

January 18, 2022

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

Re: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids (FDA-2021-N-0555)

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the proposed rule to update the regulatory framework for over-the-counter (OTC) hearing aids. NCPA recognizes the importance of the work of the FDA to reduce barriers for licensed pharmacists to address the hearing loss of patients and to improve access to medical devices for those patients in a retail pharmacy setting.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$67 billion healthcare marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Reconfiguration of Hearing Aid Classification

NCPA supports the work of the FDA to alleviate concerns surrounding access to devices to improve mild to moderate hearing loss. As the agency notes, an estimated 30 million Americans suffer from various stages of hearing loss, which can lead to other significant health issues. While there is no cure for hearing loss, technologies have been developed to assist patients with hearing issues. As the technology has developed and the ability of patients to self-calibrate the devices has matured without the assistance of an audiologist, members of NCPA are well positioned to provide these services to the mild to moderate hearing loss patient population.

NCPA supports the regulatory framework the FDA has created to allow for OTC hearing aids which results in more significant adoption by patients and a lowering of cost barriers. In anticipation of the release of the FDA framework, NCPA has been educating members on possible opportunities, as well as potential barriers to entry, to meet the needs for those with mild to moderate hearing loss¹.

¹ America's Pharmacist, May 2020 "What's that Sound?" http://www.ncpa.co/issues/APMay20_WhatsThatSound.pdf

By permitting OTC hearing aids, the FDA is allowing patients with either limited financial means or limited access to traditional audiologists to be able to achieve an improvement in the quality of hearing and life.

Conclusion

NCPA greatly appreciates the opportunity to share our thoughts on the proposed rule on OTC hearing aids. After considering stakeholder input, NCPA strongly recommends the FDA move forward in the regulatory process to finalize the rule. Should you have any questions, please contact me at ronna.hauser@ncpa.org or (703) 838-2691.

Sincerely,

A handwritten signature in cursive script that reads "Ronna B. Hauser".

Ronna B. Hauser, PharmD
Senior Vice President, Policy & Pharmacy Affairs