



---

Hearing aids are defined as class I and class II wearable sound-amplifying devices intended to compensate for impaired hearing. The FDA proposes to realign hearing aids classification regulations by sound conduction mode so that legacy air-conduction hearing aids, wireless air-conduction hearing aids, and self-fitting air-conduction hearing aids would be under one classification regulation and bone-conduction hearing aids would fall under a separate classification regulation.

---

Under the proposed rule, the outside of an OTC hearing aid package must include information for proper consumer safety and device efficacy, including proposed statements outlining the following:

- < A conspicuous warning that the device is not for users younger than 18 years old;
- < The symptoms of perceived mild-to-moderate hearing loss;
- < Considerations for seeking a consultation with a hearing healthcare professional; and
- < Red flag conditions: Warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician.

The FDA is also proposing that manufacturers clearly disclose their return policy. The regulation does not propose requiring a return, only that conditions for return, if returns are allowed, be disclosed.

There will also be certain labeling requirements for inside the OTC hearing aids package. These will include the red flag conditions and warnings about age. They will also include:



Under the proposed rule, hearing aids that do not meet the definition of, or requirements for, OTC would all be prescription devices and no longer be restricted. Specifically, hearing aids will be either prescription or OTC.

---

Under the proposed rule, the FDA interprets the FDARA as preempting certain kinds of professional or establishment requirements. For example, many states have established definitions for hearing aid fitters, dispensers, or other sellers and servicers. Identification as a hearing aid 'dispenser' would not imply licensure. However, identification as an audiologist or hearing aid fitter may imply licensure and be subject to State requirements that apply to audiologists or hearing aid fitters.

An entity that advertises itself as a hearing aid dispenser cannot be required to obtain specialized licenses to engage in selling OTC hearing aids. However, an entity which only sells OTC hearing aids but advertises as a licensed dispenser even though licensing is not required to sell OTC hearing aids would be subject to