AARP, on behalf of our nearly 38 million members and all older Americans nationwide, appreciates the opportunity to comment on this proposed rule establishing a new category for over-the-counter (OTC) hearing aids. AARP strongly supports the creation of this new category, and we commend the FDA for its thoughtful approach and prioritizing the needs of consumers in these draft regulations. Our comments focus on further strengthening consumer rights and protections.

As part of our mission, AARP works to ensure older Americans continue to lead active and engaging lives. A person’s ability to hear greatly affects their overall well-being including how they interact with other people, loved ones, and the environment around them. As you know, hearing loss is a substantial problem, affecting more than 30 million Americans. Difficulty hearing not only creates a barrier to social interaction, but can also have a negative health impact. Left untreated, hearing loss can negatively affect older people’s quality of life by preventing them from engaging with others, leading to social isolation and limiting ability to work. Hearing loss also has been associated with depression, dementia, cognitive decline, and poorer physical functioning. Unfortunately, hearing aid usage by those experiencing hearing loss is very low, with only about 20 percent of those affected using a hearing aid. A significant factor in the lack of utilization is the cost of hearing aids – which average over $2,000 per ear. In addition to cost, other factors such as access and social stigma prevent people from using these life-altering technologies. OTC hearing aids would help alleviate many of these burdens.

As you finalize the OTC hearing aid regulations, we make the following recommendations:

**Prioritize safety**

AARP believes consumers have a right to goods and services that are safe, appropriately tested, and labeled with warnings of possible risks. We support the proposed inclusion of warnings listed on the outside of the OTC hearing aid package and the indications for who should use this product and for what purposes in proposed subsection 800.30(c)(1). However, while the required
warnings and indications appropriately display who the device is for, the proposed format minimizes who the device is not for. Consumers will very likely read the bulleted description of mild to moderate hearing loss and believe that they meet these criteria, while glossing over the subsequent paragraph on reasons to seek professional help. We recommend more clearly differentiating between mild to moderate hearing loss and more significant hearing loss. For example, the “advice of availability of professional services” in proposed subsection 800.30(c)(1)(C) could be displayed in the same bulleted format as the list of symptoms for mild to moderate hearing loss and the list of red flag conditions requiring medical care and further emphasize that “this device may not be useful for more significant hearing loss or complicated hearing needs.” A consistent bulleted format is easier for the consumer to read and would more likely be perceived as a checklist of criteria to meet rather than a suggestion to be dismissed.

**Foster transparency**

AARP also believes consumers should receive understandable and accurate information about goods and services in a clear and useful format. We support FDA’s proposed requirement to include a website and telephone number on the outside of the package by which a prospective consumer could access a digital copy or request a paper copy of all labeling. We urge FDA to further specify that this website and phone number must be displayed in at least the same font size as other information on the package. It should not be buried in fine print.

Furthermore, the FDA should require that the copies of labeling information – including instruction manuals – that are available via the website or phone number also be available in large print and in an array of languages.

**Protect the right to redress**

AARP similarly believes consumers have the right to accessible, appropriate, and adequate redress when products or services do not work or cause harm. This includes the ability to return medical equipment that does not meet their health care needs. We are dismayed that FDA is allowing OTC hearing aid manufactures to not accept returns. FDA acknowledges elsewhere in the proposed rule that these devices can be refurbished and resold, which indicates that the device does not become unusable, worthless, or otherwise tainted to the manufacturer once it is purchased by a consumer. Accepting returns is an important consumer protection and is not a hardship for manufacturers.

FDA further elaborates that “prospective users of OTC hearing aids may be unsure whether an OTC hearing aid will meet their hearing needs” and that without a return policy a person may forgo using a beneficial technology rather than risk purchasing a device that winds up unused in the “dresser drawer.” Not being able to return a defective or not-useful product discourages people from trying something that might help. We urge FDA to require OTC hearing aid manufacturers to accept returns of their product within at least 60 days of purchase.
Conclusion

Thank you for the opportunity to comment on the proposed regulations establishing an over-the-counter hearing aid category. AARP looks forward to these devices assisting millions of older Americans to lead fuller, more connected lives. If you have any questions or need more information, please feel free to contact me or Andrew Scholnick of our Government Affairs staff at 202-434-3770 or ascholnick@aarp.org.

Sincerely,

[Signature]

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs