Hear ye, hear ye! FDA finalizes OTC hearing aids rule and issues updated guidance on personal sound amplification products

FDA Alert

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In a paradigm shift for the hearing aid industry and patients, the FDA has finalized a rule to establish a new over-the-counter (OTC) category of hearing aids. This rule enables consumers aged 18 or over with perceived mild to moderate hearing impairment to purchase certain hearing aids without the need for a medical examination, prescription or a fitting adjustment by an audiologist.

This long-awaited rule is accompanied by updated guidance to help address acknowledged confusion between personal sound amplification products (PSAPs, consumer products that help people with normal hearing amplify sounds) and hearing aids (medical devices).

The final rule on OTC hearing aids and the accompanying guidance, summarized below, take effect on October 17, 2022.

Final rule establishing OTC hearing aids

This new rule has been five years in the making. The FDA Reauthorization Act of 2017 ordered FDA to establish OTC hearing aid rules by August 2020. FDA did not meet this deadline, due in part to the COVID-19 pandemic. The following

year, President Joe Biden issued the Executive Order on Promoting Competition in the American Economy which demanded the HHS Secretary publish a proposed rule for OTC hearing aids by November 2021. The FDA duly published a proposed rule for notice and comment in October 2021 and published the final rule on August 17, 2022, after reviewing over 1,000 comments.

In response to public comments, 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 (generally 111 decibels of sound pressure (dB SPL), or 117 dB SPL with activated input-controlled compression, output limit)
- revising the insertion depth limit in the ear canal (limited to 10mm from the eardrum)
- requiring that all OTC hearing aids have a user-adjustable volume control and
- simplifying the required device labeling to ensure it is easily understandable for users.

Notably, FDA did not change its position on 510(k) requirements or preemption. “Self-fitting” OTC hearing aids will require 510(k) clearance, while other OTC hearing aids will not. However, FDA did address the distinction between “self-fitting” and other OTC hearing aids in the preamble to the final rule, providing some additional guidance on the difference between customization and fitting.

Despite concerns raised during the comment period, the final rule will preempt any divergent state or local law that would restrict or interfere with the new rule or the availability of OTC hearing aids. The final rule also confirms that FDA is not requiring age verification for the sale of OTC hearing aids and that OTC hearing aids will be subject to quality system requirements under 21 CFR part 820.

Looking forward: hearing aids

For hearing aids that have not been offered for sale prior to October 17, 2022, compliance with the final rule is expected from that date. Manufacturers of hearing aids sold prior to October 17, 2022 will have until April 14, 2023 to come into compliance.

Guidance on personal sound amplification products (PSAPs) and hearing aids

To accompany the final rule and address the potential for marketplace confusion, FDA finalized updated guidance to distinguish between PSAPs and hearing aids. The technology used in PSAPs and hearing aids is similar, and both obviously affect a user’s ability to hear sound, but they have different intended uses and regulatory status.

Hearing aids are wearable devices intended for aiding or compensating for impaired hearing. PSAPs are consumer products intended to accentuate sounds in specific listening environments for non-hearing impaired listeners (eg, recreationally listening for prey while hunting or listening in on distant conversations or speakers). While hearing aids are medical devices, PSAPs are not. Unlike hearing aids, PSAPs are not intended to diagnose, treat, cure, mitigate, or prevent disease and are not intended to affect the structure or function of the body.

The guidance clarifies that explicit or implicit claims that a product addresses, mitigates or improves hearing loss or impairment would cause the product to meet the device definition and be subject to the regulatory requirements applicable to hearing aid devices. Examples of such explicit or implicit claims include suggestions that the product:

- is for users with certain types or severity of hearing loss/impairment or provision of information for users to optimize the product to their hearing loss/impairment
- is for use in situations that are typically associated with and indicative of hearing loss/impairment
- is an alternative to a hearing aid.

Looking forward: PSAPs

In light of this clarification, review of existing labeling, advertising and promotional materials ahead of the October 17 deadline may be prudent for PSAP manufacturers, to ensure no explicit or implicit device claims are made.

The guidance also serves as a reminder that FDA regulates PSAPs as electronic products that emit sonic vibrations. Therefore, manufacturers of PSAPs must:

- report accidental radiation occurrences under 21 CFR Part 1002
- report defects and take other measures described in 21 CFR Part 1003 and

- comply with the requirements to repurchase, repair or replace electronic products under 21 CFR Part 1004.

Learn more about the implications of this important development by contacting any of the authors or your usual DLA Piper attorney.

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