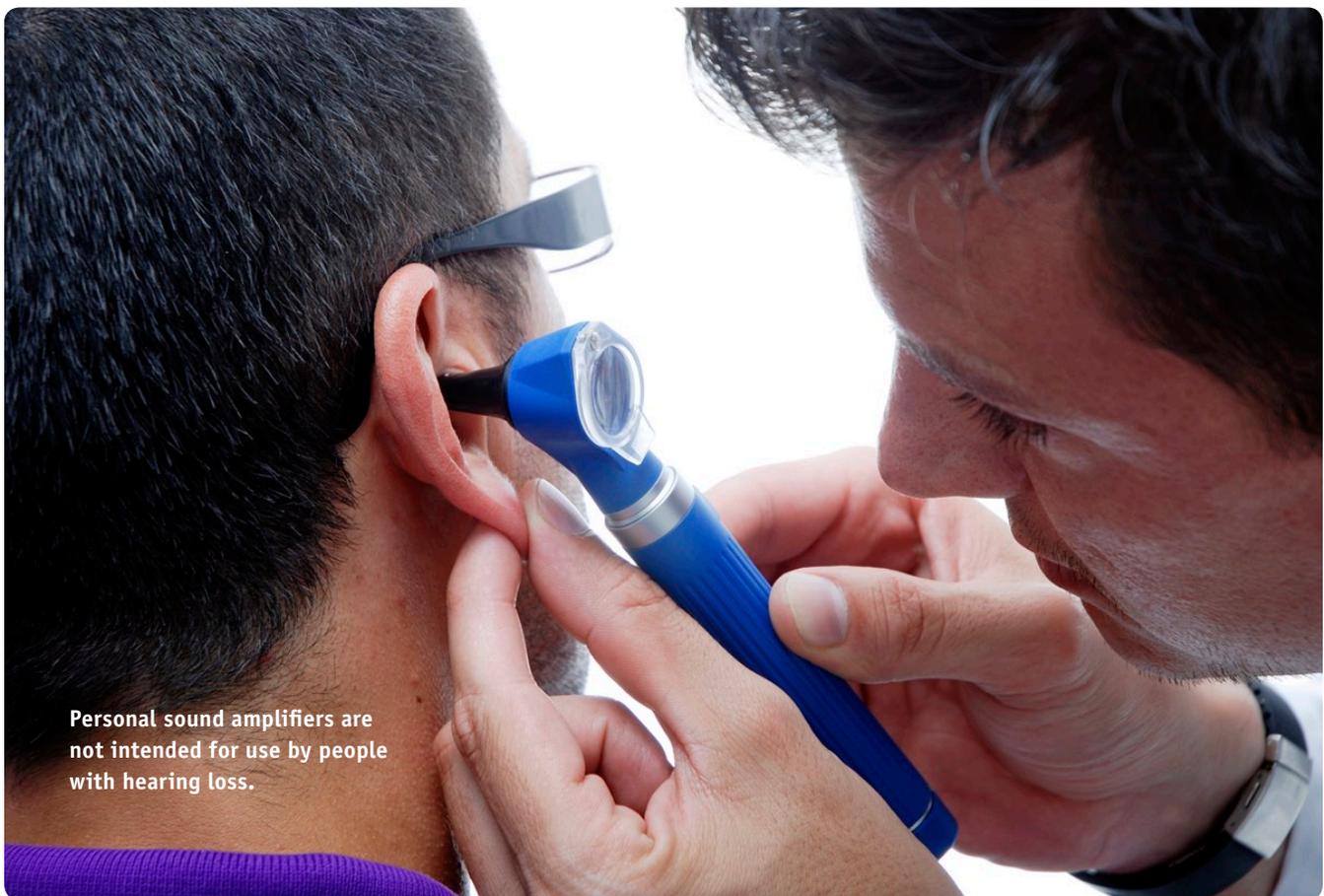


Hearing Aids and Personal Sound Amplifiers: Know the Difference



Personal sound amplifiers are not intended for use by people with hearing loss.

You've likely seen them advertised on television—small electronic sound amplifiers that allow users to enjoy nighttime TV without disturbing sleepers, or to hear their toddlers from many yards away.

While these personal sound amplifiers may help people hear things that are at low volume or at a distance, the Food and Drug Administration (FDA) wants to ensure that consumers don't mistake them—or use them as substitutes—for approved hearing aids.

"Hearing aids and personal sound amplification products (PSAPs) can both improve our ability to hear

sound," says Eric Mann, M.D., Ph.D, deputy director of FDA's Division of Ophthalmic, Neurological, And Ear, Nose, and Throat Devices. "They are both wearable, and some of their technology and function is similar."

Mann notes, however, that the products are different in that only hearing aids are intended to make up for impaired hearing.

PSAPs are intended for non-hearing-impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities.

He says consumers should buy a personal sound amplifier only after ruling out hearing loss as a reason for getting one. "If you suspect hearing loss, get your hearing evaluated by a health care professional," he adds.

Choosing a PSAP as a substitute for a hearing aid can lead to more damage to your hearing, says Mann. "It can cause a delay in diagnosis of a potentially treatable condition. And that delay can allow the condition to get worse and lead to other complications," he says.

Treatments for impaired hearing can be as simple as removal of a wax plug in the doctor's office or, in rare cases, as serious as a major surgery to remove a tumor or growth in the middle or inner ear, says Mann.

How They Differ

In March 2009, FDA issued guidance describing how hearing aids and personal sound amplifying devices differ.

The recently issued guidance defines a hearing aid as a sound-amplifying device intended to compensate for impaired hearing.

PSAPs are not intended to make up for impaired hearing. Instead, they are intended for non-hearing-impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities.

The difference between PSAPs and hearing aids are among the topics

covered in a new Web page devoted to hearing aids that FDA launched on October 20, 2009.

Signs of Loss of Hearing

Mann says that consumers who suspect they suffer from hearing loss should obtain a thorough medical evaluation, preferably by an ear specialist, to identify any medically or surgically treatable causes of hearing loss. Persons exhibiting symptoms of hearing loss should see a doctor or hearing health care professional to have their hearing tested.

You may have hearing loss if

- people say you are shouting when you talk to them
- you need the TV or radio turned up louder than other people do
- you often ask people to repeat themselves because you can't hear or understand them, especially in groups or when there is background noise
- you can hear better out of one ear than the other
- you have to strain to hear
- you can't hear a dripping faucet or a high note of a violin 

For More Information

Guidance for Industry and FDA Staff
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm127086.htm

FDA: Hearing Aids
www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/default.htm

Hearing Aids Information from the National Institutes of Health
www.nidcd.nih.gov/health/hearing/hearingaid.asp

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates), which features the latest on all FDA-regulated products.