FDA REGULATION IS ESSENTIAL FOR OTC HEARING DEVICES WHICH SHOULD BE OFFERED ONLY TO PEOPLE WITH MILD HEARING LOSS

The Hearing Industries Association (HIA) supports efforts to increase the accessibility and affordability of hearing aids, especially given the overall importance of hearing health in relation to overall health. HIA believes that if FDA were to create an Over the Counter (OTC) hearing device category, such devices should be of high quality and should be offered only to people with Mild hearing loss. While those with Mild loss represent 2/3 of all Americans with hearing loss, only 12 percent use hearing aids now. It is HIA's position that the benefits of hearing aids for this group outweigh the risks created by inaccurate self-diagnosis and self-directed treatment. The legislation as introduced, however, would also offer hearing aids OTC for use by people with Moderate hearing loss. The risks of failure and further delay in treatment are significantly greater for individuals with Moderate hearing loss.

To increase the likelihood that OTC hearing devices would be safe and effective for people with Mild hearing loss, HIA believes that FDA should require that all OTC hearing devices meet the same safety and efficacy standards that FDA requires of air-conduction hearing aids fitted by hearing health professionals. This would include regulations that address safety and efficacy, marketing claims, labelling, and manufacturing controls. HIA also believes that 510(k) requirements should apply to the initial submission of a hearing aid. This review by the Agency is particularly important here since consumers will have no professional guidance to determine the cause or degree of hearing loss or how to effectively use and adjust the device. As with regular hearing aids, subsequent OTC hearing aids should be 510(k) exempt to speed innovation unless significant changes were made that would necessitate further FDA review.

Also, HIA believes it is crucial that FDA review and finalize its 2013 draft PSAP Guidance document to make clear that unregulated Personal Sound Amplification Products (PSAPs) cannot be marketed to address hearing loss. People with Mild hearing loss who seek a self-directed solution should instead be encouraged to purchase an OTC hearing device once cleared by FDA rather than an unregulated PSAP or other consumer product.

HIA remains concerned that existing OTC hearing aid markets in Japan and South Korea feature low consumer satisfaction and low hearing aid adoption rates. However, the marketing of devices that are specifically cleared by FDA for the OTC market and sold only to people with mild hearing loss would minimize the potential for a similar market failure in the U.S. If the quality of OTC hearing devices is ensured and the products are marketed only to people with Mild hearing loss, this may lead to consumers subsequently obtaining a hearing aid if their hearing loss progresses. Conversely, if the quality of OTC hearing products is not ensured, consumers may delay or abandon their effort to address hearing loss, putting them at increased risk of multiple serious medical conditions.