



December 22, 2020

Stephen Hahn, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

Hearing loss among Americans continues to be a debilitating issue. It is estimated that 25 percent of those aged 65 to 74 and 50 percent of those who are 75 and older have disabling hearing loss¹. The National Institute on Deafness and Other Communication Disorders, National Institutes of Health estimates that 28.8 million Americans could benefit from the use of a hearing aid². Unfortunately, hearing aids are not covered through Medicare leading many Americans to go without appropriate treatment.

The Hearing Loss Association of America (HLAA), founded in 1979, provides information, education, advocacy and support to people with hearing loss and those impacted by hearing loss. The number one complaint we receive – literally, at least once a day – is the cost of traditional hearing aid. People who live on a fixed income simply do not have the resources needed to purchase a set of hearing aids with an average cost of \$4,000 a pair. They need to have alternatives available or the isolation they are experiencing as a result of the COVID-19 pandemic will be amplified by the isolation as a result of their inability to hear.

In 2017 President Trump signed into law the Over the Counter (OTC) Hearing Aid Act. This legislation allowed the Food and Drug Administration (FDA) to categorize certain hearing aids for adults with mild to moderate hearing loss as over the counter and issue regulatory guidance for this new category of OTC devices to ensure they meet the same standards of safety and labeling as other FDA regulated devices.

In October of 2018, the FDA announced these rules would be a priority on their Fall 2018 Unified Agenda and would be able to deliver the proposed rules well in advance of the August 2020 statutory deadline. It is now December of 2020 and the FDA has yet to deliver on its promises.

¹ <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing#:~:text=Nearly%2025%20percent%20of%20those,older%20have%20disabling%20hearing%20loss.&text=Roughly%2010%20percent%20of%20the,minutes%20in%20the%20past%20year.>

² <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing#:~:text=Nearly%2025%20percent%20of%20those,older%20have%20disabling%20hearing%20loss.&text=Roughly%2010%20percent%20of%20the,minutes%20in%20the%20past%20year.>



During this period of FDA inactivity, bad actors have stepped in and begun to advertise OTC hearing aids on television and on the internet³. These bad actors claim to be “FDA cleared or FDA Registered” which is a term that may be misconstrued by the general public as “FDA approved”. FDA registration is an administrative designation and is required of any owner or operator of a facility involved in the production or distribution of medical devices intended for use in the United States. The FDA website itself states that “registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA⁴.”

False and misleading advertising claims might lead some to purchase these personal sound amplification products (PSAP) over traditional hearing aids. PSAPs are not interchangeable with hearing aids, are not intended to compensate for or treat hearing loss, and do not provide the sound filtering that an FDA-approved hearing aid does⁵. PSAPs are also considered “direct to consumer” (DTC) and therefore are not regulated by the FDA⁶.

Hearing Loss Association of America urges the FDA to issue its rules on OTC hearing aids devices.

We thank you for your swift attention to these pressing matters.

Sincerely,

A handwritten signature in black ink that reads "Barbara Kelley". The signature is written in a cursive style with a long horizontal flourish at the end.

Barbara Kelley
Executive Director

³ <https://audienhearing.com/>

⁴ <https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing#:~:text=FDA%20does%20not%20issue%20Registration,a%20firm%20or%20their%20devices.>

⁵ <https://www.consumer.ftc.gov/blog/2018/05/ftc-sound-amplifier-not-hearing-aid>

⁶ <https://www.hearingreview.com/hearing-loss/patient-care/hearing-fittings/service-delivery-considerations-of-direct-to-consumer-devices-in-the-new-age-of-rehabilitative-hearing-healthcare#:~:text=While%20PSAPs%20are%20ear%2Dlevel,for%20individuals%20with%20impaired%20hearing.>