NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

January 18, 2022

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Submitted via regulations.gov

Re: Docket No. FDA-2021-N-0555 for "Establishing Over-the-Counter Hearing Aids"

Dear Dr. Woodcock,

The National Association of Chain Drug Stores (NACDS) commends the Food and Drug Administration (FDA) for its leadership in the nation's ongoing COVID-19 pandemic response, while continuing to forge ahead on additional high priority health needs of the American people. By issuing the proposed rule *Establishing Over-the-Counter Hearing Aids* ahead of the required deadline outlined in President Biden's recent Executive Order on Promoting Competition in the American Economy[1] and in correspondence with requirements of the FDA Reauthorization Act of 2017, FDA's continued, swift action on this issue will kickstart important, necessary, and timely improvements to hearing aid access across the nation, fostering meaningful impacts for the 15% of American adults (37.5 million) who suffer from hearing loss. As noted in the proposed rule, impacts may be particularly pronounced for people of color, rural Americans, low-income individuals, and others for whom barriers to hearing aid access may be especially burdensome.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

Emphasized during the COVID-19 pandemic, those affected by hearing loss have experienced uniquely damaging obstacles. For example, physical distancing and mask requirements worsen existing communication challenges by not only reducing speech volume, but also by denying lipreading ability and hindering the use of facial expressions.[2] In fact, 52% of individuals experiencing hearing loss say they feel less connected to friends and family as a result of their hearing loss during the pandemic.[3] Further, 70% of those with hearing loss say they are more aware of their hearing loss due to the pandemic, but promisingly, 47% say they are more eager to explore hearing loss solutions.

Over-the-Counter (OTC) hearing aid options have the potential to make these devices more easily accessible via retail and other outlets, including the nation's highly accessible and trusted community pharmacies. In fact, with tens of thousands of locations nationwide, most Americans live within 5 miles of a pharmacy, and many within 1 mile. Access to OTC hearing aid options at frequently visited retail outlets and pharmacies can help combat some of the known barriers,

[1] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/
[2] https://www.mayoclinicproceedings.org/article/S0025-6196(20)30843-0/fulltext
[3] https://www.hearingreview.com/hearing-products/accessories/infection-control/covid

such as cost and stigma, that have led to underutilization, with the opportunity to improve quality of life for those suffering and their families.[4, 5]

Therefore, NACDS strongly supports the FDA's proposed rule as it paves the way, as a critical first step, in meaningfully improving access to hearing aid care for the American people. NACDS urges the FDA to act swiftly in finalizing the rule to realize benefits for the public as soon as possible and without any further delays. NACDS also appreciates the opportunity to offer our perspectives on several issues outlined in the proposed rule with a lens toward helping to ensure the utmost accessibility for the public, while also preserving patient safety and effectiveness.

- **Minimum Age Requirements (Outside Labeling, Conditions for Sale):** NACDS agrees that outside packaging should include a conspicuous statement that OTC hearing aids are only intended for use by people 18 years and over, given that the cause of hearing loss in younger people is more likely to require further evaluation and diagnosis. However, NACDS strongly discourages FDA from considering requirements on sellers to verify the age of purchasers, given the negative impact such a requirement is likely to have on access. Today, most OTC products that require age verification have abuse and misuse potential, such as pseudoephedrine and dextromethorphan; additionally, age verification requirements have been used to prevent uptake and access to products known to be dangerous such as tobacco and alcohol. Therefore, using age verification requirements typically deployed to discourage access is likely to undercut the underlying public health goal that the proposed rule is working to achieve - in making hearing aids more accessible and promoting uptake. Additionally, age verification requirements broadly add friction in access and uptake, and may even promote stigma around these products, while also disproportionately hindering access for underserved populations, including those without government-issued identification, for example. Furthermore, consumers are accustomed to reviewing OTC labeling to learn about appropriate use, and pharmacies and their teams are accustomed to assisting their patients and customers in understanding appropriate use of OTC products. In this experience, outside labeling – without prohibition of sales and/or age verification requirements – would appropriately meet FDA's goals to improve access to hearing aids, without exacerbating stigma or otherwise introducing unnecessary barriers to uptake. At the same time, conspicuous labeling without prohibition of sales can help protect the health of people younger than 18.
- **Battery Information (Outside Labeling):** While many hearing aids may come with rechargeable batteries, for the best user experience, NACDS recommends FDA consider requiring that hearing aids packaged without the necessary batteries include that information on the outside labeling – including a conspicuous statement that batteries are not included with compatible battery information, so purchasers can acquire the necessary batteries for use. Not including the necessary battery information on the outside package may result in purchasers discarding without using the device they just purchased or leaving the device in the "dresser drawer." For those new to hearing aids, this information could be critical for initial use and uptake.
- **Manufacturer Return Policy (Outside Labeling):** NACDS agrees with FDA's proposal to require manufacturers to disclose their return policy on the outside labeling/package of OTC hearing aids, or if none, state that the manufacturer does not accept returns. Also, these statements should make certain to clearly emphasize the manufacturer's return policy, in addition to providing clear step-by-step instructions for consumers to return products directly to the manufacturer, if a return policy exists. Providing clear information and instructions for consumers on a manufacturer's return policy, including how the manufacturer's policy may be separate from a return policy at the retail location where the product was purchased, will help to avoid confusion with consumers that a manufacturer's return policy could be honored at a retailer and vice versa. Additionally, the FDA believes that state/local requirements for retailers to accept returned OTC hearing aids would help promote commercial activity involving the devices. However, NACDS challenges the FDA to consider that these requirements could potentially disincentivize retailers to sell the products, thereby restricting commercial activity.
- **Output Limits (Device Labeling):** NACDS supports the output limits and labeling considerations noted by FDA in the proposed rule to help ensure safety for consumers using these OTC devices, including reminders for proper

[4] https://jamanetwork.com/journals/jamaotolaryngology/article-abstract/2585381
[5] https://jamanetwork.com/journals/jamaotolaryngology/article-abstract/2627924

use or lack of use in loud listening environments. The limits outlined in the proposed rule will help to advance access for the mild to moderate hearing loss community, while helping to ensure safety. The proposed limits promote necessary safety precautions and will support access to this affordable option in hearing assistance for a broad moderate hearing loss population. NACDS opposes any effort to reduce the output limits in the final rule, which may only diminish the rule's impact for the patient population that may stand to benefit the most.

- **Performance Test Methods for Electroacoustic Performance Requirements to Help Provide a Reasonable Assurance of Safety and Effectiveness (Inside Labeling):** NACDS appreciates the outlined performance requirements to support effective and safe use of OTC hearing aid devices, especially in providing users with information that could help ease comparison between different devices using standardized baselines, tests, and measures. However the ability for consumers to compare products before purchasing may be limited given that these measures are proposed for inclusion in the inside labeling, and may not be accessible prior to purchase if the consumer does not have electronic access. To improve access to this information, FDA could consider recommending that short hyperlinks be provided to prospective users and also consider use of QR codes to prevent users from needing to manually enter a long URL to access the information. Moreover, in implementing the use of such standards across products, NACDS urges the FDA to promote expeditious implementation and use of such standards for purposes of meeting the requirements as proposed, as to not delay products being available for consumers.
- **Proposed Effective and Compliance Dates:** NACDS strongly emphasizes the importance of expeditious finalization and implementation of the proposed rule to help promote better access for the public as soon as possible, with a final rule published within 6 months of the close of the comment period – or even sooner if possible. Considering postponements that occurred earlier in the process wherein the proposed rule was delayed from being released by more than 1 year from the original deadline of August 18, 2020, expedited action is warranted. NACDS therefore encourages and appreciates any opportunity for FDA to streamline and efficiently effectuate implementation of the OTC hearing aid rule, limiting any further delays for the American people.

Conclusion:
Following the public comment period, NACDS urges the FDA to act swiftly to ensure better access is realized for those who need it in a timely manner. For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at sroszak@nacds.org or 703-837-4251.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President & Chief Executive Officer