February 14, 2023

BY E-MAIL

Dr. Jeffrey E. Shuren
Director, Office of the Center Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO-66, Room 5442
Silver Spring, Maryland 20993-0002

Dear Dr. Shuren:

With the successful implementation of the Over-the-Counter ("OTC") Hearing Aid Regulations in October of 2022, the U.S. Food and Drug Administration ("FDA") has paved the way for access to more affordable hearing options for millions of Americans. We applaud the Center for Device and Radiological Health for its hard work in implementing regulations that will facilitate expanded access to safe and effective hearing aids.

We are writing to you with the goal of ensuring that the laudable goals of the regulation and underlying legislation are actually achieved in practice. Based on behaviors we have observed in the marketplace, we are concerned that this will not always be the case and that unscrupulous actors may place consumers at risk.

We bring to bear a variety of perspectives regarding the use of hearing aids, including those of hearing healthcare providers, patients, industries, and advocates. While we bring different perspectives, our ultimate shared focus is on the consumer.

As intended, the market has seen an influx of available hearing devices. While many of these devices and their manufacturers are compliant with FDA regulations, we have noticed some very concerning practices that serve to mislead consumers and potentially put them at risk. Accordingly, we request a teleconference with you to have an open conversation regarding the market practices that we have seen over the last few months and discuss measures that can remediate them.

As several commenters noted in the docket to the Notice of Proposed Rulemaking concerning OTC hearing aids, there is a significant risk that the improper marketing of hearing

aids to vulnerable patients could cause serious harm.[1] Incidents of improper marketing could include products on the market that advertise as "self-fitting" when the required clearance has not been obtained. It also includes manufacturers making spurious performance, safety, or efficacy claims, in noncompliance with the OTC regulations and the Federal Food, Drug, and Cosmetics Act. These claims and actions put consumers at risk, particularly in light of the vulnerable nature of many of the consumers who are targeted by unscrupulous or uninformed companies.

As FDA recognizes in the preamble to the Final Rule, access to hearing aids is critical for "older adults," and "people of color, rural Americans, low-income individuals, and others for whom barriers to hearing aid access may be especially burdensome."[2] To facilitate this access in as safe a way as possible, we believe that it is important for FDA to take proactive steps to minimize these problems, which are already materializing. One important step would be for FDA to clarify the applicable requirements through a letter or statement, as the Agency issued in 2018 explaining that the OTC category of hearing aids does not yet exist and its more recent communication to state regulators about OTC hearing aids. It is our hope that hearing health stakeholders and FDA can come together to develop a communication that would educate companies about compliance with this new regulation.

In the Final OTC Hearing Aid Regulations, FDA recognized concerns that the term "self-fitting strategy" is somewhat ambiguous. While FDA declined to establish a more specific definition, the Agency noted that it may need to issue guidance in the future, as the line between self-fitting and otherwise personalized hearing aids is unclear. We would urge FDA to begin this process immediately.

We have already seen many companies marketing seemingly "self-fitting hearing aids"—or hearing aids that include "self-fitting" claims—without premarket clearance. A company called Jiuyee, for example, plans to offer OTC "AI Smart Hearing Aids" that are "Self-fitting with a Smart App" to support "mild to severe hearing loss, "[3] but there's no record of any premarket notification in FDA's 510(k) database. HearingAssist similarly offers hearing aids that allow patients to "fully customize" their hearing experience, including "app personalization" that allows for control of "volume, modes, background noise amplification of different frequencies, and more to suit your individual needs."[4] HearingAssist also has no clearance for a self-fitting hearing aid. InnerScope offers "self-adjusting hearing technology . . . to personalize

[1] FDA briefly addressed those comments in the Final Rule in response to Comment 106. Final Rule, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the- Counter Hearing Aids, 87 Fed. Reg. 50,733 (Aug. 17, 2022).

[2] *Id.* at 50,700.

[3] https://ric.jiuyee.net/

[4] https://hearingassist.com/collections/otc-hearing-aids/products/hearingassist-control-rechargeable-ric-bte-with-app-control. FDA has noted that these types of claims, particularly personalization of frequencies and full customization, suggest that the users can "independently derive and customize their hearing aid fitting and settings," falling under the category of self-fitting. 87 Fed. Reg. at 50,710. Indeed, FDA specifically has stated a hearing aid with capabilities and claims suggesting that "a hearing aid that allowed the user to make frequency-dependent modifications to a preset to suit the user's preferences likely would be self-fitting." *Id.* at 50,703.

each hearing device to their hearing needs using an on-board In-Ear Custom-Fit Self-Testing feature,"[5] but, though registered with FDA, none of its hearing aids is the subject of a cleared 510(k). Though, again, we recognize that the term "self-fitting" is somewhat ambiguous, and it is possible that some of these products are not, in fact, "self-fitting," each company has promoted its hearing aid as though it was self-fitting. Consequently, there is a need for clear guidance with respect to premarket notification for self-fitting hearing aids; parameters to clarify whether such notification is necessary for these products would be very helpful.

Additionally, multiple companies are advertising OTC hearing aids for mild-to-severe hearing loss or for other indications than mild-to-moderate hearing loss. HearGenie, for example, sells its OTC hearing aids as "a perfect fit for those with mild to severe hearing loss."[6] Jiuyee, in funding notices, plans to offer self-fitting hearing aids and claims that its product—also for mild, moderate, and severe hearing loss—can "restore your natural hearing." Others, like Hue Hearing, expressly claim that their product can be used for "Tinnitus Masking" without compliance with special controls.[7] Bossa hearing aids state that they have "built-in tinnitus management software" and "target 95% of the population with hearing loss."[8] Furthermore, companies such as Linner[9] are advertising that their devices have obtained FDA certification when FDA does not issue certificates and has stated that these types of representations are misleading.[10]

We would like to support FDA efforts to address these concerns and bring much-needed clarity to the marketplace and improved protections for consumers. To that end, we request a teleconference to discuss collaborations between FDA and hearing health stakeholders to ensure the safety and effectiveness of the OTC hearing aid market to protect consumers from exaggerated or misleading claims.

We recognize the heavy investment of resources it takes to police the market, and that while enforcement actions will sometimes be needed, taking enforcement action against individual companies cannot be the only mechanism for achieving compliance and protecting consumers in this large, emerging OTC hearing aid industry. Providing greater clarity on the agency's expectations, informed by the examples and others cited above, will be a more efficient mechanism. We believe that FDA can craft a communication that will be a valuable tool in achieving our mutually shared goal: the informed purchase of safe, effective and compliant hearing aids by American consumers.

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[5] https://innd.com/products/

[6] https://betterhearingaidco.com/products/invisible-hearing-aid

[7] https://huehearing.com/

[8] https://bossahearing.com/

[9] https://www.linnerlife.com/collections/product-center/products/100-original-lenovo-lp5-wireless-bluetooth-earbuds-hifi-music-earphone-with-mic-headphones-sports-waterproof-headset-2021new

[10] https://www.fda.gov/medical-devices/consumers-medical-devices/are-there-fda-registered-or-fda-certified-medical-devices-how-do-i-know-what-fda-approved

We look forward to meeting with you in the future. Please contact Kate Carr at kcarr@hearing.org so that we can set up such a meeting.

Sincerely,

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