



Date: 12/21/2021

To: FDA Commissioner  
Re: FDA Docket No. FDA-2021-N-0555

The Montgomery County Commission on Aging is submitting comments on the proposed rules for Establishing Over-the-Counter (OTC) Hearing Aids published in the *Federal Register* on October 20, 2021.

The Montgomery County Commission on Aging, COA, is authorized by the Older Americans Act, P.L. 116-131. The Commission on Aging was established in 1974 to advise County government on the needs, interests, and issues of older adult residents, and to advocate on their behalf at the local, state and national levels. Our work is ever more significant as our older adult population continues to grow and to become more diverse. A primary area of our concern is the protection and support for vulnerable and isolated older adults.

Forty-eight million Americans suffer from some degree of hearing loss - over 15% of the population. That number rises to 33% in older adults between ages 65 and 74. In Montgomery County, that could mean over 50,000 older adults suffer with some hearing impairment. Hearing loss can be associated with many health problems, including dementia and social isolation, currently on the rise due to the COVID pandemic. People wait an average of seven years before seeking help. According to one source, more than 38 percent of older adults with hearing loss who don't use hearing aids labeled cost as the biggest reason for avoiding the devices, <https://www.seniorliving.org/hearing/hearing-aid-study/>. Only 1 in 5 people who could benefit from a hearing aid device actually use one. Over the Counter (OTC) hearing devices would enable Marylanders to purchase needed hearing aid support that is otherwise unaffordable.

While we urge the FDA to issue these regulations as soon as possible to allow manufacturers and distributors to move forward with production and distribution, we also urge the FDA to revise the proposed rules to impose safe and effective output and gain thresholds for individuals, especially older adults with mild-to-moderate hearing loss. We support the consensus recommendations published in August 2018 by four leading professional hearing care professionals.

The COA is concerned that the proposed amplification standards outlined are the same as those used in consumer electronics. The rule states that under its current standards, an individual could experience damage to their hearing after thirty seconds of use. This could prove to be dangerous especially for those with diminished cognitive abilities or slower reaction times. Please revise

**Department of Health and Human Services**

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this ruling to impose safe and effective output and gain thresholds for individuals with mild-to-moderate hearing loss.

Hearing aids should be more widely available, much more affordable and easier to use for the average consumer so that they can maintain a high quality of life in their own home and community as they age.

Reference: *Regulator Recommendations for OTC Hearing Aids: Safety and Effectiveness, Consensus Paper from Hearing Care Associations* (August 2018)

Sincerely,

*Barbara Selter* sb

Barbara Selter, Chair  
Montgomery County, Maryland  
Commission on Aging