American Pharmacists Association

Via Electronic Submission to: www.regulations.gov

January 18, 2022

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2021-N-0555, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Food and Drug Administration Staff:

The American Pharmacists Association (APhA) is pleased to submit our comments in support of the Food and Drug Administration's (FDA) proposal on "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids," published in the Federal Register on October 20, 2021 (86 FR 58150). Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA supports FDA's proposal to establish a new category of over-the-counter (OTC) air-conduction hearing aids that could be sold in pharmacies and other locations as well as through the mail and online. As FDA notes, hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life.[1] Unfortunately, despite the large number of affected individuals, only about one-fifth of people who could benefit use a hearing aid.[2] There are

[1] 86 FR 58150, p. 58151.
[2] Id.

several reasons for this underutilization, including cost and stigma.[3] On average, hearing aids cost more than $5,000 per pair,[4] while OTC hearing aids will likely cost less than $1,000.[5] APhA agrees with Congress[6], the Administration[7], and FDA that establishing a new category of OTC hearing aids could increase accessibility, competition, and innovation in the market, lower costs, and ensure the safety and effectiveness of both OTC and prescription hearing aids. APhA offers the following comments on the proposal and the important role pharmacists can play in helping adults to safely and effectively purchase and use OTC hearing aids:

OTC Pharmacy Sale and Leveraging of Pharmacists' Expertise and Services Can Increase the Accessibility and Utilization of Hearing Aids

According to the U.S. Bureau of Labor Statistics, there were only 13,700 audiologists in the U.S. in 2020.[8] Audiologists tend to locate in metropolitan counties with higher median household incomes, younger populations, and lower proportions of older adults reporting hearing difficulty,[9] thus leading to hearing care access issues for low-income, rural, and older adults. In contrast, pharmacists are one of the most accessible health care providers in the nation, with nearly 90% of Americans living within five miles of one of the nation's 88,000 pharmacies.[10] As proven during the COVID-19 pandemic, pharmacists are an underutilized and accessible health care resource who can positively affect patient care and health outcomes.

Pharmacists are uniquely situated to assess and assist consumers in selecting and safely and appropriately using OTC hearing aids -- as they do with other OTC devices sold at pharmacies such as blood pressure cuffs, blood glucose monitors, and pulse oximeters. When an OTC

[3] Id. at p. 58152.
[4] The White House. FACT SHEET: Executive Order on Promoting Competition in the American Economy. July 9, 2021, available at: https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/
[5] Galewitz, P. Cheaper OTC devices fill void left by FDA delay on hearing aids. NBC News. August 23, 2021, available at: https://www.nbcnews.com/health/health-news/cheaper-otc-devices-fill-void-left-fda-delay-hearing-aids-n1277294
[6] FDA Reauthorization Act of 2017 (FDARA). 21 U.S.C. 360j(q); see Pub. L. 115–52. FDARA directs FDA to establish a category of OTC hearing aids through rulemaking.
[7] The White House. Executive Order on Promoting Competition in the American Economy. July 9, 2021, available at: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/. The Executive Order directs HHS to publish a proposed rule on over-the-counter hearing-aids not later than 120 days after the date of the order.
[8] U.S. Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Audiologists, (last updated December 23, 2021), available at https://www.bls.gov/ooh/healthcare/audiologists.htm.
[9] Arrianna Marie Planey, Audiologist availability and supply in the United States: A multi-scale spatial and political economic analysis, Social Science & Medicine, Volume 222, 2019, Pages 216-224, available at: https://www.sciencedirect.com/science/article/abs/pii/S0277953619300152?via%3Dihub
[10] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

hearing aid is not appropriate, pharmacists can refer consumers to audiologists and other health care providers for further evaluation.

APhA and the pharmacy profession have been proactive in preparing for OTC hearing aid availability and demand. In 2019-2020, a panel of 14 individuals representing pharmacy[11], audiology[12], hearing aid manufacturers, and persons with hearing loss participated in a Delphi consensus building process that developed 26 competency statements that describe a framework for the knowledge, skills, and abilities needed for pharmacists to safely assist patients seeking OTC hearing aids.[13] All statements were mapped to the Pharmacists' Patient Care Process[14] of Collect, Assess, Plan and Implement, Follow-up: Monitor and Evaluate, Collaborate, and Communicate.[15]

In addition to the competency statements, the University of Pittsburgh has developed educational materials on red flag exclusions to hearing self-care, as well as a 2.5 hour continuing education course to train pharmacists to provide safe and effective guidance on OTC hearing aid devices.[16] APhA also plans to develop training and resources to educate pharmacists. With the availability of OTC hearing aids, pharmacists can join audiologists and other providers in becoming champions of hearing health care.

APhA offers additional comments on the proposed rule below:

Perceived Mild to Moderate Hearing Loss

APhA believes that it is important to restrict OTC hearing aids to those adults aged 18 and older with perceived mild to moderate hearing loss, preserving prescription hearing aids for minors and those with severe hearing loss. As FDA notes, hearing loss in younger people is varied and may result from conditions that warrant prompt diagnosis to avoid serious risks to health.[17] To

[11] Pharmacy representatives included representatives from the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy (AACP), and National Association of Chain Drug Stores (NACDS).
[12] Audiology representatives included representatives from the American Academy of Audiology, American Speech-Language-Hearing Association, Council of Academic Programs in Communication Sciences and Disorders, and the Hearing Loss Association of America.
[13] Berenbrok L., et al., Pharmacist competencies for over-the-counter hearing aids: A Delphi study. Journal of the American Pharmacists Association. 61 (2021), e255-e262. Available at: https://www.japha.org/article/S1544-3191(21)00041-8/fulltext
[14] Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process. May 29, 2014. Available at: https://jcpp.net/wp-content/uploads/2016/03/PatientCareProcess-with-supporting-organizations.pdf
[15] Berenbrok L., et al., Pharmacist competencies for over-the-counter hearing aids: A Delphi study. Journal of the American Pharmacists Association. 61 (2021), e255-e262, p. e260. Available at: https://www.japha.org/article/S1544-3191(21)00041-8/fulltext
[16] University of Pittsburgh. Championing Hearing Using Accessible Medication Experts at the Community Pharmacy 2.5 hour continuing pharmacy education course, available at https://pittprofessional.catalog.instructure.com/courses/champ
[17] 86 FR 58150, p. 58158.

minimize burdens on sellers, including pharmacies, APhA supports FDA's decision not to require age verification of purchasers.[18]

Outside Package Labeling (21 CFR 800.30(c)(1))

APhA supports proposed section 800.30(c)(1), outside package labeling requirements that provide consumers with the key information they need to know prior to purchasing an OTC hearing aid device, including:

- A conspicuous warning that the device is not for users younger than 18 years old;
- The symptoms of perceived mild to moderate hearing loss;
- Considerations for seeking a consultation with a hearing healthcare professional;
- Red flag conditions: Warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician, preferably an ear specialist;
- A web address and telephone number for consumers to access a digital copy or request a paper copy of all labeling, including the labeling inside the package, for that OTC hearing aid;
- Notice of manufacturer's return policy; and
- Statement of build condition.[19]

Given the significant out-of-pocket cost of OTC hearing aids, APhA believes it is appropriate to require the manufacturer to disclose its return policy on the package or state that it does not accept returns, as well as to indicate on the package whether the OTC hearing aid is used or rebuilt.

Labeling Inside the Package (21 CFR 800.30(c)(2))

APhA supports proposed section 800.30(c)(2), in-package labeling requirements that are designed to provide consumers with adequate information to ensure that those purchasing OTC hearing aids know when to seek professional intervention, how to use the device safely and effectively, where and how to obtain additional information or assistance, and how to report adverse events to FDA.[20] APhA also appreciates the requirement for manufacturers to make an electronic version of the user instructional brochure available for download without site or customer registration and without requiring purchase of any product or service, because we believe that registration would discourage some consumers from accessing this critical

[18] Id. at p. 58166.
[19] Id. at pp. 58177 - 58179.
[20] Id. at pp. 58160, 58179 – 58182.

information.[21] We welcome FDA's issuance of a separate comprehensive guidance document that will discuss labeling information and communicating that information with the goals of increasing transparency and choice to consumers.[22]

Labeling on the Device Itself (21 CFR 800.30(c)(3))

APhA also supports proposed section 800.30(c)(3) which requires that the labeling on the OTC hearing aid device itself include the serial number and symbol(s) for proper battery insertion (if applicable), as well as a removable tag indicating that the device has been used or rebuilt.[23]

Maximum Output Limits (21 CFR 800.30(d))

To ensure patient safety, APhA supports the establishment of a maximum acoustic output limit for OTC hearing aids in order to prevent injuries from overamplification of sound. However, APhA is not in a position to comment on section 800.30(d)'s proposed maximum OSPL90 output level of 115 dB or 120 dB SPL for an OTC hearing aid that implements input-controlled compression and user-adjustable volume control.[24]

Electroacoustic Performance Requirements (21 CFR 800.30(e))

As with maximum output limits, APhA supports FDA establishing electroacoustic performance requirements in order to provide reasonable assurance of safety and effectiveness of OTC hearing aid devices. As detailed in section 800.30(e)(1) – (5), these include:

- Output distortion control limits;
- Self-generated noise level limits;
- Latency;
- Frequency response bandwidth; and
- Frequency response smoothness.[25]

In addition, APhA supports the specification of performance test methods in order to establish a common baseline to allow for the comparison of electroacoustic performance across devices.[26]

[21] Id. at p. 58179.
[22] Id. at p. 58161.
[23] Id. at p. 58182.
[24] Id.
[25] Id. at pp. 58182 - 58183.
[26] Id. at p. 58164.

Design Requirements to Ensure Proper Physical Fit and Prevent User Injury (21 CFR 800.30(f))

As with electroacoustic performance and maximum output limit requirements, FDA's establishment of design requirements to ensure proper physical fit of OTC hearing aid devices is critical to ensuring patient safety. Specifically, APhA supports the establishment of design requirements in section 800.30(f)(1) – (4) including:

- Insertion depth;
- Use of atraumatic materials;
- Proper physical fit; and
- Tools, tests, or software allowing the lay user to control the device and customize it to the user's hearing needs.[27]

Quality System Requirements

APhA believes that the quality system (QS) requirements are important and looks forward to future rulemaking on this issue.[28]

Preemption Provisions (21 CFR 800.30(h))

APhA appreciates FDA's discussion and examples of the FDA Reauthorization Act's (FDARA) preemption of state and local regulation of OTC hearing aids, especially the agency's explanation that state (or a political subdivision) requirements related to certification and examination in order to sell OTC hearing aids would be preempted.[29]

Distinguishing between OTC Hearing Aids and Personal Sound Amplification Products (PSAPs)

As noted in the proposed rule, FDA does not consider personal sound amplification products (PSAPs) to be "devices" under the Food, Drug, and Cosmetic Act when they are not intended to aid a person with, or compensate for, impaired hearing and do not otherwise meet the device definition.[30] Instead, PSAPs are intended to accentuate sounds in specific listening

[27] Id. at p. 58183.
[28] Id. at p. 58165.
[29] Id. at pp. 58166 - 58168, 58183.
[30] Id. at p. 58154.

environments for non-hearing impaired listeners.[31] FDA's Draft Guidance on *Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products* provides examples of situations in which PSAPs are typically used, including hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations).[32] Since there is likely to be consumer confusion regarding the differences between PSAPs and OTC hearing aids, APhA encourages FDA to conduct a public education campaign on OTC hearing aids that includes information on the differences between the two types of devices.

Preventing the Sale of Counterfeit OTC Hearing Aids

As APhA knows from its work with the Alliance for Safe Online Pharmacies (ASOP Global) and the Partnership for Safe Medicines, counterfeit medicines and medical products are a serious concern and threat to patient health. In order to ensure patient safety, FDA and the Federal Trade Commission should take appropriate steps and enforcement actions to protect consumers from counterfeit hearing aids, including a public education campaign that educates consumers on safe purchasing practices and ways to ensure the authenticity of OTC hearing aid devices.

Conclusion

APhA supports FDA's proposal to establish a new category of OTC air-conduction hearing aids and the important role pharmacists can play in helping consumers to assess their need for and safely choose an OTC hearing aid device. If you have any questions or require additional information, please contact Karin Bolte, Director, Health Policy, at kbolte@aphanet.org or by phone at (202) 558-2727.

Sincerely,

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[31] Food and Drug Administration. Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff. October 20, 2021, p. 9. Available at: https://www.fda.gov/media/87330/download
[32] Id.