U.S. FOOD & DRUG ADMINISTRATION

August 5, 2021

Angela Shoup, PhD, FAAA, FNAP
President
American Academy of Audiology
11480 Commerce Park Dr.
Reston, VA 20191

Dear Dr. Shoup,

Thank you for your July 16, 2021, letter to Health and Human Services Secretary Becerra. In general, the FDA's Center for Devices and Radiological Health (CDRH) has responsibility for the regulation of hearing aid devices, including the actions directed under Executive Order 14036, Promoting Competition in the American Economy (86 FR 36987, July 14, 2021), and described by the accompanying fact sheet. As such, your letter was referred to us to address your concerns.

The order directs the Secretary to issue proposed rules to allow the over-the-counter (OTC) sale of hearing aids within 120 days. More specifically, section 5(p)(i) of the Executive Order directs the Secretary to promote the wide availability of low-cost hearing aids by publishing a proposed rule as called for by section 709 of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52). FDARA provides certain requirements for those rules, and this response summarizes some of them as they relate to your concerns.

FDA is focused on implementing a science-based, comprehensive approach to hearing aid regulation. We note that the fact sheet stated that experts agree that a medical evaluation is not necessary, linking to a report by the National Academies of Sciences, Engineering, and Medicine. We do not, however, interpret this statement as dismissing the role of audiologists or to mean that audiologists and other hearing health professionals should have no role in the selection and use of OTC hearing aids. Moreover, we recognize that hearing loss is more complex than the loss of volume, and that users may derive more satisfaction from the use of OTC hearing aids under the direction of hearing health professionals such as audiologists.

Nonetheless, even though a user may benefit more from the use of OTC hearing aids with the involvement of an audiologist, depending on the circumstances, we would agree that a medical (or other hearing) evaluation prior to purchase is not always

necessary for many people. Further, section 709 of FDARA specified that OTC hearing aids will be available without the supervision, prescription, or other order, involvement, or intervention of a licensed person (21 U.S.C. § 360j(q)(1)(a)(v)). Thus, by law, a consumer will be able to purchase an OTC hearing aid before visiting a licensed person such as an audiologist. However, as with OTC treatment options for other conditions, we do not view the OTC availability of hearing aids as devaluing professional services. Indeed, we expect that audiologists and other hearing health professionals will continue to play an important role helping consumers to navigate treatment options, including OTC hearing aids.

We will publish the proposed rule in the Federal Register and announce its publication, for example, through email and social media. The proposal will provide instructions, including the date by which you would need to submit comments for FDA to consider. FDA will review the timely comments on the proposed rules and address them in developing the final rule.

Thank you for reaching out and sharing your perspective with us. As always, we especially value input from stakeholders with relevant clinical experience. If you have additional questions, please contact me, Eric A. Mann, M.D., Ph.D. at Eric.Mann@fda.hhs.gov or (301) 796-5620.

Sincerely,

Eric A. Mann -S

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