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May 6, 2016

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Regulatory requirements for hearing aid devices and personal sound amplification products (Docket No. FDA-2013-D-1295)

Dear Commissioner Califf:

Thank you for the opportunity to comment on policy regarding hearing aids and personal sound amplification products (PSAPs). AARP, with its nearly 38 million members in all 50 States and the District of Columbia, Puerto Rico, and U.S. Virgin Islands, is a nonpartisan, nonprofit, nationwide organization that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse.

Part of our mission is ensuring older Americans continue to lead active and engaging lives. A person's ability to hear greatly affects how they interact with other people, loved ones, and the environment around them. Difficulty hearing creates a barrier to social interaction, and can have a negative health impact. Roughly 40 percent of the over-60 population experiences hearing loss. Unfortunately, hearing aid usage by those experiencing hearing loss is very low, with only about 20 percent of those affected using a hearing aid.¹ A significant factor in the lack of utilization is the cost of hearing aids – which average over \$2,000 per ear. Cost and other factors, such as access and social stigma, prevent people from using these life-altering technologies.

Therefore, we support making PSAPs more widely available and removing the stigma associated with technologically-assisted hearing. While not appropriate for everyone and in all cases, PSAPs can help many individuals in their daily lives by enhancing their sense of hearing. We urge you to withdraw the Food and Drug Administration draft

guidance of November 7, 2013, which unnecessarily limits consumers' ability to access PSAPs.

AARP believes consumers should have access to affordable technologies which can improve their daily living. The November 7, 2013, draft guidance is a barrier for innovative hearing technologies coming to market. Additionally, we support further policy reforms which would encourage new technological developments and increase consumer choice. We strongly encourage you to consider the President's Council of Advisors on Science and Technology's (PCAST) recommendations from October 2015. These include adopting distinct rules for "basic" hearing aids; providing consumers with a copy of their audiogram and audio profile; and allowing consumers to authorize hearing-aid vendor access to test results and audio profiles. These reforms would help create a more consumer-friendly market for hearing devices.

AARP appreciates this opportunity to provide comments on hearing aid devices and personal sound amplification products. If you have any questions, please feel free to contact Andrew Scholnick of our Government Affairs staff, at ascholnick@aarp.org or 202-434-3770.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a long horizontal flourish extending to the right.

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs

¹ Policy Solutions for Better Hearing, Christine Cassel, MD; Ed Penhoet, PhD; Robert Saunders, PhD, *JAMA*. 2016;315(6):553-554.