



March 9, 2022

The Honorable Robert M. Califf
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

We, the undersigned, applaud the Food and Drug Administration for its efforts to provide more affordable and accessible hearing aids by establishing a new category of hearing aids that will soon be available over the counter to adult consumers with mild to moderate hearing loss. We appreciate the consideration FDA is giving to the perspectives of organizations like ours who submitted comments to the agency as part of the recently closed public comment period. The FDA's creation of OTC hearing aids has generated tremendous interest from many stakeholders, particularly among organizations that care greatly about the safety and well-being of consumers and patients. We thank you in advance for understanding and weighing these viewpoints when developing the final OTC hearing aid rule.

It is impossible to overstate how important the details of this rule will be to the potentially millions of consumers who will buy OTC hearing aids. Once they are able to do so, these consumers will largely purchase these devices without first seeing a medical professional or undergoing any kind of hearing loss assessment. As a result, we believe many consumers will use these devices without knowing whether their medical condition warrants doing so. For these reasons, we call on the FDA to ensure adequate safety measures are in place to protect the millions of Americans who will soon be using OTC hearing aids. We do not believe this is currently the case.

To ensure the safety of consumers, we believe the FDA should implement the recommendations of the nation's leading associations of hearing care professionals, including the American Academy of Otolaryngology–Head and Neck Surgery, American Academy of Audiology, American Speech-Language-Hearing Association, and International Hearing Society. These associations are urging the FDA to lower the maximum sound output to 110 decibels and establish an amplification (or gain) limit of 25 decibels. These associations, as well as respected entities like the World Health Organization and the Centers for Disease Control and Prevention, have made clear that allowing sounds to enter the ears of consumers at the proposed levels can cause serious and permanent hearing damage within mere seconds.

We believe many consumers will be at an increased risk of suffering increased hearing loss simply by using these devices without the inclusion of these recommendations in the final rule. The FDA should not ignore the fact that many consumers who turn to OTC hearing aids for help may also be suffering from other medical conditions that reduce their ability to recognize or react to excessively loud, damaging sounds. This makes these recommendations even more critical. Importantly, the adoption of these recommendations will not compromise efficacy or prevent manufacturers from offering innovative OTC hearing aids. Instead, they will ensure these devices are safe.

Again, we thank the FDA for its continued vigilance in protecting patients and consumers. By including these recommendations in the final rule, we are confident that the FDA will accomplish its goal of increasing access to more affordable hearing aids that are safe and effective for the consumers that use them.

Sincerely,

National Consumers League
Aimed Alliance
Alliance for Aging Research
American Stroke Foundation
Caregiver Action Network
Center for U.S. Policy
Chicago Hispanic Health Coalition
Coalition of Wisconsin Aging and Health Groups
Combined Health Agencies Drive
Consumers for Quality Care
Direction Home Akron Canton Area Agency on Aging & Disabilities
Easterseals Central and Southeast Ohio
Fairhill Partners
HealthyWomen
Hearing Speech + Deaf Center
Minnesota Independent Physicians Association
Minnesota Rural Health Association
NAMI Kansas
National Association of Nutrition and Aging Services Programs (NANASP)
National Consumers League
National Grange
NeedyMeds
Ohio Academy of Family Physicians
Ohio Medical Group Management Association
Ohio Osteopathic Association
Ohio Speech and Hearing Governmental Affairs Coalition
Prevent Blindness Iowa
Prevent Blindness Wisconsin
RetireSafe
Suicide Awareness Voices of Education
Village to Village Network