FDA NEWS RELEASE

FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans

More Affordable Hearing Aids Could Be in Stores as Soon as Mid-October

For Immediate Release:

August 16, 2022

Español (/news-events/press-announcements/la-fda-finaliza-una-norma-historica-que-permite-que-millones-de-personas-en-los-estados-unidos)

Today, the U.S. Food and Drug Administration issued a final rule (https://www.federalregister.gov/public-inspection/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids) to improve access to hearing aids which may in turn lower costs for millions of Americans. This action establishes a new category of over-the-counter (OTC) hearing aids, enabling consumers with perceived mild to moderate hearing impairment 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 rule is expected to lower the cost of hearings aids, furthering the Biden-Harris Administration's goal of expanding access to high-quality health care and lowering health care costs for the American public. It is designed to assure the safety and effectiveness of OTC hearing aids, while fostering innovation and competition in the hearing aid technology marketplace.

Today's action follows President Biden's Executive Order (https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/) on Promoting Competition in the American Economy, which called for the FDA to take steps to allow hearing aids to be sold over the counter and set a swift 120-day deadline for action, which the FDA met. In 2017, Congress passed bipartisan legislation requiring the FDA to create a category of OTC hearing aids, but it was not fully implemented until now. Consumers could see OTC hearing aids available in traditional retail and drug stores as soon as mid-October when the rule takes effect.

"Reducing health care costs in America has been a priority of mine since Day One and this rule is expected to help us achieve quality, affordable health care access for millions of Americans in need," said Health and Human Services Secretary Xavier Becerra. "Today's action by the FDA represents a significant milestone in making hearing aids more cost-effective and accessible."

Close to 30 million adults (https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing) in the U.S. could benefit from hearing aid use. Individuals with permanent hearing impairment can use hearing aids to help make speech and sounds louder, improving the ability to communicate effectively with others. Many hearing aids can be expensive. The final rule aims to stimulate competition and facilitate the sale of safe and effective OTC hearing aids in traditional retail stores or online nationwide, providing consumers with perceived mild to moderate hearing loss with improved access to devices that meet their needs and are less expensive than current options.

"Hearing loss is a critical public health issue that affects the ability of millions of Americans to effectively communicate in their daily social interactions," said FDA Commissioner Robert M. Califf, M.D. "Establishing this new regulatory category will allow people with perceived mild to moderate hearing loss to have convenient access to an array of safe, effective and affordable hearing aids from their neighborhood store or online."

The OTC category established in this final rule applies to certain air-conduction hearing aids intended for people 18 years of age and older who have perceived mild to moderate hearing impairment. Hearing aids that do not meet the requirements for the OTC category (for example, because they are intended for severe hearing impairment or users younger than age 18) are prescription devices.

The FDA finalized the rule after receiving and reviewing more than 1,000 public comments on the proposed rule issued on Oct. 20, 2021. Comments submitted by consumers, professional associations, hearing aid manufacturers, public health organizations and advocacy groups, members of Congress, state agencies, and other stakeholders are summarized in the final rule, along with the FDA's respective responses. In response to public comments and to assure the safety and effectiveness of OTC hearing aids, the final rule incorporates several changes from the proposed rule, including lowering the maximum sound output to reduce the risk to hearing from over-amplification of sound, revising the insertion depth limit in the ear canal, requiring that all OTC hearing aids have a user-adjustable volume control, and simplifying the phrasing throughout the required device labeling to ensure it is easily understood. The final rule also includes performance specifications and device design requirements specific to OTC hearing aids.

Furthermore, today's action correspondingly amends existing rules that apply to prescription hearing aids for consistency with the new OTC category, it repeals the conditions for sale for hearing aids, and it includes provisions that address some of the effects of the FDA OTC hearing aid regulations on state regulation of hearing aids.

Concurrently with issuing the final rule, the FDA also issued the final guidance, Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs), to clarify the differences between hearing aids, which are medical devices, and PSAPs, consumer products that help people with normal hearing amplify sounds.

The effective date for the final rule is 60 days following publication in the Federal Register. Manufacturers of hearing aids sold prior to the effective date of the final rule will have 240 days after its publication to comply with the new or revised requirements. For hearing aids that have not been offered for sale prior to the effective date, compliance with the new or revised requirements must be achieved before marketing the device, including obtaining 510(k) clearance if applicable.

Related Information

- Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids (https://www.federalregister.gov/d/2022-17230)
- Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products)
- Hearing Aids and Personal Sound Amplification Products: What to Know (https://www.fda.gov/consumers/consumer-updates/hearing-aids-and-personal-sound-amplification-products-what-know)

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