Hearing Access Program
233 East 78th Street
New York, NY 10021
Telephone: 212.988.8099 Mobile: 917.975.5642 Fax: 212.988.0306

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

Re: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

Issue: How can consumers compare hearing aid features so they can be informed consumers?

Discussion:

Hearing aids offer a number of features but it is difficult for consumers, audiologists and hearing aid dispensers to compare brands. Manufacturers do not use common names for features and many manufacturers trademark the names they use. Comparing features is virtually impossible without consistent names.

Users and parents of children with hearing loss are dependent on the audiologist or hearing aid dispenser to provide information, which may present a conflict of interest because the audiologist/hearing aid dispenser:

1- Does not represent all manufacturers nor have knowledge of all hearing aids on the market.

Audiologists/hearing aid dispensers are presumed to know all the aids on the market but the reality is that that they only dispense a few brands. The hearing aid mix they offer is based on such concerns such as but not limited to percentage of earnings, incentive pricing, delivery schedule, quality, and customer support. Some of these concerns, such as percentage of earnings, are not in the best interest of the consumer.

2- May receive bonuses/equipment based on the volume of hearing aids sold.

Many hearing aid companies provide free equipment or incentives or perks to audiologists/hearing aid dispensers based on their sales volume. This marketing program is now frowned on in the pharmaceutical business and should be

eliminated in the hearing aid business as well.

3- Has a financial incentive to maximize the likelihood of making a sale. Audiologists/hearing aid dispensers make a substantial profit when they sell hearing aids. Critical information that may obstruct or delay the sale such as the pros and cons of various features may not be disclosed.

The hearing aid manufacturers also heavily fund many of the hearing loss organizations, which can interfere with their advocacy on this issue as well. The FDA can bring greater transparency and accountability to the dispensing of hearing aids by developing a rating system for the various hearing aid features and standardizing the naming of these features.

Conclusion:

Regulation of hearing aid features is critical to enable consumers to be educated consumers and not dependent exclusively on the audiologist/hearing aid dispenser. Consumers can only educate themselves with information that is easily obtainable. This information is currently not available. There is no incentive by the manufacturers or vendors to provide this information. Therefore, the FDA should ensure that the information is made available so that consumers can become better informed and more satisfied with their purchase.

Sincerely,

Janice L. Schacter