

Subject: Personal Sound Amplification Products (PSAPs)

- 1 Whereas, hearing aids are designed to compensate for a diagnosed hearing loss, and
- 2 Whereas, PSAPs are designed to be used by individuals with normal hearing to magnify
3 environmental sounds, and
- 4 Whereas, PSAPs are not specifically adjusted for each individual and may work only in certain
5 situations by providing simple and general amplification of sound, and
- 6 Whereas, hearing aids are dispensed by an audiologist who has the education and training to
7 investigate if serious medical conditions are present, make proper referrals for treatment, and
8 adjust sophisticated hearing aids to manage the individual's hearing loss and specific
9 communication needs, and
- 10 Whereas, PSAPs are simple magnifiers of sound, much like a magnifying glass can help a person
11 with normal vision see small print in the newspaper, and are not programmed or designed based
12 on each individual's needs, and
- 13 Whereas, PSAPs are not intended to treat, cure or mitigate hearing loss and they are not medical
14 devices (such as hearing aids) as defined in the Food, Drug and Cosmetic Act, and
- 15 Whereas, there is no regulatory classification, product code, or definition for PSAPs and they are
16 not in any way specifically regulated by the FDA but are subject to applicable guidance of the
17 Radiation Control for Health and Safety Act of 1968, under which the FDA regulates electronic
18 products that emit sonic vibrations and manufacturers of PSAPs must report defects and adverse
19 events and take other measures described in 21 CFR Part 1003, and
- 20 Whereas, many products which closely meet the definition of hearing aids are being marketed as
21 PSAPs to avoid compliance with federal hearing aid regulations, and
- 22 Whereas, consumers should be aware that some advertising and marketing for PSAPs may
23 misrepresent them as hearing aids, or hearing aids as PSAPs, although these products are not
24 interchangeable, and
- 25 Whereas, these devices are often sold directly to consumers as hearing aids through mail order
26 and via the Internet without explanation regarding the risk associated with purchasing the
27 instrument for treatment of impaired hearing, and
- 28 Whereas, PSAP manufacturers are under no legal obligation to clarify to consumers the
29 difference between a hearing aid and PSAP and may market these devices in a way that misleads
30 the consumer of the intended use of the device, and

31 Whereas, an amplifying device not fit by a trained professional may provide an inappropriate
32 level of amplification and could potentially cause damage to an individual’s hearing, and

33 Whereas, the FDA encourages all consumers who believe they have hearing loss to obtain a
34 diagnostic hearing evaluation and advice of a licensed physician or audiologist due to the
35 possibility of an existing medical condition, and

36 Whereas, use of a PSAP may delay diagnosis and treatment for a potentially treatable medical
37 condition, and

38 Whereas, the Academy asserts that the safest and most effective way for individuals with hearing
39 loss to obtain appropriate treatment and/or amplification for a hearing loss is through
40 intervention by an audiologist.

41 **RESOLVED**, that the American Academy of Audiology encourages consumers who are
42 experiencing hearing loss to consult an audiologist, and

43 **RESOLVED**, that the American Academy of Audiology will continue to educate and counsel
44 consumers that PSAPs are not a substitute for hearing aids, which are fitted specifically to each
45 individual and serve to compensate for a diagnosed hearing loss.

46 References:

47 FDA Consumer Update on Hearing Aids and Personal Sound Amplifiers
48 <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm185459.htm>

49 FDA Radiation Emitting Products
50 [http://www.fda.gov/Radiation-](http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/default.htm)
51 [EmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/default.htm](http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/default.htm)

52 Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and
53 Personal Sound Amplification Products February 25, 2009
54 [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm1](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm127086.htm)
55 [27086.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm127086.htm)

56 Hearing Aids and Personal Sound Amplifiers: Know the Difference
57 <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm185459.htm>

58 Ross, M. (2009). “What About that Thing on TV That Helps You Hear Better? It’s only \$14.99!”
59 Personal Sound Amplification Products versus Hearing Aids. Hearing Loss Magazine.
60 September/October 2009, 28-31.