Comments on:

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Draft Guidance for Industry and Food and Drug Administration Staff

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The document issued on November 9, 2013 is intended to supersede the document entitled “Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” published February 25, 2009. The 2013 draft document contains new language clarifying the definition of a PSAP, and new language referring to labeling that the FDA will consider as signifying that the intended use of a device is as a hearing aid. That new language is indicated in highlighted text below:

New language in the draft guidelines:

1. Introduction

A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. Hearing aids are usually programmed to address an individual's degree of hearing loss across sound frequencies to improve speech intelligibility. Additionally, hearing aids may be coupled acoustically or wirelessly to external electronic products such as televisions, MP3 players, and telephones. A hearing health professional (such as an audiologist or a hearing aid dispenser) is usually required to program and optimize the performance of hearing aids with these more complex features.

...PSAPs typically are simpler sound amplification devices with fewer features and less functionality than hearing aids, although some of the technology and functionality of hearing aids and PSAPs may be similar.
Labeling or promotional materials that make claims, or include language that suggests the use of a PSAP for hearing impaired consumers, establish an intended use for the electronic product as a medical device, which would therefore be subject to the regulatory requirements for a hearing aid, as described in this guidance. **Examples of such labeling claims and language that would establish an intended use as a medical device include:**

- a description of the types and severity of hearing loss
- a description of listening situations that are typically associated with and indicative of hearing loss
- wording to suggest that the product is an alternative to a hearing aid.

2. Personal Sound Amplification Products (PSAPs)

PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations.

They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss. Examples of situations in which PSAPs typically are used include hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations). **Examples of listening situations that are typically associated with and indicative of hearing loss include:** difficulty listening to another person nearby, difficulty understanding conversations in crowded rooms, difficulty understanding movie dialogue in a theater, difficulty listening to lectures in an otherwise quiet room, difficulty hearing the phone or doorbell ring, or difficulty listening situations in which environmental noise might interfere with speech intelligibility. Products making these or similar claims should not be considered PSAPs. In addition, products that are sold as an “over the counter” alternative or substitute for a hearing aid should not be considered PSAPs. 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 FD&C Act. As such, there is no regulatory classification, product code, or definition for these products. Furthermore, there are no requirements for registration of manufacturers or listing of these products with FDA.

**Areas of Concern:**

1. **Many consumer products in addition to hearing aids may be coupled wirelessly to external devices.**

The language in the introductory section seems to differentiate PSAPs from hearing aids by stating that hearing aids (and therefore not PSAPs) may be coupled acoustically or wirelessly to external devices. Surely the FDA does not wish to regulate products that all consumers may
use to increase the ease with which they can communicate with their wireless mobile devices such as phones, radios, MP3 players, and tablet computers.

2. Hearing Loss vs. normal hearing cannot be inferred by the listening situations in which communication difficulty occurs

In addition to unnecessarily restricting the development and sale of wireless non-hearing aid devices, the new language is simply not supported by accepted scientific facts. In particular, the language cites as examples of "listening situations that are typically associated with and indicative of hearing loss":

- “difficulty understanding conversations in crowded rooms,” as well as
- “difficulty [sic] listening situations in which environmental noise might interfere with speech intelligibility."

It has been reported many times in the scientific literature that persons with hearing impairment usually experience more difficulty hearing in noise than do persons with normal hearing, and perhaps it was this finding that the drafters meant to use as the basis for the new language. The flaw in this reasoning, however, is that although people with hearing loss may experience more difficulty, this is not to say that normally-hearing persons do not experience difficulty in noise. The facts are that: 1) people with normal hearing also have difficulty in noisy environments (therefore such difficulty is not necessarily indicative of hearing loss) and 2) environments noisy enough to interfere with communication by normally-hearing persons occur in many homes, places of business, public places, and places where people gather to socialize.

Noisy Environments are Difficult for Normally-Hearing Persons

Although the veracity of the assertion that normally-hearing persons have difficulty in noisy places is so obvious that it hardly needs to be supported by data, we will cite two illustrative examples from the scientific literature. Figure 1, from a classic peer-reviewed paper [1] plots percent correct recognition of key words in conversational speech passages as a function of the speech-to-noise ratio in a background of noise with the same spectral shape as the speech. The subjects were 60 normally-hearing young adults, listening via headphones.

![Figure 1](image_url)

Figure 1. From [1], Figure 3. Percent correction of conversational passages at different signal-to-noise ratios. 60 young normally-hearing subjects.
Note that although recognition is 100% at high SNRs, by the time the SNR decreases to about -5 dB, persons with normal hearing can get only about 50% of the conversational speech even under non-reverberant headphone presentation.

Figure 2 [2] shows average percent words in nonsense sentences understood correctly by five normally-hearing persons, when the words were spoken conversationally, and when they were spoken by a talker trying to speak very clearly. In the leftmost six conditions the speech was either delivered in quiet or at a good SNR (+5 or +9 dB), and so subjects had little difficulty with either conversational or clear speech. But in the rightmost three conditions, the SNR was 0 dB, and in the N3LI and N3CF conditions, the noisy signal was processed to simulate the reverberation in either a living room or a conference room. These data make it clear that even in relatively nonreverberant environments like conference rooms and living rooms, even modest amounts of background noise can significantly affect normally-hearing persons’ ability to understand speech.

**Everyday Environments Are Noisy Enough To Affect Normally-Hearing Persons’ Ability To Communicate**

Most normally-hearing persons probably experience situations every day in which they find it difficult to hear. One good example is restaurants. In an article published in the ASHA Leader in May 2013 [3], the author stated:

> "Noise levels in restaurants also can exceed safety standards. Although a study I conducted with colleagues in 2000 indicated average integrated sound level (L-avg) ranging from 50 dBA to 90 dBA and maximum sound levels from 85 dBA to 109 dBA, peak unweighted levels reached as high as 142 dB SPL. Because the typical patron doesn’t spend eight hours a day in restaurants—similar to the movie situation—restaurant noise is unlikely to cause permanent hearing damage. However, restaurant noise levels certainly can be high enough to be annoying—for people with hearing loss and those with normal hearing alike."

If we assume that the level of normal conversational speech is about 60 dB SPL, then we can use the sample data shown above to estimate that at average noise levels above about 65 dB SPL normally-hearing persons will start having noticeable difficulty conversing, and probably at lower noise levels than that in reverberant rooms. That this is happening very frequently can be
inferred both from the findings cited above, and from the language on the Zagat restaurant survey website [4],

*When it comes to what annoys diners the most, noise is the No. 1 complaint nationally (27%), followed by service (24%), prices (15%) and crowds at 11%.*

A sound tour of New York City [5] reported that noise levels in all restaurants, bars, and coffee shops sampled exceeded 78 dB SPL, and in most cases exceeded 90 dB SPL. As a matter of fact, according to this sample the only place in New York in which a SNR of 0 dB (corresponding to 100% speech recognition for persons with normal hearing) could have been obtained would have been Evergreen cemetery! Obviously, our world is a noisy place and getting noisier, and this is a problem for persons with normal hearing as well as persons with hearing impairment.

**Summary and Recommendations**

The new language in the draft guidance document, although meant to clarify the FDA’s definitions of PSAPs and hearing aids, actually has the opposite effect because:

1. it assumes, incorrectly, that difficulty in certain listening situations can be indicative of hearing loss, and therefore will impose a labeling restriction that would result in restricting the use of PSAPs by persons with normal hearing; and

2. it indicates, incorrectly, that hearing aids but not PSAPs can communicate wirelessly with external devices.

Taken together, most of the new language in the draft guidance will have the effect of making the FDA’s “bright white line” between hearing aids and PSAPs much less definitive than it currently is. In addition it would severely curtail innovation in wireless devices designed to make it easier for all consumers, whatever their hearing status, to interface with mobile computing platforms, and to communicate in the sometimes challenging environments of modern life.

I therefore respectfully recommend that the *draft guidance document be withdrawn, and the current guidelines remain in effect.*
References


