In the News

FDA Finalizes Rule to Allow Over-the-Counter Hearing Aids
Joan Stephenson, PhD

US adults with hearing loss will soon have access to over-the-counter hearing aids under a final rule issued by the US Food and Drug Administration (FDA) earlier this month. These devices, which will be substantially more affordable than prescription hearing aids that routinely cost thousands of dollars, might be available as early as mid-October for purchase online and in settings such as big-box stores and pharmacies.

The FDA's long-awaited action—5 years after the US Congress passed bipartisan legislation requiring the FDA to create a category of over-the-counter (OTC) hearing aids—establishes a new category of OTC hearing devices. The agency finalized the rule after reviewing more than 1000 public comments on an earlier draft of the rule.

The new rule will enable consumers aged 18 years or older with perceived mild to moderate hearing loss "to purchase hearing aids directly from stores or online retailers without the need for a medical exam, prescription, or a fitting adjustment by an audiologist," the FDA said in a statement. "The rule is designed to provide a reasonable assurance of safety and effectiveness of OTC hearing aids, while fostering innovation and competition in the hearing aid technology marketplace."

For these reasons, the FDA's final rule on the device "marks a major milestone in advancing hearing health care," said National Institute on Deafness and Other Communication Disorders (NIDCD) director Debara L. Tucci, MD, MS, MBA, in a statement, noting that hearing loss is associated with dementia, increased risk of falling, reduced mobility, depression, social isolation, and anxiety.

Hearing aids that do not meet the requirements for the OTC category because they are intended for severe hearing impairment or users younger than 18 years will remain prescription-only devices.

According to the NIDCD, nearly 29 million US adults could potentially benefit from hearing aid use, but only 16% of people aged 20 to 69 years and 30% of people aged 70 or older currently use them. The NIDCD notes that people with mild to moderate hearing loss may find that speech or other sounds seem muffled. In particular, they may have difficulty hearing while they're in a group or in a noisy area; when they are conversing by telephone or they cannot see who is talking; or when they need to ask others to repeat what was said or to speak more slowly, clearly, or loudly.

Prescription hearing aids are expensive—those ordered through an audiologist can cost from $2000 to $7000 a pair (which typically includes visits with the audiologist and other associated costs)—and are usually not covered by insurance. The high cost for these devices, as well as the time and expense of consulting a clinician for a medical examination and a prescription and an audiologist for calibrating them, have served as barriers to addressing hearing loss.

The new OTC hearing aids will substantially lower these barriers. "The FDA estimates this rule will save consumers on the order of about $1400 per individual hearing aid or over $2800 per pair," said Brian Deese, JD, director of the National Economic Council, in a call with reporters to discuss the new rule.

The OTC hearing devices covered by the new rule are air-conduction hearing aids, which amplify sound into the ear canal, and are worn either inside the ear or on the ear with an inside-the-ear component.

The FDA notes that the OTC hearing aids differ markedly from products called personal sound amplification products (PSAPs) currently sold in stores or online. Those devices are consumer grade and are not intended to provide the same level of amplification as prescription hearing aids.
electronics used for activities such as birding and are not considered alternatives to hearing aids used to address impaired hearing.

The FDA issued final guidance and regulatory requirements for PSAPs concurrently with the final rule for the OTC hearing aids, "to clarify the differences between hearing aids, which are medical devices, and PSAPs, consumer products that help people with normal hearing amplify sounds," the agency noted.

The new OTC hearing aids will also have certain safety features to help ensure their safety and effectiveness. "To assure patient safety as well as effectiveness, the FDA set a maximum amount of output, or sound volume limit, for over-the-counter hearing aids that's intended to prevent overamplification of sound to avoid further hearing loss, while at the same time allow for adequate amplification to assure effectiveness of the products," said Jeff Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health, during the media briefing. The rule also includes a requirement to limit how far the hearing aid can be inserted into the ear canal, to minimize the risk of injury, he noted.

The rule also includes certain device performance and design requirements, such as limits on distortion, noise, delay, and the range of frequencies that the device will reproduce, Shuren noted. Labeling for OTC hearing aids will require inclusion of information for consumers, such as minimum user age limit, how to report adverse events, warnings, and conditions or symptoms of hearing loss that should prompt a consultation with a hearing health care professional.

Although the OTC hearing aids are being hailed as a welcome option for some adults, they have limitations and will not benefit everyone with hearing loss, such as individuals with more severe hearing impairment. In addition, prescription hearing aids, tailored to an individual's specific hearing loss, require a professional evaluation and individualized fitting and calibration for optimal benefits.

Moreover, because hearing aids are classified as consumer products rather than essential medical devices, they are not covered by insurance. Even at a lower cost than prescription hearing aids, the OTC devices may be too costly for many individuals.

Because the FDA did not require a specific return policy for OTC hearing aids in its final rule, the Hearing Loss Association of America, an advocacy organization for people with hearing loss, suggests that before making a purchase, consumers should check to see if a brand has a comprehensive return policy that allows time for testing the devices in different situations.