Federal Standards for Sales

The FTC is responsible for monitoring the business practices of hearing aid dispensers and vendors. Under the Federal Trade Commission Act , the FTC can take action against a company that misleads or deceives consumers. Such a company may use misleading sales and advertising practices -- giving inaccurate information about hearing loss, performance of a hearing aid, refund policies, or warranty coverage. The Magnuson-Moss Warranty Act, which the FTC enforces, provides consumers with certain protections relating to warranties. This act requires a company offering a warranty to fully disclose all its terms and conditions.

The Food and Drug Administration [FDA] enforces regulations that deal specifically with the manufacture and sale of hearing aids, because these products are recognized as medical devices. FDA regulations have the force of federal law. According to the FDA, the following conditions must be met by all dispensers before selling a hearing aid:

- Dispensers must obtain a written statement from the patient signed by a licensed physician. It must be dated within the previous six months, state the patient's ears have been medically evaluated, and state that the patient is cleared for fitting with a hearing aid.

- A patient, age 18 or older, can sign a waiver for a medical examination, but dispensers must advise the patient that waiving the examination is not in the patient's best health interest.

- Dispensers must avoid encouraging the patient to waive the medical evaluation requirement.

- Dispensers must advise patients who appear to have a hearing problem to consult promptly with a physician.

- The FDA regulations require that an instruction brochure be provided with the hearing aid that illustrates and describes its operation, use and care. The brochure also must list sources for repair and maintenance and include a statement that the use of a hearing aid may be only part of a rehabilitative program.

State Standards for Sales

In addition to federal regulations, many states have laws that apply to the sale of hearing aids. Most states license hearing aid dispensers, and several states prohibit the sale of hearing aids through the mail. Purchasers also may be protected by implied warranties, created by state law. Your state Attorney General's Office can provide you with particular information about state laws that apply to the sale of hearing aids.

The state Attorney General's Office also will have information on whether hearing aid dispensers must be licensed or certified by the state. Some hearing professionals, such as physicians and audiologists, may be licensed by a state regulatory agency. These agencies may provide helpful information for individuals considering a hearing aid purchase.

Where to Complain

If you have questions or complaints concerning the sales practices of a hearing aid dispenser, contact your state Attorney General's Office, local consumer protection agency, the Better Business Bureau, and write:

Correspondence Branch
Federal Trade Commission
Washington DC 20580

Although the FTC usually does not resolve individual disputes, the agency may take action against a company if there is evidence of a pattern of deceptive or unfair practices.

The National Fraud Information Center [NFIC] maintains a toll-free Consumer Assistance Service, 1-800-876-7060, to provide consumers with answers to questions about telephone or mail solicitations, information about how and where to report fraud, referral services, and help in filing complaints.

The NFIC Consumer Assistance Service is available from 9:00am to 5:30pm EST, Monday through Friday. The toll-free number is in service in the United States, Puerto Rico and Canada. Spanish-language service is available.

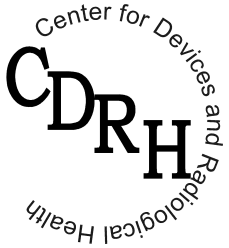
The consumer complaint information is instantly available to assist law enforcement agencies through a database operated by the Federal Trade Commission and the National Association of Attorneys General.

12/98

Guidance for Industry

Noise Claims in Hearing Aid Labeling

Document issued on: October 21, 1998



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Ear, Nose and Throat Devices Branch
Division of Reproductive, Abdominal, Ear,
Nose and Throat and Radiological Devices
Office of Device Evaluation

Preface

Public Comment:

Comments and suggestions may be submitted at any time at any time for Agency considerations to Harry Sauberman, P.E., CDRH, 9200 Corporate Blvd, HFZ-470, Rockville, MD 20850 or by e-mail to hrs@cdrh.fda.gov. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, also contact Mr. Sauberman at (301) 594-2080.

Additional Copies:

World Wide Web/CDRH home page at http://www.fda.gov/cdrh or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2210 when prompted for the document shelf number.

Noise Claims In Hearing Aid Labeling

Manufacturers who make noise claims in their labeling for hearing aids (e.g. improved speech understanding in noisy environments) are no longer required to submit a 510(k) premarket notification to obtain a “substantially equivalent” decision in support of these claims.

Under the Food and Drug Administration Modernization Act (FDAMA) of 1997, air conduction hearing aids are exempt from premarket notification subject to limitations of exemptions found in 21CFR 874.9.

The limitations of exemptions basically state that a major change in the intended use of a hearing aid or a change in the fundamental scientific technology would require a new 510(k) submission. Specifically, a change that only involves the addition of a noise claim to the labeling, including promotion and advertising materials, does not exceed the limitations of exemptions and does not require a new 510(k).

Manufacturers should develop substantiating data, from scientific and/or clinical studies, to support their claims. This data should be kept and maintained at the manufacturer’s facility. The data should be made available for review at the request of the FDA or made available during an FDA inspection. Claims that are determined to be unsubstantiated may result in the device being misbranded under Section 502 of the Federal Food, Drug and Cosmetic Act.