devices may derail the recommended, direct avenue of securing an appropriate diagnosis and treatment specific to one's acoustic needs and requirements. Very often the consumer experiences failure with these unregulated devices, thereby paving the way to further delay of appropriate diagnosis and treatment.
- The frequency responses of these devices may not be what is required for the typical patient, therefore rendering the device useless, wasteful and again, potentially hazardous with incorrect usage
- Pediatric usage of over-the-counter devices could be harmful by incurring further hearing loss due to excessive sound levels. An article published in *Pediatrics*, the official journal of the American Academy of Pediatrics, researchers estimated that 12.5% of children aged 6 to 19, approximately 5.2 million children, suffer from noise-induced hearing loss.[1] Additionally, children and adolescents may not receive appropriate treatment for medically treatable hearing loss associated with otitis media and other conductive hearing loss.
- For those children who have existing hearing loss, these devices would not provide the appropriate levels of amplification where indicated, thereby impacting speech and language development. This critical period of development would be a lost opportunity, and could place these children at risk for encountering occupational and social obstacles as adults.

Thank you for the opportunity to comment on the Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products. We applaud the Agency's continuous efforts to protect the safety of the consumer and stand ready to work alongside your efforts. If you have any questions, do not hesitate to contact Debbie Abel, Au.D., Director of Reimbursement at 703.226.1024 or dabel@audiology.org.

Sincerely,

M. Patrick Feeney

M. Patrick Feeney, Ph.D.
President

References

1. Niskar, Amanda S., Stephanie M. Kiesak, Alice E. Holmes, Emilio Esteban, Carol Rubin and Debra J. Brody. 2001. Estimated prevalence of noise-induced hearing threshold shifts among children 6 to 19 years of age: The third National Health and Nutrition Examination Survey, 1998-1994, United States. *Pediatrics* 108: 40-43