Lively

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SUBMITTED ELECTRONICALLY

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No. 2021-N-0555— *Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids; Proposed Rule,* 86 Fed. Reg. 58,150 (Oct. 20, 2021).

Lively Hearing Corporation ("Lively") is pleased to submit these comments in response to the Notice of Proposed Rulemaking ("NPRM") published in the Federal Register by the U.S. Food and Drug Administration ("FDA") on October 20, 2021 implementing section 709 of the Food and Drug Administration Reauthorization Act of 2017 ("FDARA"). In FDARA, Congress established the definition of an OTC hearing aid and directed FDA to adopt regulations applicable to such products that would "provide reasonable assurances of the safety and effectiveness of [OTC] hearing aids," including technical, regulatory, and labeling specifications. FDRARA, Pub. L. 115-52 § 709, 131 Stat. 1005, 1067 (Aug. 18, 2017). In its NPRM, FDA fulfills this directive by proposing to adopt 21 C.F.R. § 800.30, Over-the-Counter Hearing Aid Controls.

Lively is a hearing aid distributor that sells high quality hearing aids directly to consumers. Through its online evaluations and ordering system, adults with mild to moderate hearing loss can easily obtain hearing aids customized to their needs at a reasonable price from the comfort of their own home. While Lively has licensed professionals involved in every step of the customer journey and believes their involvement can bring value to anyone with hearing loss, Lively also is committed to increasing the accessibility, affordability, and convenience of hearing treatment so that more people seek and receive hearing care, and therefore fully supports the proposed establishment of an OTC category. We are particularly encouraged that the language in the Proposed Rule provides sufficient flexibility to allow for future innovations in OTC hearing aid technology that will undoubtedly expand the opportunities for more Americans to access the benefits of better hearing

Lively believes that the vast majority of the provisions outlined in the NPRM would achieve the statutory intent of FDARA, which is making hearing aids affordable and accessible for consumers with mild to moderate hearing loss, while providing reasonable assurances of safety and effectiveness for these devices. *See* 86 Fed. Reg. 58,150, 58,152 (Oct. 20, 2021). Nonetheless, we ask that FDA keep the following issues in mind when crafting the final rule.

Performance Standards – Output and Gain Limits

We believe FDA appropriately defined the performance standards for the OTC category, including the proposed output limit of 115 dB sound pressure level (SPL), or 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control (i.e., volume adjustment), which Lively believes ensures consumer safety while allowing for sufficient device performance to provide maximum benefit and utility. *See id*. at 58,161. We agree with FDA that input-controlled compression mitigates any risk associated with the proposed 120 dB SPL output limit because input-controlled compression dynamically reduces the output of the amplified signal based on the input level. Moreover, the user-adjustable volume control allows the user to reduce the output below the maximum, and the user can always remove the hearing aid in the presence of high noise levels. We are aware of no high-quality clinical evidence for hearing aid-induced hearing loss for adults with mild-to-moderate hearing loss. For example, Goel et al., *Long-Term Effects of Hearing Aids on Hearing Ability in*

Patients with Sensorineural hearing Loss, 32(6) J. of Acad. Audiology, 374-78 (2021), compared changes in hearing among unilateral hearing aid users over a 5-year period. Results indicated only a 5 dB deterioration at 5 years which the authors described as "not clinically significant for the patient population at time-period modeled in this study," likely either because it was within the test/retest variation range and/or such a change over such period in an adult was not likely to be noticeable or functionally consequential.

Moreover, permitting maximum output up to these levels is critical for OTC hearing aids to be able to serve the widest appropriate range of users, i.e. those with mild-to-moderate hearing impairment, both to ensure the ability of the hearing aid to produce high quality sound at lower levels and so that the hearing aid can faithfully reproduce and amplify all sounds (e.g., environmental, speech, and music) with sufficient dynamic range.[1] Thus, even though sustained output at or approaching these levels should be relatively rare, and only needed and comfortable for those on the far end of the mild-to-moderate spectrum, the ***ability*** of the hearing aid to perform to these levels is crucial to efficacy. Even modest reductions to output standards would significantly impact the availability, utility, and efficacy of OTC devices, which would be in direct contravention of the statutory intent of FDARA.

We support FDA's proposed output limits without a separate gain (amplification) limitation, because the output limitation on its own is sufficient to ensure consumer safety and is the approach most likely to ensure the adoption of effective OTC hearing aids while not stifling continued research and innovation in the space. By providing a maximum output, FDA is being responsive to the statutory mandate under FDARA that FDA, in promulgating the applicable regulations, "include requirements that establish or adopt output limits appropriate for the over-the counter hearing aids" while simultaneously exercising discretion and not including a requirement not articulated under FDARA such as a gain limit.[2] Additionally, by not including a gain limit in the proposed rule, FDA is fulfilling the statutory intent underlying FDARA to provide consumers access to a wide range of quality OTC hearing aids while still ensuring safety and efficacy without limiting the quality of the OTC devices by artificially and unnecessarily decreasing the dynamic range of sounds available and fidelity of the sound available in OTC hearing aids with gain limits.

Insertion Depth

We appreciate the considerations resulting in FDA proposing to include controls around insertion depth in the proposed design requirements for OTC hearing aids, *see id*. at 58,164, but believe that as drafted such requirements would severely limit the quality and types of hearing aids available to be purchased OTC. We therefore propose an alternative approach below.

FDA proposed that "[T]he design of an OTC hearing aid shall limit the insertion of the eartip to the bony-cartilaginous junction of the external auditory canal and no deeper". *Id*. at 58,183. This language implies that the bony-cartilaginous junction is a readily identifiable and consistent anatomical landmark that can serve as a design limit for manufacturers of OTC hearing aids and a functional limit for users. *Id*. at 58,164. However, it is well understood that this junction is not a discrete, easily identifiable point (especially for an average user), but rather occurs in a gradually transitioning range. Attempting to use this as an anatomical landmark as the insertion depth limit will invariably lead to an imprecise standard impossible for either a manufacturer or a user to adhere to and misses the important safety concern underlying insertion depth, which is to avoid contact with the tympanic membrane while allowing insertion into and prolonged contact with critical areas of the ear canal so that the hearing aid can perform to maximum benefit as intended. *See id*. at 58,165.

Correct placement of a hearing aid within the ear is important to prevent the hearing aid from simply falling out of the user's ear, to minimize the occlusion effect (hearing one's own voice when speaking), and to reduce unnecessary feedback, while maximizing comfort and performance (including by minimizing the need for amplification due to more efficient transmission of the audio signal in a better-sealed audio environment). We note, as did FDA, that "specific anatomical dimensions such as the length of the cartilaginous and bony portions of the external auditory canal and distance to the tympanic membrane can vary greatly among adults". *See id.* at 58,165.

Due to these considerations, we recommend that FDA not include a proscribed insertion depth as part of the design requirements for OTC hearing aids, but rather require clear instructions for use regarding how to properly

[1] *See* Marshall Chasin & Frank Russo, *Trends in Amplification*, 8(2) Hearing Aids and Music 35, 35-47 (2004).
[2] *See* FDRARA, Pub. L. 115-52 § 709, 131 Stat. 1005, 1066 (Aug. 18, 2017).

insert an OTC hearing aid (including, where these options are made available to the user in connection with an OTC hearing aid, how to determine/choose, remove, and apply correctly sized/shaped domes, wires and/or other fitting materials). We believe that this approach, combined with FDA's proposed requirement for the use of atraumatic materials for the eartip, *see id*. at 58,164, will appropriately protect users in the same manner as they are today. We note that millions of hearing aids (and other in-canal audio devices), inserted to a more flexible standard than that currently proposed by FDA, are and have been in use in the U.S. without any significant safety issues being identified.

If FDA determines it must include some form of design requirement in the final rule, we propose that FDA instead specify a maximum intended insertion depth (i.e., an explicit distance) sufficient to allow for anatomical variation among users and the varieties and modalities of air conduction hearing aids currently in existence, e.g., 20 mm and clarify that the design of the hearing aid and the associated instructions for use be intended to avoid insertion beyond such point rather than attempt to require it be prevented in all circumstances.

Definition of Self-Fitting Air-Conduction Hearing Aids

FDA classified a new category of "self-fitting" hearing aid in October of 2019 as a Class II restricted medical device that requires the submission of a 510(k) and is subject to special controls. *See id.* at 58,153, 58,171. Under 21 C.F.R. § 874.3325, a self-fitting air-conduction hearing aid is "a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings."

Under the proposed rule, self-fitting hearing aids currently classified under 21 C.F.R. § 874.3325 would be eligible for regulation as OTC hearing aids if they otherwise satisfy the OTC requirements. We note, however, that FDA's definition of self-fitting air-conduction hearing aids could be construed as including any hearing aid that has user controls made available to consumers beyond volume control. For example, users of hearing aids today commonly have the ability to adjust frequency-specific amplification such as bass, mid-range and treble; select different "programs" or "profiles" with different frequency responses, noise reduction levels, and other variations; and in some cases even directly change noise reduction levels. Indeed, there is a risk that any OTC hearing aid that incorporates technology beyond volume control, including technology that allows users to directly change the programing, programs/profiles used, or settings of their hearing aids could be construed as a "self-fitting" air-conduction hearing aid.

We do not believe that this was or is FDA's intent, nor an appropriate or accepted reading of either the existing or the proposed regulation (if it were, many hearing aids currently on the market would already be at risk of being considered and requiring clearance as "self-fitting" under the existing regulation). Nonetheless, as this definition will likely be even more critical within the context of the new OTC category, we believe it would be advisable for FDA to clarify the scope of self-fitting air conduction hearing aids to avoid any confusion regarding which type of devices will fall within this classification. We believe that the critical aspects of the definition are the concepts of "allow[ing] users to **program** their hearing aids" (emphasis added) and "integrat[ing] user input with a self-fitting strategy". We propose that these concepts be expanded to clarify aspects we believe are implicit to the current understanding of them, specifically that: (1) the user input be responses to audio stimuli generated by the device or technology made available for use in combination with it, (2) the user input be provided directly to the device or such accompanying technology for automated analysis, and (3) the results of such automated analysis be automatically applied, without human intervention, to adjust the programming or settings of the device in a way that the user cannot directly access or change.

In requesting that FDA clarify the scope of self-fitting air conduction hearing aids to avoid any confusion regarding which type of devices will fall within this classification, we agree with FDA that all OTC hearing aids should not be required to be self-fitting. Self-fitting hearing aids are a new and developing technology, and FDA itself has noted it does not have sufficient information or experience with this type of device yet to exempt it from Section 510(k) review.[3] Requiring all OTC hearing aids to be or be considered as self-fitting would put an undue regulatory burden on manufacturers that does not appear merited in light of the lack of significant risks associated with non-self-fitting OTC hearing aids, and likely would stifle innovation as well as eliminate time-tested, lower-cost hearing aid options to consumers, in direct contravention of the underlying statutory intent of FDARA. We note that FDA

[3] *See* 86 Fed. Reg. 58,150, 58,171-172 (Oct. 20, 2021).

can always revisit this determination in the future after the market for OTC hearing aids has fully developed and the technology and performance of self-fitting hearing aids has progressed and is better understood.

510(k) Clearance

FDA's proposed rule does not propose to exempt additional devices from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). 21 U.S.C. § 360(k). FDA does not, in realigning the regulations by sound conduction mode, propose to reclassify any hearing aid device or change the exemption status under section 510(m)(2) of the FD&C Act for premarket notification for any device type (see 21 U.S.C. 360(m)(2)). Legacy and wireless air-conduction hearing aids are exempt from section 510(k) premarket notification, subject to the limitations of exemption, and FDA is not proposing to alter the exemption status of such devices. Self-fitting air-conduction hearing aids are not currently exempt, and this classification will not change under the proposed rule.

We understand that some commenters have submitted or may submit comment letters advocating for the expansion of a 510(k) requirement to some or all types of OTC hearing aids beyond the self-fitting category. If FDA determines to require a 510(k) for all, or any subcategories of, non-self-fitting OTC hearing aids, we recommend that FDA ensure that such measure does not further delay the availability of OTC hearing aids or negatively impact the current market for and availability of hearing aids, either by allowing for a grace or "grandfathering" initial period for non-compliance or by extending the proposed effectiveness deadlines, in order to compensate for the time a 510(k) submission and review process could take especially with so many hearing aid product filings for clearance potentially being made in a short period.

Defining Mild-to-Moderate Hearing Loss and Self-Assessment Tests

We understand some commenters have raised or may raise the idea of defining "mild-to-moderate" hearing loss by reference to specifically measurable standards and defining what "self-assessment" tests might be appropriate to be included with OTC devices. We support FDA's approach to using a "functional" approach to users being able to determine on their own whether they might be benefitted by OTC hearing aids, *see* 86 Fed. Reg. 58,150, 58,158-159 (Oct. 20, 2021), and in permitting flexibility regarding what "self-assessment" tests might be appropriate . *See id*. at 58,177. We believe that trying to rigidly define "mild-to-moderate" hearing loss or what "self-assessment" tests might be appropriate to determine whether someone might be aided by an OTC hearing aid is unnecessary given the safety and efficacy of the category ensured by the performance and design standards, would unduly limit manufacturers' and distributors' ability to develop and innovate new approaches and technology over time, and could limit adoption of and benefits gained from OTC hearing aids. Research has shown that individuals do not adopt hearing aids simply based on the audiometric results of a hearing test; rather, a major predictor of hearing aid adoption is self-perceived hearing difficulty of the types specified by FDA in the proposed rule.[4] Similarly, whether a user is well-served by an OTC hearing aid or needs to seek more sophisticated treatment will often be determined by whether the user perceives their hearing issues to have been sufficiently addressed by the OTC hearing aid. As such, we support FDA's approach to package labeling that will include information that consumers would need to know prior to purchasing the device, such as who is a candidate for the device, how to determine candidacy, and when to seek professional help before or after trying the device. *Id*. at 58,159.

OTC Return for Credit Policy & Other Consumer Protections

FDA proposed requiring that hearing aid manufacturers disclose their return policy or, if none, state that they do not accept returns. *Id*. at 58,160. We agree with FDA that such a requirement is appropriate (although believe that it should be expanded to include the distributor and/or vendor of the hearing aids, if returns are to be made to it), because prospective users of OTC hearing aids may be unsure whether an OTC hearing aid will meet their hearing needs. We also note, as FDA does, that without the services of a licensed person, some users may be more dependent on the return policy to avoid "leaving an OTC hearing aid in one's desk drawer". *Id*. However, FDA is not requiring that manufacturers accept returns, although has stated that it would not object to a state or local requirement applicable to OTC hearing aid returns. *Id*. In the interest of insuring fair access to OTC hearing aids for all Americans and to avoid patchwork application of state standards on OTC hearing aids, many of which

[4] *See* Annie Simpson, et. al. *Time from Hearing Aid Candidacy to Hearing Aid Adoption: A Longitudinal Cohort Study*, 40(3) Ear Hearing, 468-476 (2019); *See also* Lauren Dillard, et. al., *Predicting Hearing Aid Use in Adults: The Beaver Dam Offspring Study*, 60(8), Int'l. J. of Audiology, 598-606 (2021).

we believe will be likely to be distributed, marketed and sold on a broad basis, we encourage FDA to require or at least recommend a uniform return policy applicable to OTC hearing aids. In a similar vein and for the same reasons, we believe FDA should adopt or at least recommend uniform, national consumer protection standards such as receipt requirements and minimum device warranty requirements.

Preemption

OTC. FDA makes clear in the NPRM under proposed 21 C.F.R. § 800.30(h) that OTC hearing aid requirements established by a State (or a political subdivision) are preempted when the requirements are different from, or in addition to, requirements applicable to the device under the FD&C Act and which relate to the safety or effectiveness of the device or to any other matter included in the requirements applicable to the device. *See* 86 Fed. Reg. 58,150, 58,166 (Oct. 20, 2021). We support FDA's strong position with respect to preemption. Strong Federal preemption, along the lines proposed by FDA in the NPRM, is necessary to ensure the increased availability and accessibility of OTC hearing aids.

Prescription. In the same vein, we question why FDA would eliminate the conditions for sale regulation currently applicable to all hearing aids under 21 C.F.R. § 801.421, which has been in effect since 1977,[5] including FDA's 2016 determination not to enforce certain aspects thereof,[6] rather than continuing the current regulatory framework for all non-OTC hearing aids which will fall in the "prescription" category. 21 C.F.R. § 801.421. The existing regulatory framework, combined with the States' oversight and regulation of the professional standards applicable to the personnel required to be involved in the sale and servicing of these types of hearing aids, has been appropriate and worked well to protect the interests and safety of the consumer. Eliminating the time-tested uniform condition of sale Federal requirements for all these other hearing aids, and instead reverting to a patchwork of State regulation (much of which is outdated) for these purposes, will result in a *reduction* of accessibility and likely affordability of all these other hearing aids, in many cases to the detriment of those very people who might be in most dire need of them. While the FDARA focused on the establishment of a category for OTC hearing aids in order to increase the accessibility and affordability of hearing aids to a large segment of the adult population with some degree of hearing loss, we do not believe its intent was to simultaneously *reduce* accessibility of hearing aids to the remainder, nor do we understand (or even see articulated in the NPRM) FDA's rationale for making these changes which will have that effect. Abdicating this responsibility to the States, in addition to re-instating existing and often outdated State regulation which has been established to have been pre-empted by Federal regulation,[7] could also result in State legislatures and/or licensure boards seeking to implement further requirements which could restrict innovation and accessibility. This type of unintended consequence is not only possible but likely if FDA does not retain in place the current conditions of sale regulatory framework for "prescription" hearing aids. Retaining the current conditions of sale regulatory framework for non-OTC hearing aids, and the consequent Federal pre-emption of inconsistent or additional State regulation regarding the safety and efficacy of them and their provision to users, would not require FDA to engage in or oversee State licensure requirements, just as it does not do today. We therefore urge FDA to retain and continue to apply the substantive provisions of 21 C.F.R. § 801.421 to non-OTC hearing aids to the same extent applying to hearing aids today.

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[5] *See* 42 Fed. Reg. 9,286, 9,296 (Feb. 15, 1977), https://archives.federalregister.gov/issue_slice/1977/2/15/9268-9315.pdf#page=29.

[6] FDA, Guidance for Industry and Food and Drug Administration Staff, Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids (Dec. 2016), https://www.fda.gov/media/101685/download.

[7] *See* 21 U.S.C. 360k; *Missouri Board of Examiners for Hearing Instrument Specialists vs. Hearing Help Exp., Inc.*, 447 F.3d 1033, 1037 (8th Cir. 2006) (holding "We conclude that the requirements of Mo. Stat. § 346.110(1) are in addition to the federal requirements applicable to the sale of hearing aids and that they directly relate to the safety of consumers and the effectiveness of the devices. The Missouri statute therefore 'interfere[s] with the execution and accomplishment of the objectives of the FDA's hearing aid regulation,' 45 Fed. Reg. at 67327, and must be deemed preempted by the MDA.'"); *see also METX, LLC v. Wal-Mart Stores Texas, LLC*, 62 F.Supp.3d 569, 573 (E.D. Tex. 2014) (affirming on *de novo* review the magistrate judge's recommendations, which determined "that the Texas regulations are preempted was based on three independent grounds, any one of which demonstrates the Texas statutory provisions are 'different from and in addition to' the federal counterparts relating to the 'safety and effectiveness' of hearing aids); *Taylor v. Polhill*, 964 F.3d 975 (11th Cir. 2020)(affirming preemption of conditions of sale restrictions).

Lively appreciates the opportunity to provide comments on this NPRM and looks forward to the publication and implementation of the final rule.

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