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# FDA Proposes Guidance to Clarify Differences between Hearing Aids and PSAPs

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*ROCKVILLE, MD*–The U.S. Food and Drug Administration (FDA) issued a draft guidance document on November 7 designed to clarify "the distinction between hearing aids and personal sound amplification products (PSAPs), as well as the regulatory controls that apply to each." It invited public response to the draft by February 5, 2014.

Entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," the document was published in the wake of numerous complaints from hearing aid manufacturers and dispensers about products being sold under the guise of "personal sound amplification products" (PSAPs) that really should be categorized and regulated as hearing aids since they are clearly being marketed to people looking for help with a hearing loss.

The existing 2009 FDA guidance document, states, "PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are not intended to compensate for hearing impairment."

The manufacture, marketing, and distribution of hearing aids by licensed professionals are strictly regulated by both federal and state agencies, while PSAPs can be sold by anyone online, by mail order, or over the counter with minimal regulation.

## Background

In issuing the draft document, which would supersede the 2009 guidance, the FDA explained that it "has become aware of a lack of clarity regarding how the agency defines a hearing aid versus a personal sound amplification product (PSAP), which has also led, in some cases, to inappropriate application of regulatory requirements for such products."

It added, "These inconsistent interpretations of the definitions may inadvertently result in hearing-impaired consumers bypassing safeguards that were implemented to promote the prompt diagnosis of treatable medical conditions causing hearing loss. To ensure consistent interpretation, consistent application of relevant regulatory requirements, and adequate protection of the public health, FDA seeks to further clarify the definitions of hearing aids and PSAPs."

## 2013 Revisions

The draft document is in large part unchanged from the existing guidance. However, it includes a number of additions, including to the section about PSAPs. Along with re-stating that they are intended for "non-hearing impaired consumers," the 2013 version expands this section to underscore the differences between PSAPs, which are not medical devices, and hearing aids, which are.

It states that PSAPs "are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations."

It continues, “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 in 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.”

## No “enforcement required”

One of the crucial similarities between the 2009 and the 2013 documents is that neither one requires the FDA to enforce it.

The current guidance says, “FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.”

The 2013 draft states, “This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.”

## Submitting Comments

Anyone wishing to suggest changes in the draft guidance or to offer other comments has until February 4. Written comments can be mailed to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Those wishing to e-mail their comments should go to www.regulations.gov.