



Academy of Rehabilitative Audiology

Founded in 1966

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April 20, 1999

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20850

Dear Dr. Henney:

On behalf of the members of the Academy of Rehabilitative Audiology (ARA), I am requesting your assistance to release for public comment the proposed updated regulations for *Hearing Aid Devices; Professional and Patient Labeling & Conditions for Sale* (CFR 21 §801.420-421). ARA is the national professional and scientific organization for audiologists, involved with audiologic rehabilitation of persons with hearing loss. As such, ARA is concerned with the safety and efficacy of medical devices related to hearing loss.

These updated federal regulations are long overdue and must replace the extremely outdated and often misused 1977 FDA regulations that were originally promulgated to protect consumer safety and ensure effective distribution, use and labeling of hearing aids. As you may recall, an advanced notice of proposed rulemaking was issued on November 10, 1993.

An AARP survey released in 1993 indicated that a majority of hearing aid users were not satisfied with their hearing aids. With the advent of digital and programmable hearing aids, the substantial costs of these devices (averaging over \$3000), and the increased aging and multiethnic/multicultural demographics in the United States, the problems with the 1977 regulations will only become more acute. We urge you to strongly advocate for release of the updated regulations for public comment and incorporate the following:

- 1) ARA recommends that there be more detailed labeling of hearing aid devices. Specific updated changes should be incorporated in labeling requirements to protect consumers. Since hearing aid technology has advanced tremendously since 1977, information should be required that educates consumers about the key components of their hearing aids and conditions of sale.

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- 2) ARA believes that all persons in need of mitigating the effects of hearing loss through a hearing aid, or other appropriate assistive device and rehabilitation, should receive a comprehensive audiological evaluation by a certified and licensed audiologist. This is critical not only for identifying the degree and type of hearing loss, but also to ensure that the patient is appropriately referred for medical evaluation.

The waiver provision in the current regulations, originally intended to allow the rare few who may object on religious grounds to the evaluation, has been misused. In addition, the 1977 requirement for pre-purchase medical evaluation added to the economic burden and has precluded those who could benefit from being professionally evaluated for hearing aids.

- 3) Health care professionals performing comprehensive audiological evaluations, as well as any subsequent selections, fitting and the critical follow-up care of hearing aid devices should meet appropriate educational requirements to assure consumer safety and confidence. Nationally recognized professional certification and state licensure provide consumers with legal recourse when necessary and promote standards for quality of service and professional conduct. Similar minimum requirements for mammography screening have effectively been implemented and have shown substantial improvement in the quality of those exams and confidence among consumers.

As a final note, we believe previous FDA analyses show that the cost of implementing such changes will be minor when compared to increased cost and poor patient outcomes occurring from the improper assessment and fitting of hearing aid devices. The time is now for the Administration to act and release updated hearing aid regulations for public comment.

Your thoughtful consideration to this important issue is most appreciated. ARA looks forward to working with you to ensure that the American public is protected and receives quality care in addressing hearing loss. Please do not hesitate to contact me at (352) 395-0174 should you need additional information and wish to discuss this matter further.

Sincerely,



Alice E. Holmes, Ph.D.
President

AEH/kjd