



# Educational Audiology Association

4319 Ehrlich Road • Tampa FL 33624  
800/460-7EAA (7322) • fax 813/968-3597

April 26, 1999

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

Dear Dr. Henney:

The Educational Audiology Association (EAA) is pleased to endorse the letter submitted to you by the American Speech-Language-Hearing Association requesting release of the proposed updated regulations for *Hearing Aid Devices; Professional and Patient Labeling & Conditions for Sale* (CFR 21 Sec 801.420-421). EAA is an international organization of audiologists and related professionals whose primary interest is the comprehensive management of individuals from birth through graduation from school in all educational environments who have listening and/or hearing difficulties. Determination of appropriate amplification, including hearing aids, and helping families obtain amplification for their children is a major function of the members of our organization. Thus, we, too, are concerned with the safety and efficacy of medical devices, specifically hearing aids, related to hearing loss.

As you are well aware, the 1977 FDA regulations are currently outdated. We concur with the following points made, and expanded upon, by ASHA in their recent letter to you:

1. More detailed labeling of hearing aid devices for consumer protection.
2. All people with concern regarding their hearing status and, potentially, in need of amplification, should receive a comprehensive audiological evaluation by a certified and/or licensed audiologist.
3. Provision for medical clearance for hearing aid use needs to be revised.
4. The health care professional uniquely qualified to provide comprehensive audiological management is the audiologist who meets appropriate certification and/or licensure standards. Provision of services by an audiologist would assure consumer safety and confidence.

We strongly support the release of the proposed updated regulations for *Hearing Aid Devices* for public comment. Please feel free to contact me if you have any questions or need further information.

Sincerely,

Barbara R. Murphy, M.A., CCC-A, FAAA  
President

BRM/ms

93N-0372

C 3434

---

An international network of audiologists with the purpose of facilitating the delivery of a full spectrum of hearing services to all children in educational settings