



AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

September 14, 2018

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

On behalf of the American Speech-Language-Hearing Association, I write to submit the following recommendations to the U.S. Food and Drug Administration (FDA) as the agency develops its proposed rule to implement Section 613 of the FDA Reauthorization Act of 2017 (P.L. 115-52).

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific and credentialing association for 198,000 members and affiliates who are audiologists; speech-language pathologists; speech language and hearing scientists; audiology and speech-language pathology support personnel; and students.

Section 613 of P.L. 115-52 requires the FDA to regulate so-called over-the-counter (OTC) hearing aids. Hearing loss is a complex chronic health condition that is best treated in collaboration with an audiologist. ASHA supports consumer choice and access to technologies that can enhance a consumer's ability to hear. However, regulations for OTC hearing aids must be written to ensure that appropriate safeguards are in place to protect consumers from issues that may occur when self-diagnosing or self-treating hearing loss.

Labeling

The law explicitly requires appropriate labeling for OTC hearing aids as follows: include requirements for appropriate labeling of OTC hearing aids including requirements that such labeling include a conspicuous statement that the device is only intended for adults age 18 and older; information on how consumers may report adverse events; information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss; and advisements to consult promptly with a licensed health care practitioner.

ASHA recommends the following labeling on the outside of box:

This device is intended for use only by adults (minimum age 18) with mild-to-moderate hearing loss, who have difficulties hearing conversational speech. This device is not intended for use by children. Benefits from this device may vary from individual to individual. If you have questions, concerns, or need further assistance with regard to your ability to hear, it is recommended that you consult with an audiologist before purchasing this device.

Additionally, **ASHA strongly recommends that consumers be reminded that hearing loss is a medical condition and recommends the following also be included on the outside of the box:**

Important notice for prospective users. *Hearing loss is a medical condition best addressed in consultation with an audiologist. If you experience any of the following conditions, do not purchase this product and consult a hearing health care professional before proceeding:*

- *Visible deformities of the ears since birth or from injury*
- *Fluid, pus, or blood coming out of the ear within the previous three months*
- *Sudden, quickly worsening, or fluctuation hearing loss within the previous three months*
- *Dizziness or periodic vertigo associated with hearing loss*
- *Hearing loss in only one ear or a large difference in hearing or feeling that something is in the ear canal*
- *Pain or discomfort in the ear*
- *Ear wax build up*
- *Tinnitus or ringing in one of both of your ears*

Protecting Children From Use Of Devices

As indicated by the statute, it is imperative that the FDA protect children with hearing loss. Pediatric hearing loss is not the same as adult hearing loss and may represent other medical conditions not related to the ear that require specialized treatment. Children who are treated with OTC hearing aids without involving an audiologist may be at risk for complications due to untreated ear disease or inadequate amplification, which could lead to severe, permanent, disabling language development, and additional hearing loss. ASHA acknowledges that the law only covers adults over the age of 18, but ASHA remains concerned that parents may consider purchasing OTC hearing aids because they may be less expensive than hearing aids dispensed through an audiologist or other hearing health care professional.

ASHA recommends that the following be included as part of the instructions/inside labeling:

Warning! *Hearing loss in children is not the same as hearing loss in adults and may present other non-ear related conditions that require specialized treatment. Over-the-counter hearing aids are not intended for use by children with hearing loss. Children treated with these devices are at risk for severe complications due to untreated ear disease and/or inadequate amplification. This could lead to severe, permanent, and disabling speech, language, auditory impairment, and auditory development as well as additional hearing loss due to inappropriate levels of amplification.*

Ensure Consumer Safety

ASHA maintains that consumers should not diagnose their own hearing loss. Consumers can “screen” their hearing with online do-it-yourself hearing tests, but this should not be confused with a comprehensive audiologic evaluation. The purpose of an audiologic evaluation is to determine:

- onset and time course of the hearing loss;
- degree, type, and configuration of the hearing loss;

- possible etiology of hearing loss;
- functional limitations imposed by the loss, particularly in regards to communication; and
- need for additional medical or audiological services, including the development of a treatment plan.

Current internet-based hearing screening tools may not be capable of providing an accurate diagnosis due to coupling/receiver issues on the consumer side, the inability to standardize ambient noise at the test site, the lack of bone conduction testing, and the inability to self-perform an otoscopic exam. Online hearing tests may give a consumer some estimate of hearing threshold information, but the usefulness of the information is limited because there is no explanation of what it means for function and environmental interaction perspectives. In addition, an online hearing test cannot establish the degree of functional limitations, which is often the basis for determining the need for amplification.

Given that consumers may purchase OTC hearing aids with neither a hearing screening nor an audiologic evaluation, **ASHA recommends the FDA consider the following safety precautions:**

Maximum Output Limitations

Due to potential inaccuracies associated with hearing screenings, the implications of possible over amplification need to be considered when developing regulations. **ASHA recommends that the peak output levels for OTC hearing aids should be no greater than 110 dB SPL.**

Additionally, as part of the in-box labeling, **ASHA recommends the following warnings:**

***Important notice to user:** Special care should be exercised in the use of this device. You should not use your hearing device for more than 12 hours a day nor should you use your device if the device exceeds your comfort level. If set to the maximum output level and worn for periods of time exceeding these recommendations, there may be risk of damaging the remaining hearing of the device user.*

Professional Involvement

While ASHA understands the intent of the law is to make OTC hearing aids available absent professional involvement, ASHA maintains that consumers need to understand that hearing health care is more than a hearing aid and that their hearing health care needs may not be met by OTC amplification devices, and may require consultation with an audiologist.

In order to educate consumers on when they should seek professional involvement, **ASHA recommends the following language be included in the in-box labeling:**

***Important notice about lack of benefit:** Lack of benefit with this device could indicate a more severe or complex type of hearing loss exists, requiring the assistance of an audiologist. Seek professional assistance if after use of this product you note any of the following:*

- *No or little improvement in listening in conversation settings*
- *No improvement in hearing speech in noisy environments*
- *Speech is still unclear*

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- *Poor sound quality*
- *All sounds are too loud*
- *Loud noises are uncomfortable*
- *Notice of or increased ringing in the ear*

Stop use of this product and consult with a medical professional if you experience any of the following conditions:

- *Fluid, pus, or blood coming out of the ear within the previous three months*
- *Sudden, quickly worsening, or fluctuation hearing loss within the previous three months*
- *Dizziness or periodic vertigo associated with hearing loss*
- *Ear wax build up or feeling that something is in the ear canal*
- *Pain or discomfort in the ear*

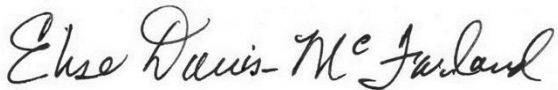
Consumer Protection Laws

The statute preempts state laws that would restrict or interfere with the serving, marketing, sale, dispensing use, customer support, and distribution of these devices. This would exempt OTC hearing aids from current state laws that address consumer protections as well as return and refund policies. ASHA is concerned that this preemption leaves the consumer with no recourse should they have any adverse effects from the product or if it is of poor quality. Therefore, **ASHA recommends that the FDA, in coordination with the Federal Trade Commission, establish strong consumer protection regulations to address such issues as return policies, false claims, and means by which consumers can lodge complaints.** Such processes should be fully funded to ensure appropriate enforcement.

Conclusion

ASHA is committed to working with you and your colleagues to develop regulations for OTC hearing aids that will ensure consumer safety. If you or your staff have any questions, please contact Ingrida Lusic, ASHA's director of federal and political affairs, at ilusic@asha.org.

Sincerely,



Elise Davis-McFarland, PhD, CCC-SLP
2018 ASHA President