Westlaw Today
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Papa, can you hear me? Now you can, thanks to OTC hearing aids

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SEPTEMBER 29, 2022

After 5 long years, FDA has finally[1] adopted the long-awaited OTC hearing aid rules. While the Proposed Rule was a year and a half overdue, FDA impressively turned out the Final Rule about 7 months after the close of comments on the Proposed Rule, which is only one month after it was due and before Congress could pass a bill[2] chastising FDA for the anticipated delay.

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Kudos to FDA for getting this out so quickly and even making some significant changes and clarifications in response to the comments it received on the Proposed Rule. We note, however, that some of the most important clarifications are not codified in the actual rule but are presented in the Preamble; thus, while FDA *currently* plans to interpret the rule as it states in the Preamble, it is not bound to do so.

Nevertheless, FDA clearly put a lot of effort into clarifying the major points that led to confusion in the Proposed Rule. As we previously noted, a lack of clarity was one of the biggest concerns throughout the submitted comments. This was especially a concern in the context of self-fitting hearing aids.

As the Proposed Rule suggested, self-fitting hearing aids are OTC hearing aids, but not all OTC hearing aids are self-fitting. This is important because self-fitting hearing aids require the submission and clearance of a 510(k) while regular OTC hearing aids do not, which provides incentive for manufacturers to self-classify their hearing aid products as regular OTC rather than self-fitting. (FYI, FDA does not use the term "regular hearing aids," but we are for simplicity.)

And FDA provided no dividing line between self-fitting and regular OTC, leaving the self-fitting hearing aid category vulnerable to evasion. The Preamble to the Final Rule addresses this issue by explaining the intended distinction.

While there's a lot more technicality to the discussion in the Preamble, it basically boils down to user preferences versus user-specific profile; when the hearing aid frequency changes are based on a specific audiogram or hearing profile, the product is "self-fitting."

While FDA declined to change any definitions from the Proposed Rule, the Preamble provides much-needed guidance in this area though notably, the distinction here is still subjective.

With respect to 510(k)s, FDA stood by its position that 510(k)s would not be required for all OTC hearing aids. Despite many comments that requested this, FDA declined to implement this position and declined to define all OTC hearing aids as self-fitting devices.

Thus, only self-fitting hearing aids need to be cleared by FDA prior to marketing; regular OTC hearing aids — ones that are customizable based on user preference — do not, and consumers must rely on FDA postmarket enforcement activities to ensure safety and effectiveness of OTC hearing aids (more on that later).

With respect to design specifications, FDA made some significant changes. The most important change is the reduction in output limit.

While previously FDA planned to impose a 115 dB SPL limit (or 120 dB SPL for devices with activated input-controlled compression), FDA lowered that threshold to 111 dB SPL (or 115 dB SPL with activated input-controlled compression). FDA made this change in response to a multitude of comments recommending a limit of 110 dB SPL.

Rather than the lower limits of 110 dB SPL (or 115 dB SPL), which FDA noted "would reduce device effectiveness for people with perceived mild to moderate hearing impairment to such a degree that the limits would exclude some intended users from obtaining sufficient benefit of OTC hearing aids," FDA found a compromise with 111 dB SPL (or 117 dB SPL).

FDA, however, refused suggestions to adopt a gain limit, noting that a gain limit would reduce the ability to amplify soft sounds, again decreasing device effectiveness and user satisfaction. FDA did agree that user adjustable volume control should be a design feature for all OTC hearing aids, and insertion depth should be limited to 10 mm.

FDA also updated some of the required labeling to make it more user-friendly, though ultimately the Agency decided that usability studies for such language are not necessary due to the immense amount of public input the Agency has already received. FDA also clarified that all hearing aids, OTC or otherwise, are subject to Quality System Requirements (QSRs).

While FDA addressed some major controversial issues that arose from the Proposed Rule, other areas remained untouched. The preemption provisions, for example, have not changed.

Inherently, the Agency has set up a system in which any seller of a given hearing aid that has a license is required to comply with more stringent state regulations than one without.

Under both the Final and the Proposed Rule, FDA determined that the OTC hearing aid rules should preempt any state or local government law that is different from the applicable regulations and "would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids, as defined under section 520(q) of the Federal Food, Drug, and Cosmetic Act, through in-person transactions, by mail, or online."

While some comments, including those from 41 State Attorneys' General,[3] raised concerns about the implications of the ambiguity of that preemption proposal and the application to state law, FDA decided against any further clarification. Essentially, FDA stated that it will look to the plain terms of "restrict or interfere" to determine whether a state law should be preempted, and states can reach out to the CDRH ombudsman for clarification.

Of particular note is that there are numerous consumer protection laws baked into state hearing aid laws, and while they may be protected under FDA's approach to preemption, it is not entirely clear because the preemption provisions, on their face, could be interpreted in multiple ways.

In response to these concerns, FDA noted that state consumer protections are "not necessary to provide reasonable assurance of the safety and effectiveness of OTC hearing aids." Rather than directly addressing consumer protection concerns therefore, FDA explained that it would assess preemption of specific state consumer protection provisions on a case-by-case basis.

Nonetheless, FDA stood firm in its position that consumer protections would not "restrict or interfere" with OTC hearing aid distribution but drew no hard-lines that would provide guidance to states and industry. FDA explained that its intent in adopting the preemption provision language was merely to codify the preemption language as set forth in FDARA.

Further, FDA explained that state consumer protection laws can continue to be imposed through any licensing requirements that remain for hearing care professionals, meaning that some consumer protection laws may apply to some OTC hearing aids but not others depending on the seller.

In other words, it's a get-what-you-pay-for type situation. Where a consumer spends additional money to receive an OTC hearing aid from a licensed professional, the consumer protections required to be provided by the licensed professional apply; otherwise, those consumer protections may not, as state consumer protections typically are required only of licensees.

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Thus, consumers worried about protections can either shop with a licensed professional or can rely on FTC to enforce its regulations precluding false and misleading advertising and unfair or deceptive business practices. In other words, consumer protections are not, and will not be, FDA's problem.

It's clear that FDA put a lot of thought and consideration into these Final Rules, but it remains to be seen how the proliferation of OTC hearing aids will affect uptake and consumer retention. Success here depends on FDA enforcement, as there is no premarket review for regular OTC hearing aids.

While it's great that FDA has published such detailed and thoughtful Final Rules, consumers may not be able to actually — and safely — hear using OTC hearing aids without FDA's committed oversight.

But the Agency has not made hearing aid enforcement a priority in previous years, which is why "[s]everal comments shared a concern for an influx of unsafe or ineffective devices to the marketplace, for example, devices that do not satisfy the requirements of the OTC Hearing Aid Controls because of lax enforcement and/or manufacturers or sellers evading regulatory controls necessary for reasonable assurance of safety and effectiveness of OTC hearing aids."

And FDA makes no promises here of increased enforcement now that the Final Rule is out; in fact, the Agency states that it "intends to apply existing practices for monitoring the market and will take action, including enforcement as necessary and appropriate."

Existing practices for monitoring the market and enforcement — even in the face of the trade complaints that FDA encourages in the Final Rule Preamble — has led to almost no enforcement in the last five years.

Without increased resources devoted to enforcement now to ensure compliance with the Final Rule, it will be difficult to ensure that market entrants are complying with the detailed design and labeling requirements that FDA has established in this rulemaking, and, without that strong enforcement, OTC hearing aid consumers have no other safeguards.

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The Final Rule goes into effect 60 days from publication on October 17, 2022. Unless a device is currently on the market and does not require a new 510(k), FDA expects that any hearing aid complies with these regulations as soon as the law is in effect. Legally marketed devices that do not need a new 510(k) must comply with these regulations by April 14, 2023.

Notes

[1] https://bit.ly/3eTYxva

[2] https://bit.ly/3BJyU9u

[3] https://bit.ly/3BKk8PZ

About the author

Sara W. Koblitz of **Hyman, Phelps & McNamara PC** in Washington, D.C., advises clients regulated by the Food and Drug Administration on a range of issues, with a focus on Hatch-Waxman patent and exclusivity, biosimilars and the Orange Book. She helps drug and device manufacturers in various stages of product development and guides clients through regulatory requirements with respect to applications and submissions, device classification, potential exclusivities, promotional issues and post-marketing requirements. Koblitz also counsels cosmetics, food and dietary supplement clients, with experience regarding genetically modified foods, medical foods, food labeling and dietary supplement claims and substantiation. She can be reached at skoblitz@hpm.com. This article was originally published Aug. 18, 2022, on the firm's website. Republished with permission.

This article was published on Westlaw Today on September 29, 2022.