



January 18th, 2022

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

RE: Docket No. FDA-2021-M-0555, RIN 0910-AI21

Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Dr. Woodcock:

As the largest seller of Direct to Consumer hearing aids over the last 10 years, MDHearingAid appreciates the opportunity to comment on the draft rule, *Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter (OTC) Hearing Aids*.

We have sold high-quality, affordable hearing aids to over 500,000 customers since our founding more than decade ago. As opposed to the ~\$4,600 average pair of hearing aids a typical consumer pays buying hearing aids from a clinic, we charge an average of \$500 per pair. We pair our low prices with a full staff of licensed Audiologists and Hearing Aid Specialists so our customers can enjoy both low prices and care from licensed medical professionals.

Although we believe that consumers deserve affordable prices, we also strongly advocate that consumer safety and health remains paramount. In that spirit, we strongly agree with the feedback presented by Professor Frank R. Lin, M.D. Ph.D. of Johns Hopkins University. Specifically, we agree with Johns Hopkins' recommendations of:

- A maximum permissible output of 120 dB SPL
- that the FDA clarify that OTC hearing aid controls may only be applied to self-fitting hearing aids and hence subject to 510(k) review

In addition, we urge the FDA to consider further requirements to safeguard consumer health. Unfortunately, unscrupulous sellers fill the Direct to Consumer market today. The sellers do not offer any reasonable support, much less support from licensed hearing professionals. They do not test their products to ensure safety. Some outsource their support to untrained foreign call centers and put roadblock after roadblock in the way of customers returning their aids, racking up thousands of consumer complaints. Since our founding we have always employed licensed medical professionals and have tested every single batch of hearing aids for quality.

Specifically, we offer the following input for your consideration to maximize consumer health:



- Specify a minimum return policy at the national level instead of leaving it to state regulations. If left to the states, this will create an opening for unscrupulous sellers to game the system.
- Require every seller of OTC hearing aids staff customer support in the US with the ability for customers to meet with a licensed hearing professional via telemedicine technology
- Require serial number tracking of every device shipped in case a device recall is needed
- Require the frequency response and ANSI specifications of the aids to be included in the user manual
- Require that every seller of OTC hearing aids demonstrate relevant ISO certification and comply with appropriate FDA quality systems
- Define a national standard to sell Prescription hearing aids via telemedicine to adult patients over 18 who suffer from age-related hearing loss, as long as those patients do not have other medical issues that affect their hearing. We recommend calibrated, in-home air conduction and bone conduction tests, and video telemedicine appointments with licensed hearing professionals to achieve this goal.

In conclusion, we applaud the FDA for recognizing the need for more affordable hearing healthcare. MDHearingAid has led this charge for over a decade, serving over a half a million customers., giving us a unique perspective on offering affordability while ensuring consumer safety. We encourage the FDA to consider the recommendations from Johns Hopkins, and our additional input regarding consumer safety.

Sincerely,

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