



# ALL ABOUT THE FDA PROPOSED OVER-THE-COUNTER HEARING AID RULE

Within the FDA's proposed rule for over-the-counter (OTC) hearing aids, there are few areas of concern that have the potential to negatively impact patients. *Join us in encouraging the FDA to Listen Carefully and put patients first.*

## THE PROPOSED RULE



### Puts the health and safety of hearing aid users at risk.

- The proposed rule gives the FDA few tools to enforce age restrictions and would define the new device in a way that poses safety risks to the public.
- It puts the responsibility on users to self-diagnose “mild-to-moderate” hearing loss, without proper labeling guidance.
- Sound is measured in decibels (dB). The proposed rule allows amplification in OTC hearing aids of up to 120 dB, about the noise level of a chainsaw.



### Lumps hearing aids in with other consumer electronics.

- The proposed rule throws into question state and local consumer protections.
- It creates minimal federal protections for OTC hearing aid consumer.

## THE SOLUTION

These decisions pose a safety risk not only to those with severe hearing loss, but also to American consumers with near-normal hearing, who may overcorrect by using powerful new OTC products.

To minimize safety risks, the FDA should **impose a gain limit of 25 dB and an overall output limit of 110 dB.**

In addition, the FDA should validate proposed labeling statements to ensure users can accurately self-diagnose their level of hearing loss.

The final rule should require warranties and returns as conditions of sale for all hearing aids – something that is more critical with the creation of an OTC category of hearing aids.

The final rule should retain restricted device status for OTC and non-OTC hearing aids to ensure a consistent, federally mandated standard of protection while preserving additional protections at the state and local level.

*We encourage you to join us and submit public comments to make sure the FDA gets hearing health solutions right.*

