



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

August 18, 2021

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

Via email: janet.woodcock@fda.hhs.gov

Re: Request for Expedient Issuance of Proposed Rule on Over-the-Counter (OTC) Hearing Aids

Dear Dr. Woodcock,

The National Association of Chain Drug Stores (NACDS) commends your leadership in the nation's ongoing COVID-19 pandemic response. While pandemic-related challenges persist, widespread vaccination efforts and corresponding decreases in case rates are providing a glimmer of hope for Americans as they begin to reunite and connect with friends and family after a tough year of isolation and other hardships. On the contrary, the hope of new access promised by the Over-the-Counter Hearing Aid Act of 2017 continues to be delayed. These delays are keeping millions of Americans who experience hearing loss without the access options they need to fully participate in and enjoy the beginnings of our nation's post-pandemic reopening.

NACDS urges the Food and Drug Administration (FDA) to quickly publish the long-anticipated proposed rule on OTC hearing aids for notice and comment, as outlined in President Biden's recent Executive Order on Promoting Competition in the American Economy.¹ The Executive Order directs the Department of Health and Human Services (HHS) Secretary to, not less than 120 days after the date of the order, publish for notice and comment a proposed rule on OTC hearing aids. To this end, we request this action be taken immediately ahead of the 120 day directive deadline of November 6, 2021. We are aware that competing priorities during the COVID-19 pandemic led FDA to miss the August 18, 2020 deadline to issue a proposed rule, and a final rule within 6 months of the close of the comment period on the proposed rule. FDA's swift action on this issue now will launch important, necessary, and timely improvements to hearing aid access across the nation.

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.

While the COVID-19 pandemic has introduced expansive and unprecedented challenges for most Americans, the 14% of American adults, nearly 28 million, affected by hearing loss, have experienced uniquely damaging obstacles. For example, physical distancing and mask requirements worsen existing communication challenges

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>

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.

OTC hearing aid options have the potential to make these solutions more easily accessible via retail and other outlets, including the nation's highly accessible and trusted community pharmacies. Hearing aids typically are not covered by health insurance, and these new regulations have the potential to greatly enhance access to these devices, thereby improving quality of life for Americans who are hard of hearing. Better access at frequently visited retail outlets and pharmacies can help combat some of the known barriers to uptake including cost and stigma,^{4, 5} and the promise of enhanced, direct access options for OTC hearing aids should not be unfairly delayed any longer.

NACDS urges the FDA to urgently take the next step in advancing access for consumers by issuing a proposed rule on OTC hearing aids for notice and comment immediately, and acting swiftly thereafter, to ensure better access is realized for those who need it. We would welcome the opportunity for a meeting to discuss this issue further. Please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at sroszak@nacds.org or 703-837-4251.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

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

² [https://www.mayoclinicproceedings.org/article/S0025-6196\(20\)30843-0/fulltext](https://www.mayoclinicproceedings.org/article/S0025-6196(20)30843-0/fulltext)

³ <https://www.hearingreview.com/hearing-products/accessories/infection-control/covid>

⁴ <https://jamanetwork.com/journals/jamaotolaryngology/article-abstract/2585381>

⁵ <https://jamanetwork.com/journals/jamaotolaryngology/article-abstract/2627924>