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Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Docket No. FDA-2021-M-0555, RIN 0910-AI21
Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Acting Director Woodcock:

The American Geriatrics Society (“AGS”) appreciates the opportunity to comment on the proposed rule issued by the Food and Drug Administration (“FDA”) to establish over-the-counter hearing aids. Founded in 1942, AGS is a nationwide, not-for-profit society of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of older people. Our nearly 6,000 members include geriatricians, geriatric nurses, social workers, family practitioners, physician assistants, pharmacists, and internists. The AGS believes in a just society, one where we all are supported by and able to contribute to communities where ageism, ableism, classism, homophobia, racism, sexism, xenophobia, and other forms of bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their caregivers. The AGS provides leadership to healthcare professionals, policymakers, and the public by implementing and advocating for programs in clinical care, research, professional and public education, and public policy.

The AGS is supportive of this FDA Proposed Rule and we are confident that the proposed changes are necessary to reduce barriers to access appropriate treatment for the millions of Americans who are adversely affected by hearing loss. Hearing impairment is both common and serious among older adults, in that it impairs fundamental activities of communication and socialization and has been linked to additional serious problems such as cognitive decline, falls, and disability.¹ Despite the serious consequences of untreated hearing loss and the potential benefit of hearing aids, only about 1 in 5 people who could benefit from hearing aids use them.² While barriers to hearing aid use are likely multifactorial, we believe that this change of rule by the FDA is a necessary step in the right direction for reducing some barriers.

¹ Deal JA, Reed NS, Kravetz AD, et al. Incident Hearing Loss and Comorbidity A Longitudinal Administrative Claims Study. *JAMA Otolaryngol Head Neck Surg.* 2019;145(1):36-43. <https://doi.org/10.1001/jamaoto.2018.2876>.

² Chien W, Lin FR. Prevalence of Hearing Aid Use Among Older Adults in the United States. *Arch Intern Med.* 2012;172(3):292-293. <https://doi.org/10.1001/archinternmed.2011.1408>.

Overall, we strongly support the proposed changes and believe that the FDA has set appropriate safety limits (i.e., maximal volume output) while not directly limiting the gain which would reduce the functionality of these devices for those with moderate levels of hearing loss. The focus of our comments below relates to the package labeling requirements providing information to persons planning to buy/use the OTC hearing aids.

The FDA has proposed that information be included inside the device packaging, in an insert, that customers will need after purchase for safe and effective use of the device. This includes a warning regarding “red flag” medical conditions to prompt consumers to consult with a licensed physician and note about how to report adverse events to FDA. We suggest the Final Rule include other health care practitioners (including nurse practitioners and physician assistants) from which a consumer may get an evaluation if the person does have any of the “red flag” conditions. This is in part due to persons living in rural settings who may not have reasonable access (i.e., live within a reasonable proximity) to a full range of practitioners and may not have access to hearing health care specialists.^{3,4} We also strongly recommend that the “red flag” warnings be included on the outside packaging to ensure that consumers are fully informed of whether the product is appropriate for them, in addition to the insert inside the packaging. Currently, it is only required for inside.

Since the patient in most instances will not be seeing a provider prior to the purchase of an over-the-counter hearing aid, the AGS also recommends that all the information provided by the FDA is clear, easy to read, and easy to see. We believe it would be valuable to at least indicate that the material needs to be designed to maximize font size and readability given the target population. Alternatively, consideration could be given to providing a sign next to the product inside the store that includes the requisite information but in a font size that is readable by persons whose vision may be somewhat limited. Then the size of the text on the packaging or the insert will be less critical.

In addition to considering text size, we would also recommend that the information included on the package and in the insert be written in language consistent with a sixth-grade reading level. Studies have shown that hearing aid manufacturers do a poor job of ensuring critical product information is comprehensible to the average consumer,^{5,6,7,8} so if the FDA is looking to increase access, it would benefit consumers for the FDA to address health literacy and vision issues in the Final Rule.

Finally, we note that the warnings to persons under 18 also was not consistent across the Proposed Rule. Accordingly, we urge the FDA to make this language consistent in the Final Rule. In particular, we think it is important that the FDA use language that does not confer a negative

³ Powell W, Jacobs JA, Noble W, Bush ML, Snell-Rood C. Rural Adult Perspectives on Impact of Hearing Loss and Barriers to Care. *J Community Health*. 2019;44:668-674. <https://doi.org/10.1007/s10900-019-00656-3>.

⁴ Chan S, Hixon B, Adkins M. Rurality and Determinants of Hearing Healthcare in Adult Hearing Aid Recipients. *Laryngoscope*. 2017;127(10):2362-2367. <https://doi.org/10.1002/lary.26490>.

⁵ Brooke RE, Isherwood S, Herbert NC, Raynor DK, Knapp P. Hearing Aid Instruction Booklets: Employing Usability Testing to Determine Effectiveness. *Am J Audiol*. 2012;21:205-214. [https://doi.org/10.1044/1059-0889\(2012\)12-0008](https://doi.org/10.1044/1059-0889(2012)12-0008).

⁶ Caposecco A, Hickson L, Meyer C. Hearing Aid User Guides: Suitability for Older Adults. *Int J of Audiol*. 2014;53(S1):S43-S51. <https://doi.org/10.3109/14992027.2013.832417>.

⁷ Caposecco A, Hickson L, Meyer C, Khan A. Evaluation of a Modified User Guide for Hearing Aid Management. *Ear & Hearing*. 2015;37(1):27-37. <https://doi.org/10.1097/AUD.0000000000000221>.

⁸ Joseph J, Svider PF, Shaigany K, et al. Hearing Aid Patient Education Materials: Is There Room for Improvement? *J Am Acad Audiol*. 2016;27(4):354-359. <https://doi.org/10.3766/jaaa.15066>.

connotation with hearing loss, nor imply that hearing aid users under the age of 18 have a “condition.” We believe it is critically important that the rule not deter younger persons with hearing loss from seeking out a healthcare provider for further information. Across the rule, FDA should use language that reduces the concerns that people with hearing loss may have about the stigma associated with hearing loss and/or the visibility of hearing aids.⁹

Thank you for taking the time to review our feedback and recommendations. Should you have any follow-up questions, please contact Alanna Goldstein at agoldstein@americangeriatrics.org.

Sincerely,



Peter Hollmann, MD
President



Nancy E. Lundebjerg, MPA
Chief Executive Officer

⁹ Rawool V. Denial by Patients of Hearing Loss and Their Rejection of Hearing Health Care: A Review. *J Hear Sci.* 2018;8(3):9-23. <https://doi.org/10.17430/906204>.