

What is the difference between a hearing aid and a personal sound amplifier?

Hearing aids are designed to compensate for a defined hearing loss. Personal sound amplification products (PSAPs) are designed to assist individuals without hearing loss to magnify environmental sounds.

- U.S. Food & Drug Administration (FDA) definitions stipulate that hearing aids are designed to provide compensation for hearing impairment whereas personal sound amplifiers are for individuals with normal hearing who seek amplification for environmental sounds for recreational purposes.
- Personal sound amplifiers are not regulated by the FDA. Because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the Food, Drug and Cosmetic Act. As such, there is no regulatory classification, product code, or definition for these products.
- Hearing aids are considered medical devices under the FDA and must comply with labeling requirements; may be purchased by a consumer only with a medical evaluation (or appropriate waiver); and may be subject to premarket review.
- Personal sound amplifiers are not programmed and designed to address specific hearing loss needs and are simply magnifiers of sound, much like a magnifying glass can help a person with normal vision see small print in the newspaper, for example.
- Hearing aids are dispensed by an audiologist who has the ability to personalize and adjust these sophisticated devices for an individual's hearing loss and hearing needs. Personal sound amplifiers are not adjusted for you specifically and may work only in a few instances by providing simple magnification of sound.
- Consumers should be aware that some advertising and marketing may misrepresent personal sound amplifiers as hearing aids. To report deceptive business practices, you can contact any of the following groups: Federal Trade Commission, Your state Attorney General, Better Business Bureau, Your local consumer protection office.

See the FDA's Consumer Updates on Personal Amplifiers for more information: <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM187224.pdf>

Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products
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