Promoting policies to provide consumers with accessible solutions for safe and effective hearing care

www.hearabouthearing.org
In August 2017 Congress passed the Over-The-Counter Hearing Aid Act, mandating the FDA to create a new category of OTC hearing aids.

The FDA will decide over the coming months how these devices are regulated and marketed to consumers. NOW IS THE TIME to get engaged and express your views and opinions to ensure safety and effectiveness.

The major hearing healthcare professional associations in the U.S. are submitting evidence-based recommendations to help ensure safety and effectiveness within this new medical device category, while ensuring accessibility and affordability for millions of Americans with hearing healthcare needs. A working group was formed that includes the American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language and Hearing Association (ASHA), and the International Hearing Society (IHS).

In a jointly authored “Consensus Paper” released in August 2018, the working group offered input and recommendations to the FDA based on substantial data and scientific evidence, along with suggestions on how to incorporate these recommendations into the rule.

RECOMMENDATIONS TO THE FDA

Following are recommendations to the FDA for consideration in the rulemaking process and in alignment with the Congressional mandate for regulating OTC hearing devices, to ensure safe and effective consumer use of these products:

RECOMMENDATION 1:
Product Requirements

The FDA should establish product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment. Specifically, the FDA should carefully consider the following critical issues for all OTC products:

Audiometric Definition

As these devices are to be distributed over the counter without supervision of or evaluation by a licensed professional, the FDA should take steps to ensure that the product specifications are based on an audiometric definition of hearing loss. The product requirements for a mild-to-moderate hearing impairment should consider a set of amplification characteristics that fit a range of hearing loss from 26 to 55 dB HL (over a 30 dB range), a variety of possible hearing loss configurations (flat, sloping, reverse, notch), and a range of user characteristics (experienced and new wearers, sound tolerance issues).

Self-Assessment

Studies show that only one half to two-thirds of individuals can correctly classify their level of hearing loss, and self-perception of hearing difficulty may not be accurate. The FDA needs to account for
the implications of self-assessment by two groups: Intended users over 18 years old who correctly report mild to moderate hearing loss of 26-55 dB HL; and unintended but foreseeable users who may perceive they have a mild to moderate hearing loss, but actually have normal hearing or more severe hearing loss.

**Gain Limit**

The FDA must address how to define the “gain requirements” needed to maximize conversational speech and ensure adequate audibility for the broadest range of individuals in the “mild-to-moderate” spectrum. The FDA should establish a HFA full on gain limit of 25 dB, as measured in a 2cc coupler with an input level of 30 dB SPL. It is also recommended that all OTC devices use a signal processing scheme that reduces gain as input level increases.

**Amplification**

Any sound exposure that can cause deterioration of hearing for individuals with normal hearing can cause additional hearing loss for people with a hearing impairment, and FDA must consider the safety and efficacy implications of possible over-amplification. It is recommended that FDA set the peak 2 cc coupler OSPL90 not be greater than 110 dB SPL.

**Compression**

FDA should establish product specifications that include, as the minimum standard, input compression and a volume control and maximum output limit. A compression strategy is key to achieving the goals of ensuring protection from (further) damages, delivering comfortable listening, and maximizing speech intelligibility.

**RECOMMENDATION 2: Outside-the-box Labeling**

FDA should require concise, outside-of-the-box labeling that is appropriate for medical devices sold over-the-counter. This should include recognition of intended use/usage and an important notice for the prospective users about hearing loss being a medical condition best addressed in consultation with a licensed hearing healthcare professional.

Since these devices will be available to consumers without professional assistance, proper labeling is essential to ensure safe and effective use for this new category of hearing devices. Exterior package labeling needs to empower potential users to make informed choices about whether these devices are the right hearing care option for them based on their intended use and the benefits and risks.

**RECOMMENDATION 3: Inside-the-box Labeling**

FDA should define comprehensive, inside-the-box labeling that should include a User Instructional Manual with directions for the consumer on its safe and effective use, and which explains how to identify whether the device is delivering benefits, and what to do if the device is not performing as expected.

The information on the inside labeling should provide the user of the device information relating to the device’s operation, care and maintenance, information concerning potential problems that the
user may encounter with the device, and guidance on what to do if the device is not performing as expected. These instructions should include a strong warning that the devices are not intended for children under the age of 18.

RECOMMENDATION 4: Category Classification

FDA should define the category for the new OTC class of devices so consumers can easily comprehend how these devices compare with traditional hearing aids and personal sound amplification products (PSAPs).

The new category should be called “Self-Fit Over-the-Counter Hearing Devices” to clearly distinguish this category from traditional hearing aids that are fit by health professionals, and from PSAPs, so that consumers can make informed decisions. The FDA should reinforce that these devices are classified as “medical devices” regulated by the FDA, are differentiated from “consumer electronic devices,” and are different from traditional hearing aids that require diagnosis by a health professional, proper fitting and adjustment, and follow up care.

The new device category should maintain the same risk classification as air conduction hearing aids. In addition, it is strongly recommended that the first OTC device marketed by each manufacturer undergoes a 510(k) authorization process.

RECOMMENDATION 5: Consumer Protection

FDA, in coordination with the FTC, should establish strong consumer protection laws and put in place adequate processes and resources to enforce them, especially in the first years of introduction of the new category.

Consumer protection for prospective hearing aid users should continue to be a primary concern of the FDA. Return and refund policies should also be defined for this new category; it is recommended that specific attention be called to claims for this new category. Additionally, FDA and FTC should establish a process to ensure that all claims are substantiated by data, scientific evidence and/or clinical studies.
WHAT YOU CAN DO

Politics, and helping shape good policy, is all about relationships. Elected officials get their information from many sources. Some of the most important sources are constituents they know and trust.

THAT’S WHERE YOU COME IN. JOIN HEAR ABOUT HEARING TODAY!

At www.hearabouthearing.org, you can learn about your elected officials, and you’ll be able to take direct action by sending your letters supporting hearing healthcare to your senators and congressperson.

- Learn about where the medical professionals stand on over-the-counter hearing aids by reading the industry consensus paper, available at www.hearabouthearing.org.
- Learn about the issues. Read the dedicated section on Hear About Hearing and learn the suggested solution.
- Learn about your elected officials. Visit their websites, learn what issues they focus on and are responsible for, ask us for help if you need it.

GET INVOLVED. TAKE ACTION.

- Go to www.hearabouthearing.org and sign up to become a member of HAH. There’s no obligation and, of course, it’s totally free.
- Learn about Hear About Hearing’s Take Action platform on www.hearabouthearing.org. It allows you to easily send emails to your elected officials based on where you live and vote.
- Look for email alerts from Hear About Hearing. We’ll send you emails when important issues are “working”, asking for your help.
- FOLLOW THROUGH WHEN YOU GET AN ALERT.