AMERICAN ACADEMY OF AUDIOLOGY
11730 Plaza America Drive, Suite 300, Reston, VA 20190-4798 • 1-800-AAA-2336

September 7, 2012

Mr. Steven Silverman
Director of the Office of Compliance
FDA Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Silverman:

The American Academy of Audiology is the world's largest professional organization of, by, and for audiologists, representing over 11,000 members. The American Academy of Audiology (the "Academy") promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research.

As noted in our May 4, 2012 correspondence, the Academy commends the U.S. Food and Drug Administration (FDA) cease and desist proclamation with regard to the hi HealthInnovations online hearing test. The benefit, in its current state, poses health and efficacy concerns to consumers and we applaud the FDA's recognition of that fact. In the same vein, we would like to bring to your attention an online hearing test as well as a sound "therapy" application, which purports to restore hearing loss, available at www.thegoodear.com.

The downloadable 'Hearing Guardian,' available for free on the Good Ear website claims to allow users to test their hearing and identify "weak spots." Individuals can then "treat" their hearing loss through repeated sound "therapy" offered via the 'Hearing Guardian' or through a 'Threshold Sound Conditioning' hearing aid, which purports to reverse hearing loss. The Academy believes there are consumer safety concerns with this delivery model of purported hearing healthcare.

There is limited empirical evidence to suggest that the sound "therapy" offered through this application is in any way effective in the treatment of hearing loss. The evidence presented on the website appears to include internally conducted studies with no external, non-conflicted sites conducting randomized, blinded clinical trials. The 'guardian' program, available free of charge for a two week trial period, is a potential threat to consumer safety based on the inability to fully calibrate the earphones associated with the end-users' computer. The average user, in an unregulated environment, could be subjecting him or herself to more harm than good. Additionally, the confusing message regarding possible regeneration of hearing would likely

deter the individual from seeking and receiving the appropriate hearing health care from an audiologist.

With regard to the online hearing test offered through 'Hearing Guardian', the Academy asserts that this test is akin to the hi HealthInnovations online hearing test and therefore be subject to the same regulations and policy by which the FDA identified the hi HealthInnovations online hearing test a violation of the Federal Food, Drug and Cosmetic Act. While the Good Ear website references "patents pending in over 39 countries," there is no documentation of FDA approval.

The Academy strongly believes that the best model for hearing health care includes a comprehensive hearing evaluation by a licensed audiologist. This diagnostic evaluation may result in the recommendation of a hearing aid or other assistive listening device and will include performance of verification measures, rehabilitation and counseling as needed. Intervention by a highly qualified, licensed health care provider is not a part of the direct-to-consumer model that is marketed at www.thegoodear.com. This critical component is necessary to ensure the safety of the consumer as part of an audiologic evaluation and includes identifying FDA "red flags" which may indicate the presence of a physical condition that requires medical intervention and referral from the audiologist to a licensed physician. Through the www.thegoodear.com online hearing test, there are no safeguards in place to identify conditions which may require medical intervention such as cerumen impaction, acoustic/vestibular tumors, infection or cholesteatoma. As such, it is possible that an individual with one of the aforementioned conditions who does not obtain the necessary diagnostic evaluation could delay the identification of a medically-treatable condition that could worsen over time.

We appreciate the FDA's consideration on this important matter of unregulated testing and products to address hearing loss. This questionable technology and service delivery model raises patient safety concerns and may lead to risks associated with misdiagnosis and/or unnecessary use of amplification.

If you have any questions, or if there is any additional information we may provide, please contact Melissa Sinden, the Academy's Senior Director of Government Relations at msinden@audiology.org or by phone at (202) 544-9335.

Sincerely,

Deborah L. Carlson, PhD
President

Cc: Dr. Eric Mann
Mr. Ronald Swann