AMERICAN ACADEMY OF AUDIOLOGY

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February 4, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

VIA ELECTRONIC SUBMISSION

RE: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff

Docket No. FDA-2013-D-1295

The American Academy of Audiology (the "Academy") is the world's largest professional organization of, by, and for audiologists, representing nearly 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research.

Below are the Academy's comments regarding the Food and Drug Administration (FDA) Draft Guidance for Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs), published in the Federal Register on November 7, 2013. We commend the Agency on its commitment to improving the quality of care for consumers seeking appropriate amplification and appreciate the opportunity to comment on the areas described below. We are pleased to see of some of the Academy's comments on this subject matter, submitted to the FDA in January 2013 following our meeting with agency officials, incorporated into this draft guidance.

The Academy's principal concern remains with advertising and marketing practices in which PSAPs are misrepresented as hearing aids, or hearing aids as PSAPs, when clearly these products are not interchangeable. Hearing aids are wearable, complex, sound-amplifying *medical* devices intended to compensate for impaired hearing and used solely for the treatment of patients with diagnosed hearing loss and are usually modified, adjusted and/or programmed to address the specific needs of the patient. Conversely, PSAPs are simple wearable, sound-magnifying electronic products with severely limited functionality, used primarily for recreational purposes, not treatment of hearing loss. Given the two distinct intended uses of each product, and the related level of regulatory oversight, marketing for these devices should appropriately and clearly convey to consumers under which category the corresponding product falls.

The intended use of each determines whether it is a medical device (hearing aid) or a simple electronic magnifier product (PSAP). The intended use *must* be established by labeling materials that accompany the product. Promotional materials that make claims or suggest the use of a PSAP as an option for consumers with diagnosed or suspected hearing loss, such as in the description of the types and severity of hearing loss, establish an intended use that would define the product as a medical device and therefore would be subject to the regulatory requirements for a hearing aid, as described in this guidance. We appreciate and agree with the specific labeling examples cited in this draft policy.

Lastly, the Academy would note two additional items of concern within the draft. First, the specific example in this guidance of using PSAPs for hunting is troublesome. PSAPs, by their simplistic design, are not able to compensate for the explosive sound pressure which emanates from guns used in hunting. Uncontrolled amplification coupled with loud noise produced from gunshots can increase the likelihood of the hunter acquiring noise-induced hearing loss and tinnitus requiring medical treatment. Second, tinnitus maskers are classified separately from hearing aids although some hearing aids now act, or have the ability to be used as, tinnitus maskers. The FDA might therefore consider their classification under the same category.

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The Academy appreciates the opportunity to comment on this draft guidance and remains apt and committed to any opportunities to work with the FDA in its efforts to improve the consumer experience in obtaining appropriate amplification. With the exception of the items noted above, we endorse prompt adoption of this draft guidance. Please contact Melissa Sinden, Senior Director of Government Relations, at 202.544.9335 or by email, msinden@audiology.org if you should need additional information or clarification regarding the Academy's comments.

Sincerely,

Bettie Borton, AuD
Board Certified in Audiology
President, American Academy of Audiology