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SUBJECT
Bose Corporation Comments
Docket No. FDA-2021-N-0555
Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Bose Corporation is a U.S.-based company that designs, manufactures, and sells electronics and audio equipment and consumer products worldwide. We are dedicated to producing innovative customer experiences through research in audio engineering and hearing science. We applaud FDA for its detailed review of the existing regulatory requirements for hearing aids as part of its work to establish a new regulatory category of over-the-counter ("OTC") hearing aids as required by the Over-the-Counter Hearing Aid Act of 2017 (enacted as Sec. 709 of the FDA Reauthorization Act of 2017, or "FDARA," Pub. L. 115-52) and section 5(p)(1) of President Biden's Executive Order on Promoting Competition in the American Economy (July 9, 2021). Bose offers the following comments to assist FDA in promptly finalizing the proposed regulations for OTC hearing aids, which will greatly benefit millions of adult Americans with mild-to-moderate hearing impairment.

Our comments to the proposed rule *Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*, dated October 20, 2021 (the "Proposed Rule"), will address six topics:

1. Our support for FDA's proposed approach to gain and output limits (§800.30(d));

2. Our support for FDA's approach to preemption (§800.30(h));

3. Our suggestions for modifying the proposed on-packaging labeling requirements (§800.30(c)(1)(i));

4. Our request for further clarification of the distinction between OTC Hearing Aids (§800.30(b)) and Self-fitting OTC Hearing Aids (§874.3305(b)(3));

5. Our suggestions for modifying the proposed approach to Quality System Requirements; and

6. Our support for the use of the ANSI/CTA-2051:2017 standard, with minor modifications.

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1. Output limits; no gain limit (§800.30(d))

1.A. The proposed maximum OSPL90 output level of 115/120 dB is appropriate for the intended population of OTC hearing aid users with mild to moderate hearing loss.

The Proposed Rule would establish a maximum OSPL90 output level of 115 dB SPL, or 120 dB SPL for OTC hearing aids that implement input-controlled compression and a user-adjustable device volume control (volume adjustment).[1] These proposed output limits are intended to balance the risk of injuries from exposure to loud sounds when amplified by OTC hearing aids with the ability to provide effective amplification for users with perceived mild to moderate hearing loss. In establishing the proposed output limits, FDA considered both ANSI/CTA and National Institute for Occupational Safety and Health ("NIOSH") standards, as well as stakeholder input. Please refer to Section 6 of this letter for our specific comments regarding the ANSI/CTA standards.

The output limit is the most important electroacoustic specification for OTC devices. Getting this right has implications for safety and for the proportion of the intended user population that will be able to be usefully served with OTC hearing aids. Bose believes that FDA has made an appropriate, well-reasoned choice with the proposed 115/120 dB SPL values.

Several commenters have recommended a lower limit of 110 dB SPL, apparently based on a 2018 "consensus" report from four professional hearing care groups.[2] Bose believes, however, that this proposal on maximum output is fundamentally flawed. As discussed in more detail in the technical comments set out in Appendix A to this comment letter, the 2018 report's recommendation of an OSPL90 limit of 110 dB SPL misconstrues the relationship between the maximum output for any single tone and that for a broadband signal. The report indicates that broadband signals include many tones and, therefore, can cause hearing aid outputs far above those indicated by OSPL90. This is wholly incorrect. Broadband signals can be output from the hearing aid only at average (i.e., root mean square) levels that will be well below OSPL90. Even if they are allowed to be highly distorted (*i.e.*, clipped), they will still not exceed OSPL90.

It is also important to emphasize that an output limit of 115/120 dB SPL does not mean these levels will be frequently presented to an OTC hearing aid user. For the reasons discussed in more detail in Appendix A, an OSPL90 limit of 120 dB SPL will allow actual speech (and music) to be played only up to around 105 dB SPL. While listening at such levels is not common, it does occur occasionally, and the proposed OSPL90 limits of 115/120 dB SPL are needed to ensure there is adequate headroom for undistorted outputs in these situations.

Finally, we note that hearing aids are currently available with OSPL90s (2 cc) ranging from around 105 to 140 dB SPL. This range is intended to cover the range of hearing losses from mild to profound. The limit of 115/120 dB SPL, which is near the middle of this range, provides appropriate coverage for mild through moderate perceived hearing impairment as prescribed by the OTC hearing aid legislation.

In summary, an OSPL90 limit of 115/120 dB SPL is a good, well-reasoned choice. Bose strongly supports FDA's recommendation for OSPL90 output levels of 115/120 dB. Applying a lower limit, such as 110 dB SPL, would restrict the effectiveness of OTC devices despite the lack of any evidence that the higher proposed limit would be unsafe. We believe that FDA's proposed

[1] Proposed Rule, 86 FR 58150 at 58161.
[2] Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness. Consensus Paper from Hearing Care Associations. August 2018. https://www.asha.org/siteassets/uploadedfiles/consensus-paper-from-hearing-care-associations.pdf

approach appropriately balances safety and effectiveness without unnecessarily constraining innovation and improved performance for future OTC hearing aid designs.

1.B. Establishing a maximum output limit without a gain limit provides reasonable assurance of safety and effectiveness without limiting the device gain or constraining its design.

Prior to publishing the Proposed Rule, including in an April 2016 public workshop and its associated docket, FDA received comments from certain stakeholders recommending that the agency establish gain limits for OTC hearing aids.[3] In the Proposed Rule, FDA proposes not to limit the device gain, concluding that the proposed maximum output limit, together with the other proposed requirements, will provide reasonable assurance of safety and effectiveness.[4] Bose strongly agrees with FDA and the National Academies of Sciences, Engineering, and Medicine ("NASEM"), both of whom concluded that relying solely on a maximum output limit is sufficient to assure reasonable safety and effectiveness. Indeed, evidence from several published studies shows that when given control over their devices, users are unlikely to over-amplify. Instead, users tend to choose gain near (or somewhat below) values selected by a clinician.[5,6,7 8]

The most visible proposal in favor of gain limits has been from the hearing care groups' 2018 "consensus" report referred to above. The hearing care groups' proposed gain limit of 25 dB relies on a methodology that is problematic for several reasons, as outlined in technical comments provided in Appendix B to this comment letter. A proposed HFA gain limit of 25 dB would be overly constraining, such that the needs of some potential OTC device users would not be met. Such a result would be contrary to Congress' intent in enacting FDARA.

Safety considerations do not support the imposition of gain limits for OTC hearing aids. We expect most OTC devices will have input-controlled compression. Therefore, maximum gains will occur with low level inputs, typically with speech at 50 dB SPL. Even with high gains (i.e., above that proposed in the consensus report) at 50 dB SPL input levels, output levels will be insufficient to cause hearing damage.

Furthermore, input-controlled compression and user-adjustable volume control increase comfort by dynamically adjusting gain and keeping outputs lower. A gain limit would unduly constrain manufacturer's circuit design flexibility without a corresponding safety benefit. We believe that allowing flexibility in gain will allow device manufacturers to maximize the effectiveness of their particular designs and allow for continued innovation and improvements in effectiveness, which would benefit consumers with mild to moderate perceived hearing

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[3] *See* Public Workshop, Streamlining Regulations for Good Manufacturing Practices (GMPs) for Hearing Aids, page 131, *available at* http://wayback.archive-it.org/7993/20171115155158/https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM502750.pdf; see also, Comment from Dr. Nancy McKenna PhD, AuD, CCC-A, *available at* https://www.regulations.gov/comment/FDA-2015-N-4602-0095.

[4] Proposed Rule at 58162.

[5] Sabin, AT, Van Tasell, DJ, Rabinowitz, B, & Dhar, S (2020). Validation of a self-fitting method for over-the-counter hearing aids. Trends in Hearing 24: 1-19.

[6] Mackersie, C, Boothroyd, A, & Lithgow, A (2019). "A "Goldilocks" approach to hearing-aid self-fitting: Ear-canal output and speech intelligibility index." Ear & Hearing 40(1): 107-115.

[7] Moore, BCJ, Marriage, J, Alcantara, J, & Glasberg, BR (2005). Comparison of two adaptive procedures for fitting a multi-channel compression hearing aid. International Journal of Audiology, 2005. 44(6): 345-357.

[8] Vaisberg, JM, Beaulac, S, Glista, D, Macpherson, EA, & Scollie, SD (2021). Perceived sound quality dimensions influencing frequency-gain shaping preferences for hearing aid-amplified speech and music. Trends in Hearing, 25: 1-17.

impairment while maintaining an appropriate safety margin through the Proposed Rule's other provisions.

In summary, a gain limit is not needed to protect individuals with mild to moderate perceived hearing impairment, and it will unnecessarily constrain device design. Bose strongly agrees with FDA's carefully considered rationale for excluding gain limits from the proposed regulations.

2. Preemption (§800.30(h))

Section 709(b)(4)-(5) of FDARA makes clear that Congress intended a broad preemption of any state or local requirements that could present obstacles to a wide range of commercial activities relating to OTC hearing aids. That Congress saw fit to include this OTC hearing aid-specific preemption language in addition to the express preemption language of section 521(a) of the Federal Food, Drug, and Cosmetic Act shows the importance of strong preemption in ensuring a thriving new, nationwide marketplace for OTC hearing aids that minimizes unnecessary regulatory burdens.

Bose believes the preemption provisions in the Proposed Rule generally strike the right balance between preserving states' traditional authority to establish minimum standards for healthcare-related professions and to regulate unfair trade practices as a general matter, with ensuring that such regulation does not restrict or interfere with consumer access to safe and effective OTC hearing aids. We appreciate that FDA has drawn a distinction between certain requirements for the regulations of professions and establishments.

Some comments to the docket have suggested that FDA's proposed preemption provisions would remove important layers of state-level protections for consumers, and that FDA should consider new state exemption proposals from federal pre-emption. We disagree.

Under the preemption provisions in the Proposed Rule, manufacturers and distributors of OTC hearing aids remain subject to numerous laws and regulations intended to protect consumers, including FDA labeling and misbranding provisions; Federal Trade Commission prohibitions on unfair or deceptive acts or practices and truth in advertising; and generally applicable state and local consumer protection laws that would not be preempted under the Proposed Rule. The Proposed Rule also reflects the statutory language that the preemption provisions do not modify or affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law. We believe that, as proposed, the preemption provisions would support broad access to OTC hearing aids for adult U.S. consumers with mild to moderate hearing loss, regardless of the state or locality where they reside and shop. We believe that any weakening of the proposed preemption provision could result in unneeded logistical complications that would interfere with commercial activity related to OTC hearing aids, as well as disparate treatment of consumers depending upon their place of residence or purchase.

The preemption provisions in the Proposed Rule also provide manufacturers and sellers of OTC hearing aids with the clarity and confidence they need to invest in this new category of medical devices. We believe that this will benefit consumers by encouraging continued innovation in OTC hearing aids.

Lastly, we applaud FDA for providing detailed discussion and examples of preemption to help clarify the agency's intent and approach and for incorporating the preemption provisions into the text of the Proposed Rule, to assist stakeholders in identifying the uncodified statutory

language from FDARA Section 709(b)(4)-(5). We encourage FDA to retain clear and strong preemption provisions in the final rule.

3. On-packaging labeling requirements (§800.30(c)(1)(i))

Bose agrees with FDA that labeling on the package should be understandable and help consumers answer the threshold question of whether they are suitable candidates for purchasing an OTC hearing aid. Given the limited space available on small OTC hearing aid packaging, labeling on the outside packaging should be limited to essential pre-purchase information. Streamlining the package labeling requirements will help ensure the information can be presented in a manner that is prominent and clear, making it more likely consumers will read and understand it.

To achieve this, Bose recommends FDA modify the following aspects of its proposed on-package labeling requirements: (1) replace the description of the "manufacturer's" return policy with a statement encouraging consumers to seek information about the "seller's" return policy, the content of which shall be made available on the seller's website or at the seller's retail location where the transaction takes place, and (2) streamline the content of all on-packaging labeling to improve clarity and brevity.

3.A. The labeling should advise consumers to seek information about the "seller's" return policy, rather than the "manufacturer's" return policy, because the manufacturer's return policy will not always be applicable.

Bose recommends replacing the description of the *manufacturer's* return policy with a statement encouraging consumers to seek information about the *seller's* return policy. Because the manufacturer will frequently not be the entity selling the device to the customer, the manufacturer's return policy will not apply in many cases. Instead, it is the seller's return policy that will apply. Bose is concerned that the requirement to include the manufacturer's return policy on the outside packaging will lead to consumer confusion, unnecessarily consume limited packaging space, and create counterproductive complexity for manufacturers and sellers.

FDA is not proposing to require that manufacturers accept returns of OTC hearing aids. This makes sense, particularly because consumer return policies are generally controlled by the *seller* of goods, not the *manufacturer* of goods. In addition to selling devices directly to consumers (in which case the manufacturer's return policy will be applicable), Bose expects that many manufacturers such as Bose will distribute OTC hearing aids via third party sellers. In such cases, the return policy of those sellers – not the return policy of the manufacturer – would apply to the purchase. This practice is evident in the current marketplace for other types of OTC medical devices, such as continuous glucose monitors and blood pressure monitors.

Disclosing the manufacturer's return policy on the outside packaging could therefore be confusing and even misleading to consumers purchasing the device from third party sellers with return policies that differ from the manufacturer's return policy. For example, a manufacturer may choose to offer a 60 day return policy for purchases made directly from the manufacturer, whereas a third party seller of the same device may choose to offer a 30 day return policy. Under the Proposed Rule, the outside packaging of the device would disclose the manufacturer's return policy for direct purchases (60 days), even though a customer purchasing the device from the third party seller would be entitled only to the seller's return policy (30 days).

While one theoretical option to address this issue could be to require manufacturers to include a description of seller return policies on the outside package of the hearing aid, such an approach would be impractical and would add substantial costs that could increase prices to consumers. Manufacturers do not dictate the return policies of sellers, which can vary by seller and by jurisdiction, and are subject to change over time. As a result, there is no straightforward way for the manufacturer to include these policies on the product packaging. Such packaging would have to be printed and applied on a case-by-case basis, creating significant quality control challenges to avoid inaccurate labeling. Such a mandate for product packaging would immeasurably complicate the product supply chain, increasing costs of production and distribution and ultimately consumer prices.

Additionally, any requirement to include details of a return policy on the package would have the practical effect of limiting sellers' flexibility to modify return policies, such as temporarily extending return policies as a promotional incentive. Unfortunately, this could discourage competition among sellers of OTC hearing aids to offer more favorable return policies as a differentiating feature or benefit for consumers.

In addition, it would be difficult in some cases to relay accurate information about a return policy without consuming an inordinate amount of packaging space (*e.g.*, the time period for the return, the condition of the device when presented for return, the process for initiating a return, etc.).

Bose agrees with FDA's intent that consumers understand applicable return policies prior to purchasing an OTC hearing aid. Therefore, Bose recommends that the outside packaging include a statement such as: "Before purchasing, consult the seller of this device about the terms of any applicable return policy." This will encourage consumers to seek information about the return policy prior to purchase from the entity that is transacting the sale with the consumer and in control of the applicable return policy. It will also have the effect of encouraging sellers to offer reasonable return policies, while eliminating confusion and allowing manufacturers and sellers to retain flexibility and control over their respective return policies without consuming undue packaging space.

3.B. The proposed labeling under §800.30(c)(1)(i)(A) through (E) should be streamlined for clarity and brevity.

Bose recommends replacing the proposed labeling under §800.30(c)(1)(i)(A) through (E) with a single statement about the device's indication for use and a reference to where additional information can be obtained. Specifically, Bose proposes the following modified labeling content in lieu of the existing content in §800.30(c)(1)(i)(A) through (E):

> WARNING: If you are younger than 18, do not use this product. See a doctor about your hearing.
>
> This hearing aid is intended for perceived mild to moderate hearing loss in adults. This device may not help if you have more significant hearing loss.
>
> For information about symptoms of mild to moderate hearing loss and when to seek assistance from a hearing healthcare professional instead of using this device, refer to the user instructional brochure and other labeling for this device at: [weblink to all labeling and any additional resources], or call [telephone number] to request a paper copy.

Alternatively, if FDA believes more information is warranted on the outside packaging, then Bose recommends modifying the proposed labeling under §800.30(c)(1)(i)(A) through (E) to

improve clarity and relevancy, and to reduce the amount of packaging space needed for the text. Specifically, Bose proposes the following modified labeling content in lieu of the existing content in §800.30(c)(1)(i)(A) through (E):

> WARNING: If you are younger than 18, do not use this product. See a doctor about your hearing.
>
> This hearing aid is intended for perceived mild to moderate hearing loss in adults. If you experience any of the following, you may have this kind of hearing loss:
> - Difficulty hearing conversations, especially in groups or noisy places
> - Difficulty hearing while using a telephone
> - Fatigue due to greater listening effort
> - Needing to turn up the volume of television or music louder than normal
>
> This device may not help if you have more significant hearing loss, for example if you have difficulty hearing conversations in quiet places or hearing loud sounds.
>
> WARNING: Conditions that Require Medical Care
>
> Prior to purchasing this device, you should consult with a doctor if you have any of the following:
> - Visible deformity of the ear, either present since birth or from trauma
> - Fluid, pus, or blood coming out of the ear in the past 6 months
> - Pain or discomfort in the ear
> - History of excessive ear wax or suspicion that something is in the ear canal
> - Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
> - Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
> - Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
>
> This information and other labeling, including the user instructional brochure, are available at: [weblink to all labeling and any additional resources], or call [telephone number] to request a paper copy.

Although most of these proposed changes are simple edits for clarity and brevity, we are recommending that the final sentence of the labeling requirement under §800.30(c)(1)(i)(C) be removed completely. That sentence reads: "If you try this device and continue to struggle with or remain concerned about your hearing, you should seek a consultation with a hearing healthcare professional." This statement does not meet FDA's rationale for including information on the outside packaging because it does not convey information consumers need to know *prior to purchase*. This sentence advises medical consultation *after using the device* and finding the results unsatisfactory. This is not a consideration that would play into the consumer's decision whether to purchase the device and therefore should be removed from the outside package labeling requirements.

4. Distinction between OTC Hearing Aids and Self-fitting OTC Hearing Aids (§800.30(b) and §874.3305(b)(3))

The proposed definition of "over-the-counter hearing aid" in §800.30(b) and the proposed classification of "self-fitting hearing aid" in §874.3305(b)(3) overlap in certain respects that are confusing and require further distinction. Bose requests clarification regarding the distinction between self-fitting OTC hearing aids and non-self-fitting OTC hearing aids, in order to eliminate potential confusion for manufacturers and consumers.

The proposed definition of OTC hearing aid includes the statutorily-mandated requirement that the device type, through tools, tests, or software, allow the user to *control* the hearing aid and *customize the device to the user's hearing needs*. Specifically, consistent with the requirements of section 520(q)(1)(A)(iii) of the FD&C Act, proposed 21 C.F.R. § 800.30(b) defines "over the counter hearing aid" to require, among other things, that "the device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs." The Proposed Rule further defines "tools, tests, or software" as "components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device's output, to meet the user's hearing needs."

The proposed classification of "self-fitting hearing aid" in 21 C.F.R. § 874.3305(b)(3), on the other hand, includes a requirement that the device incorporate technology that "allows users to *program their hearing aids*," which is defined as technology that "*integrates user input* with a *self-fitting strategy* and enables users to *independently derive* and *customize their hearing aid fittings and settings*" (emphasis added).

It is unclear from the Proposed Rule what parameters, degree and methods of customization could be present in an OTC hearing aid *without* constituting "programming," leading to their classification as "self-fitting." For example:

- *Parameters subject to customization* - Would frequency-dependent user control and customization of compression parameters constitute programming, whereas user control and customization of a simple broadband linear volume control fall short of programming?
- *Degree of customization* – Would a user's self-selection among a small number (*e.g.*, three to five) of presets (*i.e.*, non-personalized, preprogrammed hearing aid settings) constitute "programming" via user input? If not, would the answer differ if the user were selecting among a large number (*e.g.*, one hundred or more) of such presets?
- *Methods of customization* – Would a device with software that programs initial hearing aid settings automatically for the user based on a hearing test or evaluation constitute programming?

This is an important distinction. Under the Proposed Rule, self-fitting hearing aids would be subject to 510(k) premarket notification and special controls (such as clinical data evidencing effectiveness of self-fitting), which would not apply to OTC hearing aids that are not self-fitting.

It is vitally important that manufacturers of OTC hearing aids understand what types and/or degrees of customization will result in a self-fitting classification, in order to prepare for the appropriate path to market, and to formulate claims about their devices that appropriately represent the device's technological capabilities and intended function with respect to the customization achievable by the user. Moreover, absent additional regulatory clarity on which attributes render hearing aids self-fitting, we are concerned there will be disparate regulatory oversight with respect to OTC hearing aids that provide similar customizable functions, because different manufacturers will reach different conclusions as to the appropriate regulatory classification for similar devices. Unfortunately, given the significantly higher regulatory burdens that would apply to self-fitting devices (e.g., 510(k), additional special controls), some manufacturers may be incentivized to interpret ambiguity in FDA regulations and conclude erroneously their devices are not self-fitting, thereby evading important regulatory controls. Although FDA could, in theory, address this problem through aggressive enforcement, FDA cannot know at this time how substantial an enforcement challenge this

would be. The result could be either a diversion of valuable FDA enforcement resources that otherwise could go to better use, or insufficient enforcement, shifting the burden of discerning between distinct device types and their associated features, benefits, and prospective efficacy to consumers.

It is also important to clarify the distinctions between self-fitting and non-self-fitting OTC hearing aids in order to ensure that additional regulatory burdens for self-fitting hearing aids are not arbitrary, and are grounded in safety and efficacy risks inherent to self-fitting devices that are not present in other over-the-counter devices.

It is equally important that consumers clearly understand the differences between self-fitting and non-self-fitting devices, in order to make informed purchasing decisions and select a device that meets their needs.

In response to questions received during a webinar hosted by FDA on December 7, 2021, FDA explained the distinction between self-fitting and non-self-fitting OTC hearing aids as relating to the degree of individualized programming and the extent to which the user interface is interactive. FDA also indicated that the agency expects that "most" OTC hearing aids would be self-fitting devices.[9] While these comments provide some very high-level insight into FDA's intentions, they do not provide sufficiently clear guidance to manufacturers. This lack of clarity is likely to result in many devices entering the market without prior FDA review, even if such devices include functionality that FDA believes warrants special controls and premarket notification. We strongly recommend including additional information in the final rule to clarify what parameters, degrees, and methods of control and customization constitute "programming" of OTC hearing aids and consequently result in classification of the device as "self-fitting".

5. Quality System Requirements

Bose believes that the full Quality System Regulation ("QSR") under 21 C.F.R. Part 820 should apply to all hearing aids, including the OTC hearing aids contemplated by the Proposed Rule. We believe that robust QSR requirements help ensure safety and effectiveness and are appropriate for all medical devices, including OTC hearing aids.

During its April 2016 public workshop, FDA received input from stakeholders regarding the application of the QSR to hearing aids. Certain stakeholders suggested that FDA reduce the burdens of the QSR applicable to OTC devices as the provisions are overly burdensome, while others stated that the current requirements are important and do not pose a burden. The President's Council of Advisors on Science and Technology ("PCAST") argued both in its October 2015 report entitled "Aging America & Hearing Loss: Imperative of Improved Hearing Technologies" and in the April 2016 workshop that "FDA should exempt this class of hearing aids from QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids."[10] On the other hand, NASEM argued that OTC hearing aids "[b]e subject to quality system regulation (QSR) requirements, but be considered for exemption from certain QSR requirements as determined by FDA to be appropriate for this category." [11]

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[9] Webinar, Hearing Aids and Personal Sound Amplification Products, December 07, 2021, *available at* https://www.fda.gov/media/155020/download
[10] Proposed Rule at 58155.
[11] *Id.*

We do not agree with the PCAST's position that OTC hearing aids should be exempted from the QSR in its current form. We agree with the FDA's statement in the Proposed Rule that application of the quality system for medical devices, as opposed to a more general quality systems intended for consumer electronics, is appropriate and necessary to provide a reasonable assurance of safety and effectiveness for hearing aids.[12] We appreciate the inclusion of this clarification in the Proposed Rule and appreciate FDA's willingness to solicit further feedback from stakeholders regarding the application of QSR requirements.

We believe that applying the QSR, including the associated design control requirements, to OTC hearing aids will best ensure the quality of these medical devices while also maximizing efficiency and innovation and provide an overall benefit to patients. We agree with the comments made by the Hearing Industries Association ("HIA") during the April 2016 workshop. During the workshop, HIA stated that "design controls support innovation by identifying risks and design problems early so we can concentrate resources on the most promising new ideas in technologies. Good documentation allows us to keep what works well and effectively investigate what does not. This continuous improvement model not only saves money and lessens time to market over the long run, it is the hallmark of ISO global quality standards, not just the QSR."[13] We agree with this position and believe that strong QSR requirements benefit patients by allowing us to identify problems, ensure consumer confidence in our devices, and focus on innovation. Furthermore, we do not believe that compliance with the QSR is unreasonably costly for manufacturers or patients. The HIA noted that compliance with FDA regulations accounts for only a "negligible fraction" of total manufacturer revenues and that elimination of the QSR would not lead to significant savings by consumers.

During the April 2016 meeting, PCAST also argued that a failure in the design and/or manufacturing and performance of a hearing aid does not pose a health risk, and that the market forces in the consumer electronics industry coupled with the increased volume would be sufficient to protect consumer interests and the health of consumers.[14] We do not agree with this assessment. We believe that consumer interests could be harmed by the failure of a hearing aid to perform as intended, and that market forces alone may not be enough to ensure compliance. In the preamble to the QSR in 1996, FDA stated that preproduction design controls were adopted due to findings that a significant proportion of device recalls were attributed to faulty design.[15] The QSR helps ensure that manufacturers adhere to certain standards for validating and documenting compliance with design requirements. Additionally, it also provides an assurance to customers that devices will perform as intended when they are produced for commercial distribution. If OTC hearing aids do not adhere to design controls and other aspects of the QSR, consumers could lose confidence in the OTC hearing aid category overall.

Furthermore, if OTC hearing aid manufacturers wish to sell their products outside the United States, or to certain federal government agencies, they may be required to comply with ISO 13485 international quality standard for medical devices.[16] Although not identical to the QSR, ISO 13485 is generally similar to the QSR. Moreover, FDA is in the process of working towards more complete harmonization of the QSR and ISO 13485 through planned publication of a proposed rule updating the QSR.[17] Because many manufacturers likely will need to comply

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[12] *Id.* at 58165.
[13] Public Workshop at 377-378.
[14] *Id.* at 29.
[15] 61 FR 52602.
[16] *See* Public Workshop at 85.
[17] *See* FDA-TRACK, RIN 0910-AH99, Harmonizing and Modernizing Regulation of Medical Device Quality Systems.

with ISO 13485 in any event, eliminating or reducing the scope of QSR applicability to OTC hearing aids may be counterproductive: it will not benefit manufacturers, yet will leave FDA without authority to address quality system lapses that might arise.

For these reasons, Bose strongly suggests that FDA not exempt OTC hearing aids from the QSR framework that generally applies to medical devices.

6. CTA/ANSI Standards

Bose commends FDA's adoption of the CTA standard (ANSI/CTA-2051:2017) for the technical requirements of OTC devices. Although developed for consumer PSAPs, the CTA standard imposes measurement procedures and limits that will reasonably ensure safety and efficacy for OTC hearing aids. In contrast, and as FDA has noted, ANSI/ASA S3.22 (the technical standard for hearing aids) prescribes detailed technical measurements but has no performance requirements or limits. This is appropriate for prescription devices, since a professional can use these data to determine whether a device is a good fit to a particular patient. However, we believe that for an OTC device, without professional involvement, ANSI/ASA S3.22 is not helpful, and that the CTA standard is well suited for this purpose.

FDA has adopted the CTA's requirements for maximum output, frequency response bandwidth and smoothness, input and output distortion, self-generated noise, and latency. For each one of these measures, FDA has given arguments that are highly nuanced and detailed. They represent reasoned and practical balancing among differing goals. We concur fully with their arguments and their specific proposed requirements.

We have provided two additional recommendations below, which include (6.A) changing the self-generated noise limit to include the A weighting, and (6.B) expanding the allowance of couplers and permitting ear simulators and standard acoustic manikins.

6.A. The self-generated noise limit should be changed to include the A weighting, *i.e.*, to 32 dBA.

FDA indicates that it adopted the technical requirements from CTA-2051:2017. However, for self-generated noise, FDA has proposed a limit of 32 dB, whereas CTA specifies 32 dBA. Using the A weighting specified in the CTA would work better than the proposed limit of 32 dB. Without the A weighting, further specification of the bandwidth over which the measurement should be made is necessary, thus introducing potential complication and confusion between devices and manufacturers. Leveraging the well-established dBA metric sets a uniform standard that is appropriate and will be consistent across devices and manufacturers.

6.B. FDA should broaden the allowance of couplers, and permit ear simulators (*e.g.*, 711) and standard acoustic manikins (*e.g.*, HATS and KEMAR) for all the mandated technical requirements in order to enable valid electroacoustical measurements on OTC devices that leverage new technologies.

CTA-2051:2017 specifies the couplers to be used as follows: (a) Both 2 cc and 711 couplers are permitted for frequency response bandwidth and smoothness. (b) Only 2 cc is given for OSPL90, distortion, and self-generated noise. (c) No coupler indication is given for latency.

Although the standard was written only five years ago and was approved in January 2017, the standard did not anticipate some technological developments. For example, active noise cancellation ("ANC") provides significant benefits in consumer products and could well appear in future hearing aids. Optimizing ANC requires couplers that approximate the human ear (*e.g.*, 711). When placed on a 2-cc coupler (a hard metal enclosure), these systems are unstable,

precluding the ability to perform electroacoustic tests. Another example would be a form factor for hearing aid devices that could place speakers adjacent to the ear but not within the ear (similar to form factors that have been introduced in various consumer electronics products). It is unlikely these types of devices would be able to be fit to 2-cc or 711 couplers. However, they could likely be measured on a standard acoustic manikin (*e.g.*, HATS or KEMAR). Modifying the requirement would therefore provide the necessary flexibility to enable future innovation in OTC hearing aids.

CONCLUSION

In closing, Bose greatly appreciates and supports FDA's work on the Proposed Rule. We recognize that developing regulations for OTC hearing aids represents the first major re-write of the rules governing hearing aids since their inception in 1977, and we commend FDA's detailed and comprehensive approach to this task. As FDA works to finalize the regulations, we hope that our comments will be helpful and that the agency will consider the changes and clarifications we have recommended.

Respectfully,

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APPENDIX A: Technical Comment Regarding Proposed Output Limits for OTC Hearing Aids

For FDA's consideration, Bose Corporation offers the following technical comments regarding the proposed output limits discussed in the report titled, Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness. Consensus Paper from Hearing Care Associations (Aug. 2018), which is *available at* https://www.asha.org/siteassets/uploadedfiles/consensus-paper-from-hearing-care-associations.pdf.

The hearing-care groups' report recommends an OSPL90 limit of 110 dB SPL (2 cc coupler). However, there is no clear scientific consensus on what the maximum output limits of hearing aids should be, mainly because, for obvious ethical reasons, there have never been any large-scale prospective studies of effects of hearing aid output limits on noise-induced permanent threshold shift ("NIPTS"). Instead, the authors of the consensus statement have based their recommendation on the recent paper by Johnson,[18] which made use of Macrae's[19] method for predicting NIPTS in hearing impaired persons. The method considers exposure via hearing aids to sound that is analogous to that of industrial noise. For different levels of hearing loss described simply by their 4FPTAs, putative sound exposures given are applied. The sound exposures are described by their overall levels in a diffuse field and then converted to levels in the ear canal. The model calculates the new threshold arising from a given noise exposure. There were no experimental data collected. The model predicts that a person with 4FPTA of 55 dB HL will incur 3.5 dB of NIPTS, *i.e.*, a 3.5 dB increase to their existing 4FPTA, at an overall ear canal level of 111 dB SPL. The model also assumes this exposure level is continuous, i.e., that a user wears the hearing aid all day, and as for industrial noise, this incremental loss accrues after many years of use (decades). The consensus authors therefore took this value to be the maximum recommended OSPL90.

Use of the Macrae model is appropriate, although as stated above, no prediction method has been or can be adequately validated. Beyond that, however, the authors of the consensus statement have not applied the data or conclusions of the paper correctly to the problem of estimating maximum safe output of hearing aids. There are two important issues.

First, Johnson defined the threshold of damage as an NIPTS of 3.5 dB. This is a far lower threshold of damage than that used by either NIOSH[20] or the Occupational Safety and Health Administration ("OSHA")[21] (15 or 10 dB threshold shift, respectively). A threshold shift of 3.5 dB would not even be measurable using the standard clinical audiometric step of 5 dB. If Johnson had specified a threshold of NIPTS consistent with the standards governing permissible noise exposures, the estimated level at which NIPTS would occur would have been significantly higher.

Second, OSPL90 is measured using a pure tone input. It is necessary to convert the 111 dB broadband ear canal SPL (as assumed in NIPTS comments above) into expected output in a 2 cc coupler with a pure tone test input. The authors recognized the importance of this issue and wrote:

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[18] Johnson E (2017). Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss. International Journal Audiology 56(11): 829-836.

[19] Macrae JH (1994): Prediction of asymptotic threshold shift caused by hearing-aid use. J Speech Hear Res 37(6): 1450-1458.

[20] National Institute for Occupational Safety and Health (1998). Occupational Noise Exposure: Revised Criteria 1998. DHHS (NIOSH) Publication No. 98-126.

[21] Occupational Safety and Health Administration (1983). 29CFR1910.95 Occupational Noise Exposure: Hearing Conservation Amendment.

> *"… when a broadband signal (such as speech or music that includes energy over a broad range of frequencies) is presented to the hearing aid, the output of the hearing aid is the sum of the energy at all the frequencies. Indeed, the maximum output of the hearing aid will be limited by the peak OSPL90 at each frequency but summed across all the frequencies of interest. Thus, a sinusoid or a very narrow band of noise of the same spectral level presented at a 90 dB SPL level may have an overall output closely related to the value of the peak OSPL90. However, a broadband signal (such as speech or music) of the same spectral level at all frequencies will have an overall output level far exceeding the value of the peak OSPL90."*[22]

This is incorrect and reflects a fundamental misunderstanding of the relation between the maximum output for any single tone and that for a broadband signal. This issue was already noted by Johnson:

> *"The safe output SPLs in Table 1 are RMS levels so that peak levels 15 dB higher could be allowed to preserve the sound quality of incoming speech inputs so as not to clip the speech and perhaps allow higher peak levels for other inputs like music."*[23]

However, this is not considered in the consensus statement. Instead, the report indicates that broadband signals include many tones and, therefore, can cause hearing aid outputs far above that indicated by OSPL90. This is wholly incorrect. Broadband signals can be output from the hearing aid only at RMS levels that will be well below OSPL90. Even if they are allowed to be highly distorted (*i.e.*, clipped), they will still not exceed OSPL90.

The proper conversion between maximum level of a pure tone OSPL90 test signal and the estimated maximum safe level of speech in the ear canal is accomplished by first considering that speech (the presumed signal in the Macrae model and in the analysis performed by Johnson) has a crest factor (dB Ratio of instantaneous peak to RMS level) of 15 dB, whereas a pure tone has a crest factor of 3 dB. In order for a pure tone to produce the same peak level as speech at any given RMS level, the RMS level of the pure tone would have to be 12 dB <u>higher</u> than that of the speech. Even for the recommended maximum broadband output level of 110 dB SPL derived from the Johnson analysis, making this allowance for difference between the tonal test signal and the modeled broadband signal will yield OSPL90 close to 120 dB SPL.

It is also important to recognize that an output limit of 115/120 dB SPL does not mean these levels will be frequently presented to an individual. OSPL90 is tested with pure tones; it is the highest level achieved at any single frequency. For most hearing aids, it is the output level that can be achieved when the device becomes unstable and is overtaken by (unmanaged) feedback. Actual OSPL90 responses are frequency dependent, and this peak level is typically several dB higher than that at all other frequencies. These lower levels at other frequencies determine the highest level at which real-world signals can be played under normal operating conditions (*i.e.*, without feedback). Furthermore, as noted above, real-world signals are dynamic, unlike steady tones. Speech at a constant level has a crest factor of about 15 versus that of 3 dB for a tone. Music often has crest factors that are even higher. These crest factor differences (re: a tone) correspondingly decrease the highest level that these signals can be played without distortion (from clipping) and consequent poor sound quality. Therefore, due to the frequency dependence of OSPL90 and the above crest factors, an OSPL90 limit of 120 dB SPL will allow actual speech (and music) to be played only up to around 105 dB SPL. While listening at such levels is not common, it does occur occasionally, and the proposed OSPL90 limits of 115/120 dB SPL are needed to ensure there is adequate headroom for undistorted outputs in these situations.

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[22] Consensus Report at 15-16.
[23] Johnson at 835.

APPENDIX B: Technical Comment Regarding Proposed Gain Limits for OTC Hearing Aids

For FDA's consideration, Bose Corporation offers the following technical comments regarding the proposed gain limits discussed in the report titled, Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness. Consensus Paper from Hearing Care Associations (Aug. 2018), which is *available at* https://www.asha.org/siteassets/uploadedfiles/consensus-paper-from-hearing-care-associations.pdf.

1. The report considers two forms of moderate hearing loss, described as 55 dB (HL): (a) a flat loss of 55 dB across all frequencies, and (b) a sloping loss of 0 dB at 250 Hz, 10 dB at 500 Hz, 20 dB at 1000 Hz, 30 dB at 2000 Hz, and 55 dB at 4000 Hz and beyond. Sloping losses are overwhelmingly predominant, but the characterization of this loss as being 55 dB does not follow traditional definitions of hearing loss severity. The report describes this hearing loss as "moderate" because the *worst* point on the hypothetical audiogram is at 55 dB HL (at 4 kHz). This is highly unusual and potentially misleading. Hearing loss severity is typically quantified as an *average of thresholds across multiple frequencies.* Using the common four-frequency average (4FPTA, covering 0.5, 1, 2, and 4 kHz)[24], the sloping loss in their report would be 29 dB HL – near lower edge of a *mild* loss (*i.e.*, 25 – 40 dB HL). Alternatively, consider a hearing loss with a 4FPTA of 55 dB and a slope of 10 dB/oct from 500 to 4000 Hz. For a 50 dB sound pressure level ("SPL") input, the high frequency average (HFA, covering 1.0, 1.6, and 2.5 kHz) target gain is 29 dB, and the target at 4 kHz is 36 dB[25].

2. The report's gain targets include values (from NAL-NL2) for both new and experienced users. This is important because new hearing-aid users typically prefer – and NAL-NL2 prescribes – lower gains than that for experienced users. For the assumed 55 dB HL flat loss, a gain of 25 dB (HFA) is sufficient for new users. However, experienced users have HFA prescribed target gain reaching 29 dB for binaural use and 30 dB for monaural use.[26] While most OTC device users may begin as new users, with continued use they will become experienced users. Gain limits should not preclude meeting their evolving needs.

3. The report's proposed 25 dB gain limit does not acknowledge the variation in individuals' anatomy (head, torso, pinna, and ear canal) and the consequent variation in acoustic responses.[27] Specifically, for some individuals, a higher coupler gain may be required in order to achieve a desired target real-ear gain. Such acoustic variations can be up to 5 to 10 dB across different individuals.[28,29] A gain limit based on an average (*i.e.*, coupler) response would compromise the hearing benefit in an individual whose anatomy has less

[24] What the numbers mean: An epidemiological perspective on hearing. https://www.nidcd.nih.gov/health/statistics/what-numbers-mean-epidemiological-perspective-hearing

[25] NAL-NL2 v 2.0 (dll v2.15). Targets generated using the following characteristics: unspecified gender, experienced user, non-tonal language, bilateral fit, dual compression speed.

[26] Consensus Statement at 10 (Table 1).

[27] Denk, F, Ernst, SM, Ewert, SD, & Kollmeier, B (2018). Adapting hearing devices to the individual ear acoustics: Database and target response correction functions for various device styles. Trends in Hearing, 22: 1-19.

[28] Hawkins, DB, & Cook, JA (2003). Hearing aid software predictive gain values: How accurate are they? The Hearing Journal 56(7): 26-34.

[29] Azah, H, & Moore, BCJ (2007). The value of routine real ear measurement of the gain of digital hearing aids. J Am Acad Audiol 18: 653-664.

favorable acoustics. Indeed, corrections for these individual differences are a part of clinician-based best practices.[30]

4. Finally, the report's proposal ignores the widely-recognized large variation in user preference around the prescriptive targets. This preference is incorporated in hearing aid fitting best practices via a "fine tuning" session. In particular, individuals with the same hearing loss severity (i.e., the same 4FPTA) are known to have preferences for overall gain that span a 15 dB range, the top end of which exceeds their prescribed targets.[31] Thus, again, a limit based on an average across individuals does not accommodate variations among individuals.

[30] Almufarrij, I, Dillon, H, & Munro, KJ (2021). Does probe-tube verification of real-ear hearing aid amplification characteristics improve outcomes in adults? A systematic review and meta-analysis. Trends in Hearing, 25: 1-18.

[31] Keidser G, Dillon H, Carter L, & O'Brien, A (2012). NAL-NL2 Empirical adjustments. Trends in Amplification 16(4): 211-223, see Fig 1.