



January 13, 2022

Janet Woodcock, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

On behalf of the American Speech-Language-Hearing Association (ASHA), I write to comment on the U.S. Food and Drug Administration's (FDA) proposed rule to "establish a regulatory category for over-the-counter (OTC) hearing aids and to make related amendments to update the regulatory framework for hearing aids." ASHA appreciates the FDA's effort to promulgate regulations that set standards for OTC hearing aids while ensuring consumer protection. ASHA's comments are designed to further those goals while ensuring that consumers can benefit from the most appropriate hearing aids based on their individual circumstances.

ASHA is the national professional, scientific, and credentialing association for 218,000 members and affiliates who are audiologists; speech-language pathologists (SLPs); speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. ASHA is the national association representing the most audiologists across the country with our current membership totaling 13,727 audiologists. ASHA's vision is to make effective communication, a human right, accessible for all.

In 2018, ASHA joined the Academy of Doctors of Audiology (ADA), the American Academy of Audiology (AAA), and the International Hearing Society (IHS) in developing a consensus paper, *Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness*, that outlined five evidence-based recommendations related to the safety and effectiveness of this new regulatory type of device.<sup>1</sup> ASHA appreciates the positive aspects of the FDA's proposed rule that align with the consensus paper's five primary recommendations to:

1. establish product requirements appropriate for OTC hearing aids targeting mild-to-moderate hearing impairment;
2. define concise, outside-of-the-box labeling appropriate for OTC hearing aids, with strong recommendation to consult with a hearing health care professional;
3. define comprehensive, inside-the-box labeling appropriate for over-the-counter medical devices;
4. define the new OTC category so that it is easily comprehensible by consumers and in line with risk class requirements for safety and effectiveness; and
5. provide adequate provisions for consumer protection, in coordination with the Federal Trade Commission (FTC).

Given the significant impact this rule will have on hearing health and consumers with self-perceived mild-to-moderate hearing loss, ASHA strongly recommends that the FDA revise the proposed rule to strengthen shared goals of ensuring appropriate access, consumer protection, efficacy, and patient safety grounded in the most robust and up-to-date research from the field. Specifically, ASHA recommends a series of revisions that build on and reaffirm the five primary recommendations of the 2018 Consensus Paper in the context of the proposed rule.

## 1) Establish product requirements appropriate for OTC hearing aids targeting mild-to-moderate hearing impairment

### Maximum Power Output Limitation

**ASHA maintains that it is imperative to ensure the maximum output level of these devices is no greater than 110 decibels (dB) in sound pressure level (SPL)** for consumer protection, device efficacy, and patient safety. To help facilitate the FDA's goal of greater access and appropriate patient safety guardrails, it is important to note that the evidence base suggests a safe output SPL limit for an individual with maximum moderate hearing loss, which is the top range of candidacy for an OTC hearing aid, is no greater than 111 dB.<sup>2,3,4</sup> The maximum power output of a hearing aid is measured as the output of a device set to full volume with a 90 dB SPL input signal. This value is termed output sound pressure level 90 or OSPL90. The OSPL90 output limits in the proposed rule (115 dB SPL or 120 dB SPL if the device is equipped with a user-adjustable volume control) do not optimally align with the goal of protecting the consumer from the risk of permanent hearing damage.

The rationale cited in the proposed rule states that a 120 dB SPL limit (e.g., the decibel level of a jackhammer or jet engine) would allow a user 28 seconds to react before putting them at risk for noise induced hearing loss. This reaction time does not appear to fully take into consideration individuals with reduced cognition, mobility, and/or dexterity. Since the incidence of hearing loss increases with advancing age, it is likely that many OTC users will experience deficits in one or more of these areas.

Additionally, the proposed rule does not require devices to be equipped with a user-adjustable volume control; therefore, individuals may not be able to reduce the level of the sound to a safe and/or tolerable level in loud noise situations. Furthermore, individuals are often unable to self-determine when a prolonged exposure to over amplification can cause damage. Even if individuals may be physically able to remove their device or remove themselves from the situation, they may not know that they should for their safety.<sup>5</sup>

ASHA appreciates the FDA proposing to limit output of OTC hearing aids. However, ASHA strongly maintains that the proposed levels do not optimally protect the safety of consumers with mild-to-moderate hearing impairment. **ASHA recommends a maximum output of 110 dB for consumers with mild-to-moderate hearing loss, which aligns with best practices and evidence for consumer protections.**

### Gain Requirement

**ASHA recommends requiring a full-on gain limit of 25 dB.** This recommendation is based on a calculation of gain for adults with mild-to-moderate hearing loss using the most widely used prescriptive gain formula worldwide, NAL-NL2. This recommendation considers variables that influence desired gain such as configuration of hearing loss, user experience level, and mode of usage (monaural vs binaural). Excessive gain is problematic for many reasons including increasing an individual's risk of noise-induced hearing loss, tinnitus, and loudness discomfort. Too much gain, especially in the high-frequency range, may also cause acoustic feedback (or whistling) from the hearing aids. Beyond being unpleasant for the user and those around them, feedback can hinder one's ability to understand speech. If hearing aids are uncomfortably loud or have acoustic feedback, individuals will be less likely to use them.

ASHA understands the FDA's concern regarding "unduly constraining the design of effective devices." However, permitting gain greater than 25 dB will allow manufacturers to target individuals who do not meet OTC criteria, with greater degrees of hearing loss, who have more complex needs and are more likely to have additional medical conditions.<sup>6,7,8, 9,10,11,12</sup>

### Compression Strategy and Volume Control

ASHA values the FDA's acknowledgement of the safety benefits of input-controlled compression and a user adjustable volume control. **ASHA strongly urges the FDA to require input compression and volume control for all OTC hearing aids.** These safeguards, along with limiting output above 110 dB SPL recommended above, will significantly reduce individuals' risk of further hearing loss due to loud noise exposure. To ensure perceptual functionality, ASHA recommends that the volume control allows for at least 6 dB of potential adjustment to the output of the device. On average, individuals require a 3 dB change in signal intensity to perceive a change in loudness.<sup>11</sup> A 6 dB adjustment range would allow individuals to perceive both an increase and a decrease in output through use of their volume control, which will improve the efficacy and safety of the product. By implementing these safeguards, the FDA would help to ensure greater patient safety and increased access to OTC hearing aids by reducing the risk for irreversible ear and hearing damage and other health problems. For instance, other connected health problems related to cardiovascular disease, sleep disturbance, annoyance, and cognitive impairments have been shown to occur due to loud noise exposure.<sup>13,14, 15,16,17</sup>

### Other Product Requirements

ASHA appreciates the FDA acknowledging the risks of improperly fitting or poorly constructed devices causing harm and physical discomfort to consumers. ASHA strongly agrees that devices must be constructed using atraumatic materials and not sit deeper than the bony-cartilaginous junction of the user's ear. While recognizing and supporting the FDA's intention to not impede design innovation by restricting OTC hearing aids to one device style, ASHA recommends limiting the customization of earpieces to non-invasive (e.g., scanning) procedures.

A custom impression, using impression material, should not be obtained without the individual first undergoing a thorough visual (otoscopic) examination of the ear by a hearing health professional to rule out a medical pathology such as a hole in the ear drum or a history of surgery resulting in anatomical changes to the ear. Improper impression techniques or impressions taken when a medical pathology is present put the consumer at risk for permanent ear or hearing damage.<sup>18,19</sup>

## **2) Define concise, outside-of-the-box labeling appropriate for medical devices sold OTC, with strong recommendation to consult with a hearing health care professional**

Hearing loss is a serious and complex medical condition that affects roughly 48 million Americans.<sup>20</sup> It can significantly impact a person's overall health, physical safety, and quality of life. ASHA continues to maintain that hearing loss is best addressed in consultation with an audiologist—a health care professional who provides patient-centered care in the prevention, identification, diagnosis, and evidence-based treatment of hearing, balance, and other auditory disorders for people of all ages. Without the professional support of an audiologist, individuals who purchase an OTC hearing aid may not benefit from the full scope of technological support, holistic hearing health care, and audiologic rehabilitation that many with hearing loss require.

ASHA appreciates the proposed outside-of-the-box labeling advising consumers of the availability of professional services with a hearing health care professional. While recognizing the intent of making hearing aids available direct to consumers, ASHA recommends revising of the current labeling to place a stronger emphasis on the availability of professional services to individuals with any degree of hearing loss. The current proposed language suggests that only those individuals who have trouble hearing loud sounds (e.g., loud music, motor vehicles, power tools, or noisy appliances) should seek consultation with a hearing health care professional. While certainly not required, the recommendation to consult a hearing health care professional will improve a patient's device selection process and maximize the effectiveness of their device.<sup>21,22,23,24</sup> **ASHA recommends clearly acknowledging the value of obtaining an audiologic assessment prior to obtaining any type of hearing aid by clearly stating that:**

**“it is beneficial to seek consultation with a hearing health care professional before using any type of hearing aid, in order to ensure adequate suitability to your hearing needs and maximize benefit with the device.”**

While certainly not required, the recommendation to consult a hearing health care professional will improve a patient's device selection process and maximize the effectiveness of their device.

Individuals have trouble accurately self-diagnosing the degree of their hearing loss.<sup>25,26,27,28,29</sup> Specifically, younger individuals tend to overestimate their hearing loss, while older individuals tend to underestimate their hearing loss. ASHA agrees that clearly stated symptoms of mild-to-moderate hearing loss on the outside of the packaging will improve a user's ability to self-determine device candidacy, which will lead to increased consumer satisfaction. To better identify those who are not candidates for OTC hearing aids and who would be more appropriately served by prescription hearing aids, **ASHA proposes adding the following symptom of mild-to-moderate hearing loss in the list of functional descriptors:**

**“able to hear well in a quiet place when people speak at a normal, or slightly louder than normal level, but have difficulty following conversation in a noisy environment.”**

This text is adapted from the recommended functional classification systems from the Global Burden of Disease Expert Group on Hearing Loss and the World Health Organization's World Report on Hearing.<sup>30,31</sup>

Individuals with moderately severe hearing loss or greater are more likely to have trouble hearing in a quiet environment regardless of the volume level of the speaker. If individuals with greater than a mild-to-moderate degree of hearing loss utilize OTC hearing aids and do not perceive benefit, they may become frustrated with their devices and either use them with incorrect settings or stop using them altogether. In the absence of a federally regulated return policy, these individuals may be deterred from pursuing additional efforts to treat their hearing loss.<sup>32</sup>

### **3) Define the new OTC category so that it is easily comprehensible by consumers and in line with risk class requirements for safety and effectiveness**

ASHA understands the FDA Reauthorization Act (FDARA) of 2017 (P.L. 115-52) directs the FDA to establish a category of OTC hearing aids through rulemaking and to “clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a [OTC] device [...] and which products meet the definition of a personal sound

amplification product [PSAP].”<sup>33</sup> Clearly defining the device types and their intended applications will maximize user uptake, promote correct usage, and decrease consumer confusion. As evidenced in the findings from a recent ASHA commissioned YouGov Poll, the public knows very little about OTC hearing aids and their intended usage.<sup>34</sup>

ASHA recognizes that the FDA is not proposing to create a new device type, rather a device regulatory category. However, the proposed rule’s definition of OTC hearing aids could more clearly delineate how these devices, and their programming capabilities, will differ from PSAPs and prescription hearing aids. Such a change would ensure greater alignment with our shared goals of ensuring appropriate access, consumer protection, efficacy, and patient safety.

The proposed rule states that OTC hearing aids, “would need to include tools, tests or software, or some combination of those features, sufficient to customize the device to meet the user’s hearing needs” and have, “the ability for a layperson to perform such activities.” While the document cites several examples of tools, tests, and software, such as a volume control or a program change button, it does not appear to explicitly require that the user have control of the output of the device. This ambiguity may allow manufacturers to market devices that only permit the user control of the physical fit of their device. For example, providing the user with more than one eartip option or configuration. ASHA recommends that OTC hearing aids must allow users the ability to adjust the output of their devices to meet their hearing needs. Furthermore, we firmly suggest that OTC hearing aids should be labeled as “self-fit” and come with tools, tests, or software, appropriate for lay users, that allow consumers to customize the physical fit and output of the device to meet their individual hearing needs. Research suggests that individuals are capable of successfully self-selecting satisfactory and beneficial hearing aid parameters.<sup>35</sup> **ASHA strongly maintains that requiring OTC hearing aids to be “self-fit” devices, and labeling them as such, will not only improve device efficacy, consumer satisfaction, and device uptake but also emphasize that they are self-fit medical devices intended to treat hearing loss, which would distinguish them from PSAPs.**

ASHA is also concerned by the estimation that approximately 90% of prescription hearing aids being fit today by hearing care professionals will be able to be relabeled as OTC hearing aids based on the proposed device specifications. Many of the prescription hearing aids audiologists fit are not appropriate for individuals with mild-to-moderate hearing loss without the involvement of an audiologist. **ASHA strongly believes that limiting the gain of OTC hearing aids to 25 dB will not only protect consumers from noise-induced hearing loss but also assist in clearly defining OTC hearing aids as a separate device category from prescription hearing aids, one that is only intended for individuals with mild-to-moderate hearing loss.** As such, ASHA reinforces our previous recommendation that a gain limit is critical in not only ensuring consumer safety but also clearly defining this new category of devices in a way that is comprehensible to consumers.

#### **4) Clarification on preemption of state laws and ensuring adequate provisions for consumer protection**

ASHA requests clarification from the FDA that the proposed rule does not preempt state laws or regulations requiring an audiological or medical evaluation before dispensing a prescription (non-OTC) hearing aid under § 800.30 and § 808.1 (as amended). The FDA's description of the rule indicates that such laws are allowed because previous preemption rulings made under part 808 "would no longer apply because the state or local requirements that differed from, or were in addition to, § 801.421 would no longer be preempted."

Many of the exemption decisions repealed under § 808 (as amended) concern state laws requiring an audiological or medical evaluation before dispensing a hearing aid. For example, under § 808.71, Massachusetts was granted an exemption to require an audiological evaluation for persons under the age of 18. By contrast, the agency denied exemption requests that would require audiological evaluations for adults. ASHA recognizes the FDA's need to repeal these decisions because the preemption standard under the FDA Reauthorization Act of 2017 (FDARA) differs from the Federal Food, Drug, and Cosmetic Act (FD&C Act) (P.L. 75-717), and the decisions may no longer be relevant under the OTC rule. Moreover, ASHA's understanding of the agency's intent is that state restrictions previously subject to an exemption ruling would now only be preempted if they apply to OTC hearing aids and OTC eligible consumers. However, other sections of the rule potentially conflict with this interpretation.

For instance, under § 808.1 (as amended), the FDA is clear that the preemption standard established under the FD&C Act still applies. Under this standard, a state may not establish a requirement that is "different from or in addition to" a medical device regulated under the act (e.g., a prescription hearing aid).<sup>36</sup>

Unfortunately, neither the FDA's amendments to § 808 nor its description of these changes clarifies whether state requirements consistent with the previous exemptions granted under § 808 must obtain a new exemption. Moreover, it's unclear whether state requirements that only apply to prescription (non-OTC) hearing aids would now be allowed because the preemption standard under § 808 no longer applies.

Further clarification from the FDA on this topic will help states and other stakeholders correctly interpret the rule. Therefore, **ASHA requests that the agency revise its guidance and provide examples of the types of state laws requiring an audiological or medical evaluation before dispensing a prescription (non-OTC) hearing aid that would not be subject to preemption under the rule.**

Thank you again for the opportunity to provide these comments and lend our members' expertise to help further inform the FDA's deliberative process. ASHA appreciates the elements of alignment between the currently proposed rule and our 2018 Consensus Paper. ASHA welcomes the FDA's consideration of these additional comments in the spirit of professional collaboration to strengthen this rule aligned to our shared goals of ensuring appropriate access, consumer protection, efficacy, and patient safety grounded in a strong research based epistemic foundation. If you or your staff have any questions, please contact Bill Knudsen, ASHA's director of education policy, at [bknudsen@asha.org](mailto:bknudsen@asha.org).

Sincerely,



Judy Rich, EdD, CCC-SLP, BCS-CL  
2022 ASHA President

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<sup>1</sup> American Speech-Language-Hearing Association. (2018). *Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness. Consensus Paper from Hearing Care Associations.*  
<https://www.asha.org/siteassets/uploadedfiles/consensus-paper-from-hearing-care-associations.pdf>.

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- <sup>2</sup> Johnson, E. (2017). *Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss*. *International Journal of Audiology*, 56(11), 829-836.
- <sup>3</sup> Tedeschi T, Jones C, Stewart E. Real world evidence on gain and output settings for individuals with mild-to-moderate hearing loss. *Hearing Review*. 2020;27(7):9-11.
- <sup>4</sup> Bisgaard N, Vlaming MSMG, Dahlquist M. *Standard audiograms for the IEC 60118-15 measurement procedure*. *Trends in Amplif*. 2010;14(2):113-120.  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4111352/pdf/10.1177\\_1084713810379609.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4111352/pdf/10.1177_1084713810379609.pdf)
- <sup>5</sup> World Health Organization (WHO). (2015). *Make Listening Safe*. [https://www.who.int/deafness/make-listening-safe/MLSBrochureENGLISH\(1\).pdf](https://www.who.int/deafness/make-listening-safe/MLSBrochureENGLISH(1).pdf).
- <sup>6</sup> Stevens, G., Flaxman, S., Brunskill, E., Mascarenhas, M., Mathers, C.D., & Finucane, M. (2013). *Global Burden of Disease Hearing Loss Expert Group. Global and regional hearing impairment prevalence: an analysis of 42 studies in 29 countries*. *Eur J Public Health*, 23(1),146–52.
- <sup>7</sup> Lin, F., & Ferruci, L. (2012). *Hearing loss and falls among older adults in the United States*, *Intern Med*. 172(4), 369-371.
- <sup>8</sup> Lin, F.R., Metter, E.J., O'Brien, R.J., Resnick, S.M., Zonderman, A.B., & Ferrucci, L. (2011). *Hearing loss and incident dementia*, *Arch Neurol*, 68(2), 214-220.
- <sup>9</sup> Lin, H-C., Chao, P-Z., & Lee, H-C. (2008). *Sudden sensorineural hearing loss increases the risk of stroke: a 5- year follow-up study*, *Stroke*, 39(10), 2744-2748
- <sup>10</sup> Lerman-Garber, I., Cuevas-Ramos, D., Valdés, S., Enríquez, L., Lobato, M., Osornio, M, Gómez-Pérez, F.J. (2012). *Sensorineural hearing loss- a common finding in early-onset type 2 diabetes mellitus*, *Endocr Pract*, 18(4), 549-57.
- <sup>11</sup> Bainbridge, K. (2010). *Diabetes and hearing impairment: an epidemiological perspective 19*.  
<https://www.asha.org/Articles/Diabetes-and-Hearing-Impairment-An-Epidemiological-Perspective/>.
- <sup>12</sup> Romlin, L. P., Rabelo, C. M., Lobo, I.F.N., Moreira, R.R., & Samelli, A. G. (2015) Interaction between diabetes mellitus and hypertension on hearing of elderly, *Codas*, 27(5), 428-432.
- <sup>13</sup> Emanuel, D.C., Letowski, S., & Letowski, T. (2009). The decibel. In P. Sabatini, A. Klingler, & E. Malakoff-Klein (Eds.) *Hearing Science* (pp. 129-147). Baltimore, MD: Lippincott Williams & Wilkins, a Wolters Kluter business
- <sup>14</sup> . Daniel, E. (2007). Noise and hearing loss: A review, *Journal of School Health*. 77(5), 225-231.
- <sup>15</sup> World Health Organization. Regional Office for Europe. (2011). Burden of disease from environmental noise: quantification of healthy life years lost in Europe. World Health Organization. Regional Office for Europe.  
<https://apps.who.int/iris/handle/10665/326424>.
- <sup>16</sup> World Health Organization. Regional Office for Europe. (2018). Environmental noise guidelines for the european region. World Health Organization. Regional Office for Europe.  
[https://www.euro.who.int/\\_data/assets/pdf\\_file/0008/383921/noise-guidelines-eng.pdf](https://www.euro.who.int/_data/assets/pdf_file/0008/383921/noise-guidelines-eng.pdf).
- <sup>17</sup> World Health Organization (WHO) (2021). World report on hearing. <https://www.who.int/publications/i/item/world-report-on-hearing>.
- <sup>18</sup> Jacob, A., Morris, T.J., & Welling, D.B. (2006). Leaving a lasting impression: ear mold impressions as middle ear foreign bodies. *Ann Otol Rhinol Laryngol*, 115(12), 912-916.
- <sup>19</sup> van den Boer, C., van Spronsen, E., Holland, C.T.Q., Ebbens, F.A., & Waterval, J.J. (2019). Clinical approach after complicated ear mold fitting: A case series of six patients and evaluation of literature. *Ann Otol Rhinol Laryngol*. 128(12), 1141-1146.
- <sup>20</sup> American Speech-Language-Hearing Association. (2021). *New Poll of U.S. Adults Reveals Widespread Inaction on Hearing Loss*. <https://www.asha.org/news/2021/new-poll-of-us-adults-reveals-widespread-inaction-on-hearing-loss/>.
- <sup>21</sup> Tedeschi, T.J., & Kihm, J. (2017). Implications of an over-the-counter approach to hearing health care: a consumer study. *Hearing Review*. 24(3), 14-22.
- <sup>22</sup> Humes, L. E., Rogers, S. E., Quigley, T. M., Main, A. K., Kinney, D. L., & Herring, C. (2017). *The effects of service-delivery model and purchase price on hearing-aid outcomes in older adults: A randomized double-blind placebo-controlled clinical trial*. *American Journal of Audiology*, 26(1), 53-79.
- <sup>23</sup> Leavitt, R., Bentler, R., Flexer, C. (2018). *Evaluating select personal sound amplifiers and a consumer-decision model for OTC amplification*. *Hearing Review*, 25(12), 10–16.
- <sup>24</sup> Bennett, R.J, Meyers, C.J., Eikelboom, R.H., Atlas, M.D. (2018). *Investigating the Knowledge, Skills, and Tasks Required for Hearing Aid Management: Perspectives of Clinicians and Hearing Aid Owners*. *American Journal of Audiology*, 27 (1), 67-84.
- <sup>25</sup> Kim, S.Y., Kim, H-J., Kim, M-S., Park, B., Kim, J-H, & Choi, H.G. (2017). Discrepancy between self-assessed hearing status and measured audiometric evaluation, *PLoS One*, 12(8), e0182718.
- <sup>26</sup> Ibid
- <sup>27</sup> Kamil, R.J., Genter, D.J., & Lin, F.R. (2015). Factors associated with the accuracy of subjective assessments of hearing impairment. *Ear Hear*. 36(1), 164-167.

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<sup>28</sup> Kiely, K.M., Gopinath, B., Mitchell, P., Browning, C.J., & Anstey, K.J. (2012). Evaluating a dichotomized measure of self-reported hearing loss against gold standard audiometry: prevalence estimates and age bias in a pooled national data set. *J Aging Health*, 24(3), 439-458.

<sup>29</sup> Nondahl, D.M., Cruickshanks, K.J., Wiley, T.L., Tweed, T.S., Klein, R., Klein, B.E. (1998). Accuracy of self-reported hearing loss. *Audiology*, 37(5), 295-301.

<sup>30</sup> Ibid.

<sup>31</sup> Ibid.

<sup>32</sup> Larry E. Humes. (2019). The World Health Organization's hearing-impairment grading system: an evaluation for unaided communication in age-related hearing loss, *International Journal of Audiology*, 58:1, 12-20, DOI:

[10.1080/14992027.2018.1518598](https://doi.org/10.1080/14992027.2018.1518598).

<sup>33</sup> FDA Reauthorization Act (FDARA) of 2017, Sec. 709. <https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf>.

<sup>34</sup> American Speech-Language-Hearing Association. (2021). *Americans want professionals' guidance on hearing care, know little about coming over-the-counter hearing aids (OTCs)*. <https://www.asha.org/news/2021/americans-want-professionals-guidance-on-hearing-care-know-little-about-coming-over-the-counter-hearing-aids-otcs/>.

<sup>35</sup> Sabin A.T., Van Tasell, D.J., Rabinowitz, B., & Dhar, S. (2020). *Validation of a self-fitting method for over-the-counter hearing aids*, *Trends in Hearing*, 24, <https://doi.org/10.1177/233121651990058>.

<sup>36</sup> Scope, 21 C.F.R. § 808.1(b).