

January 18, 2022

Janet Woodcock, MD
Acting Commissioner
U.S. Food and Drug Administration

RE: Docket No. FDA-2021-N-0555
Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations

Dear Acting Commissioner Woodcock

The Gerontological Society of America (GSA) appreciates the opportunity to provide comments to the draft rule, ***Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations***. In 2017, GSA was pleased to support the [Over-the-Counter Hearing Aid Act of 2017](#), subsequently included in the FDA Reauthorization Act of 2017.

[GSA](#) is the oldest and largest interdisciplinary organization devoted to research, education, and practice in the field of aging. The mission of GSA is to cultivate excellence in interdisciplinary aging research to advance innovations in practice and policy. GSA's 5,400 members include gerontologists, health professionals, behavioral & social scientists, biologists, demographers, economists and many other disciplines. These experts study all facets of aging with a life-course orientation. The multidisciplinary nature of the GSA membership is a valued strength, enabling the Society to provide a 360-degree perspective on the issues facing our population as we age. GSA is advancing major initiatives related to improving adult immunization rates, earlier detection of cognitive impairment, improving oral, hearing, and vision health, framing our language to improve the public's understanding of aging, and understanding the impact of the longevity economy.

Among our many multidisciplinary interest groups, GSA is pleased that the [Sensory Health interest group](#) provides a forum to foster collaboration and dissemination of research and clinical/educational resources for professionals who are interested in sensory health, including vision, hearing, olfaction, taste, and proprioception, and the effects of sensory impairments on the overall health and well-being of older people. One of our conveners for this interest group is Frank Lin, MD, PhD, Professor of Otolaryngology, Medicine, Mental Health, Epidemiology and Director, Cochlear Center for Hearing and Public Health at Johns Hopkins University.

Improving accessibility and affordability of hearing aids aligns with GSA's vision of ***meaningful lives as we age*** in terms of increased quality of life, decreased falls and isolation, and ability to effectively interact with health care professionals, family, friends, and others during daily activities. Both the financial and human benefits of promoting better access to over-the-counter hearing aids have been clearly stated in the National Academies of Sciences, Engineering, and Medicine report ["Hearing Health Care for Adults: Priorities for Improving Access and Affordability"](#).

Importantly, the FDA's actions in developing this regulatory classification for OTC hearing aids also directly fulfills recommended actions issued as part of the updated [National Plan to Address Alzheimer's Disease](#)ⁱⁱ that was released on December 27, 2021 by the Office of the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services. These recommendations were developed in response to prior researchⁱⁱⁱ that implicated hearing loss as being the single largest potentially modifiable risk factor for dementia^{iv}. The actions in the updated 2021 National Plan to Address Alzheimer's Disease that specifically cite the imminent FDA issuance of regulations for OTC hearing aids are [Action 6.B.2 and Action 6.E.3](#) which call for, respectively, increasing access to and reducing financial barriers to hearing aids for individuals with hearing loss.

We offer the following specific input for your consideration:

Maximum Output

GSA supports the current proposed maximum output of 120 dB SPL with a volume control (or 115 dB SPL without volume control). We acknowledge that the topic of maximal permissible noise is a controversial topic as others have proposed lower overall maximum output limits with a 25 dB gain limitation. However, narrower restrictions would limit the effectiveness of OTC hearing aids, restrict the population of individuals with hearing loss who could benefit from OTC hearing aids, and substantively hinder technological innovation. A maximum permissible output of 120 dB SPL will allow OTC devices to work within a sufficient dynamic range for the signal outputs to maintain the integrity of the original amplified sound without forcing excessive compression and/or clipping of the signal which would introduce distortion and render listening more difficult. We agree with the FDA that this proposed output limit is strict enough that users have adequate time to remove the hearing aid before output levels become dangerous to the ear.

Minimum Technologic Specifications for OTC Hearing Aids

We applaud the inclusion of minimum technologic specifications (e.g., permissible internal noise levels, latency, harmonic distortion, frequency response range, and response smoothness). These criteria are aligned with ANSI/CTA-2051 "Personal Sound Amplification Performance Criteria." Importantly, these criteria are an appropriate deviation from the current ANSI standards for hearing aids which allow permissible deviations from self-stated criteria. Such a step ensures that FDA-approved OTC hearing aids would meet the minimum technologic criteria needed for hearing aid efficacy.

Clarification of OTC hearing aids as being self-fitting and role of the 510(k) pathway

Under the proposed regulations, it appears that OTC hearing aid controls could be applied to 510(k) exempt legacy hearing aids, 510(k) exempt wireless air-conduction hearing aids, or 510(k) non-exempt self-fitting air conduction hearing aids. This would raise the possibility that certain hearing aids (i.e., legacy or wireless air-conduction hearing aids that are not considered to be self-fitting) could be marketed as OTC while still being 510(k) exempt.

We urge the FDA to clarify that OTC hearing aid controls may only be applied to self-fitting hearing aids and hence subject to 510(k) review. As presently defined, a self-fitting hearing aid (§ 874.3325 (21 CFR 874.3325)) is "a hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings." Such a definition of a self-fitting hearing aid

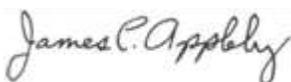
appears substantively similar to the attribute of an OTC hearing aid per the FDA Reauthorization Act (FDARA) which states that an OTC hearing aid is a device that “through tools, tests or software allows the user to control the OTC HA and customize it to the user’s hearing needs.” The present rule language in E.2.d. is also consistent with FDARA and states, “We are proposing to codify the requirement that an OTC hearing aid must include tools, tests, or software through which a lay user can control the device and customize it to the user’s hearing needs”.

Failure to clarify that OTC hearing aid controls can only be applied to self-fitting hearing aids (and hence subject to 510(k) review) raises the risk that companies may choose to market OTC hearing aids that are **not** explicitly self-fitting to avoid the review required by the 510(k) process. In a nascent OTC hearing aid market, companies may be particularly incentivized to pursue this route to bring their hearing aids more quickly to market. Such actions could, therefore, potentially lead to many of the early OTC hearing aids on the market being ineffective and sow consumer distrust and skepticism of this class of devices.

For the present time, we agree with the FDA that self-fitting OTC hearing aids should be subject to 510(k) review to ensure the safety and efficacy of early OTC hearing aids reaching the market. However, in order to not hinder innovation or unnecessarily delay companies from being able to bring an OTC hearing aid to market, we strongly recommend that: 1) the FDA provide clear guidance on the specific data and information needed for 510(k) review in order to streamline the process for companies trying to bring devices quickly to market; and 2) the FDA evaluate an exemption for OTC self-fitting hearing aids from the 510(k) pathway no later than two years after enactment of these regulations and when sufficient experience will have accrued to evaluate this potential exemption.

We appreciate your consideration of these comments. We look forward to continuing to work with FDA on these and other related issues. If we can be of any further assistance please contact Patricia M. D’Antonio, BSPHarm, MS, MBA, CGP, Vice President, Policy and Professional Affairs at 202-587-5880 or by email at pdantonio@geron.org.

Sincerely,



James C. Appleby, BSPHarm, MPH, ScD (Hon)
Chief Executive Officer

ⁱ <https://www.nationalacademies.org/our-work/accessible-and-affordable-hearing-health-care-for-adults>

ⁱⁱ <https://aspe.hhs.gov/reports/national-plan-2021-update>

ⁱⁱⁱ Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing loss and incident dementia. Arch Neurol. 2011 Feb;68(2):214-20. Deal JA, Betz J, Yaffe K, Harris T, Purchase-Helzner E, Satterfield S, Pratt S, Govil N, Simonsick EM, Lin FR. Hearing Impairment and Incident Dementia and Cognitive Decline in Older Adults: The Health ABC Study. J Gerontol A Biol Sci Med Sci. 2017 May 1;72(5):703-709.

^{iv} Livingston G, Huntley J, Sommerlad A, et al. Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. Lancet. 2020 Aug 8;396(10248):413-446