

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**EEB 13 2004**

Mead C. Killion, Ph.D., Sc.D.  
Etymotic Research, Inc.  
61 Martin Lane  
Elk Grove Village, IL 60007

Re: Docket No. 03P-0362

Dear Dr. Killion:

This letter responds to your citizen petition dated August 7, 2003, which was filed by the Food Drug Administration ("FDA") on August 11, 2003.

Your petition requests that FDA create a new over-the-counter hearing aid classification that would grant over-the-counter sale, distribution, and use status to "one size fits most" hearing aid devices that meet safety and efficacy requirements established by the rule. After careful review of your petition, along with the public comments received in response to your request, the FDA has determined that it is in the public's interest to deny your petition.

### **Background**

Pursuant to Section 520(e) of the Medical Device Amendments to the Food, Drug and Cosmetic Act (the Act), FDA is authorized to restrict the sale, distribution, or use of a device, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. Restrictions may include limiting a device to sale, distribution, or use only on oral or written authorization by a licensed practitioner or upon other conditions specified by regulation.

Hearing aids are restricted devices. The FDA's current regulations governing the labeling and conditions for sale of hearing aids are contained in Title 21 of the Code of Federal Regulations (21 CFR) sections 801.420 and 801.421. These regulations were enacted on February 15, 1977 and promulgated pursuant to section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (h)). Under the terms of the current regulations, before the sale of a hearing aid, the hearing aid dispenser must obtain from each prospective purchaser a written statement signed by a licensed physician stating that the physician has evaluated the patient's hearing loss and that the patient may be considered a candidate for a hearing aid. The physician must have performed the medical evaluation within 6 months prior to the sale of the hearing aid. However, a prospective hearing aid user who is 18 years of age or older may waive the medical evaluation requirement. The hearing aid dispenser must inform the user that the waiver is not in the user's best health interests, must not actively encourage the user to waive the medical evaluation requirement, and must obtain from the prospective user a written statement that the user has been

advised that the waiver is not in the user's best health interests and that the user does not wish to have a medical evaluation.

The waiver provision addresses the practical and logistical problems of medical evaluation, the limited availability of licensed physicians in some areas, the potential immobility of the hearing impaired, and the personal and religious beliefs of individuals who refuse to consult with physicians. Although the regulations do not limit who can be a hearing aid dispenser, some states do have such restrictions.

The regulations also require the manufacturer or distributor of a hearing aid to develop a User Instructional Brochure containing certain defined information for the benefit of the user and make this brochure available to hearing aid dispensers for distribution to prospective hearing aid users. The hearing aid dispenser must provide the prospective user with a copy of the User Instructional Brochure for any hearing aid the user is considering purchasing, review the contents of the brochure with the prospective user orally or in the predominant method of communication used during the sale, and provide the prospective user an opportunity to read the brochure. Finally, the labeling of hearing aids must provide information on their use and maintenance.

These hearing aid restrictions were recommended in 1976, when the FDA's Interdepartmental Task Force on Hearing Aids (the "Task Force") found that the miscalculation of a patient's need for a hearing aid and the subsequent sale of a hearing aid that is ineffective and possibly unsafe for its intended use were major problems in the hearing aid delivery system. In its report to FDA, the Task Force cited studies indicating that patients bought hearing aids when their hearing loss required medical treatment. In the preamble to the 1977 hearing aid final rule, FDA adopted the recommended restrictions and concluded that the safe and effective use of hearing aids required that persons with hearing loss have a medical evaluation by a licensed physician (preferably one who specializes in diseases of the ear) before purchasing a hearing aid. The primary purpose of the medical evaluation is to identify medically treatable conditions for which a hearing aid is not the appropriate or effective treatment.

## Action

Your request to create a new over-the-counter hearing aid classification that would permit over-the-counter sale, distribution, and use of "one size fits most" hearing aid devices seeks to exempt these devices from the current medical examination and waiver requirements contained in Sections 801.420 and 801.421. FDA is concerned that if prospective purchasers of hearing aids are not examined by a physician prior to using the hearing aid, "red flag" ear conditions will go *undiagnosed and unevaluated*. *Red flag ear conditions are signs, symptoms, or audiometric findings that a licensed physician must evaluate to determine whether a person experiencing hearing impairment is an appropriate candidate for a hearing aid, or whether his impairments may be medically or surgically treated.* Examples of red flag ear conditions include: visible congenital or traumatic deformity of the ear; history of active drainage or bleeding from the ear within the previous six months; sudden or rapidly progressive hearing loss in either ear within the previous six months; air-bone gap of 15 decibels or greater at 500 Hz, 1,000 Hz, and 2,000 Hz; asymmetric hearing loss; acute or chronic dizziness; visible evidence of excessive ear wax (cerumen) or a foreign body in the ear canal; and ongoing pain or discomfort in the ear.

Several of these red flag conditions cannot be diagnosed by the patient and instead require physical examination or audiometric studies. Without appropriate screening for red flag

conditions by a licensed physician, persons with hearing loss may purchase hearing aids to remedy their problems and may even experience some relief, while continuing to have serious medical conditions that should be properly diagnosed and treated. In some cases, this lack of, or at best delayed, diagnosis can lead to irreparable damage, further deterioration of hearing, or increased risks of surgery for the hearing aid user.


Older adults are most likely to suffer as a result of the elimination of the medical examination and waiver requirements. A recent study by the Journal of American Medicine Association ("JAMA") indicates that hearing loss is the third most prevalent chronic condition in older adults in the United States, after hypertension and arthritis.<sup>1</sup> The authors note that while most hearing loss in the elderly is sensorineural and due to presbycusis, up to 30% of these patients may have cerumen impaction and chronic otitis media that can be treated by the primary care physician. They further conclude that prompt recognition of potentially reversible causes of hearing loss is important to maximize the possibility of functional recovery.

FDA believes that elimination of the existing medical evaluation and waiver requirements may result in significant delays in the diagnosis and management of medically and surgically treatable causes of hearing loss. Delay in diagnosis and treatment of some of these conditions (e.g., cholesteatomas, autoimmune sensorineural hearing loss, tumors, ototoxicity, and infections) may lead to further, irreversible loss of hearing and other adverse health consequences.

### Conclusion

FDA continues to believe that the safe and effective use of hearing aids depends on the collateral measure of a physical examination to ensure that a hearing aid, rather than medical or surgical treatment, is the appropriate solution to a particular person's hearing impairment. If a patient over the age of 18 is unable or unwilling to seek a medical examination, after being advised that doing so is not in his or her best interests, that patient may utilize the waiver provision. Accordingly, your request to create a new over-the-counter hearing aid classification that grants over-the-counter sale, distribution, and use status to "one size fits most" hearing aid devices is denied. If you have any questions regarding letter, please contact Joseph M. Sheehan of our Regulations Staff at (301) 827-2974.

Sincerely yours,

  
Beverly Chernaik Rothstein  
Acting Deputy Director  
For Regulation and Policy  
Center for Devices and Radiological Health

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<sup>1</sup> Yueh et al., *Screening and Management of Adult Hearing Loss in Primary Care*, 289 JAMA 1976-85 (2003).



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**FEB 13 2004**

Gail Gudmundsen, Au.D.  
Gudhear, Inc.  
41 Martin Lane  
Elk Grove Village, IL 60007

Dear Dr. Gudmundsen:

This letter responds to your citizen petition dated August 8, 2003, which was filed by the U.S. Food & Drug Administration ("FDA") on August 11, 2003.

Your petition requests that the FDA (1) revoke 21 CFR 801.421 in its entirety; (2) remove all references to 21 CFR 801.421 in 21 CFR 801.420; and (3) replace 21 CFR 801.421 (c)(3) with the new language proposed in your petition. You state that you are requesting only to eliminate any and all references to the required medical evaluation and waiver in 21 CFR 801.421, so that prospective hearing aid users would not be required to obtain a medical evaluation – or waive that requirement - in order to purchase a hearing aid. After careful review of your petition, along with the public comments received in response to your requests, the FDA has determined that it is in the public's interest to deny your petition.

### **Background**

Pursuant to Section 520(e) of the Medical Device Amendments to the Food, Drug and Cosmetic Act (the Act), FDA is authorized to restrict the sale, distribution, or use of a device, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. Restrictions may include limiting a device to sale, distribution, or use only on oral or written authorization by a licensed practitioner or upon other conditions specified by regulation.

Hearing aids are restricted devices. FDA's current regulations governing the labeling and conditions for sale of hearing aids are contained in Title 21 of the Code of Federal Regulations (21 CFR) Sections 801.420 and 801.421. Under the current regulations, before the sale of a hearing aid, the hearing aid dispenser must obtain from each prospective purchaser a written statement signed by a licensed physician stating that the physician has evaluated the patient's hearing loss and that the patient may be considered a candidate for a hearing aid. The physician must have performed the medical evaluation within six months prior to the sale of the hearing aid.

However, a prospective hearing aid user who is 18 years of age or older may waive the medical evaluation requirement. The waiver provision addresses the practical and logistical problems of medical evaluation, the limited availability of licensed physicians in some areas, the potential

immobility of the hearing impaired, and the personal and religious beliefs of individuals who refuse to consult with physicians. The hearing aid dispenser must inform the user that the waiver is not in the user's best health interests, must not actively encourage the user to waive the medical evaluation requirement, and must obtain from the prospective user a written statement that the user has been advised that the waiver is not in the user's best health interests and that the user does not wish to have a medical evaluation. Although the regulations do not limit who may dispense hearing aids, some states do have such restrictions.

The regulations also require the manufacturer or distributor of a hearing aid to develop a User Instructional Brochure containing certain defined information for the benefit of the user and make this brochure available to hearing aid dispensers for distribution to prospective hearing aid users. The hearing aid dispenser must provide the prospective user with a copy of the User Instructional Brochure for any hearing aid the user is considering purchasing, review the contents of the brochure with the prospective user orally or in the predominant method of communication used during the sale, and provide the prospective user an opportunity to read the brochure. Finally, the labeling of hearing aids must provide information on their use and maintenance.

These hearing aid restrictions were recommended in 1976, when the FDA's Interdepartmental Task Force on Hearing Aids (the "Task Force") found that the miscalculation of a patient's need for a hearing aid and the subsequent sale of a hearing aid that is ineffective and possibly unsafe for its intended use were major problems in the hearing aid delivery system. In its report to FDA, the Task Force cited studies indicating that patients bought hearing aids when their hearing loss required medical treatment. In the preamble to the 1977 hearing aid final rule, the FDA adopted the recommended restriction and concluded that the safe and effective use of hearing aids required that persons with a hearing loss have a medical evaluation by a licensed physician (preferably one who specializes in diseases of the ear) before purchasing a hearing aid. The primary purpose of the medical evaluation is to identify medically treatable conditions for which a hearing aid is not an appropriate or effective treatment.

### **Action**

FDA is concerned that if prospective purchasers of hearing aids are not examined by a physician prior to purchasing and using the hearing aid, "red flag" ear conditions will go unrecognized and unevaluated. Red flag ear conditions are signs, symptoms or audiometric findings that a licensed physician must evaluate to determine whether a person experiencing hearing impairment is an appropriate candidate for a hearing aid, or whether his impairments may be medically or surgically treated. Examples of red flag ear conditions include: visible congenital or traumatic deformity of the ear; history of active drainage or bleeding from the ear within the previous 6 months; sudden or rapidly progressive hearing loss in either ear within the previous 6 months; air-bone gap of 15 decibels or greater at 500 Hz, 1,000 Hz, and 2,000 Hz; asymmetric hearing loss; acute or chronic dizziness; visible evidence of excessive ear wax (cerumen) or a foreign body in the ear canal; and ongoing pain or discomfort in the ear.

Several of these red flag conditions cannot be diagnosed by the patient, and instead require physical examination or audiometric studies. Without appropriate screening for red flag conditions by a licensed physician, persons with hearing loss may purchase hearing aids to

remedy their problems and may even experience some relief, while continuing to have serious medical conditions that should be properly diagnosed and treated. In some cases, this lack of, or at best delayed, diagnosis can lead to irreparable damage, further deterioration of hearing, or increased risks of surgery for the hearing aid user.

Older adults are most likely to suffer as a result of your proposed elimination of the medical examination and waiver requirements. A recent study by the Journal of American Medicine Association ("JAMA") indicates that hearing loss is the third most prevalent chronic condition in older adults in the United States, after hypertension and arthritis.<sup>1</sup> The authors note that while most hearing loss in the elderly is sensorineural and due to presbycusis, up to 30% of these patients may have cerumen impaction and chronic otitis media that can be treated by the primary care physician. They further conclude that prompt recognition of potentially reversible causes of hearing loss is important to maximize the possibility of functional recovery.

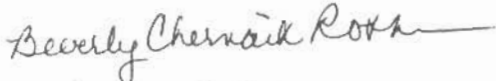
FDA believes that elimination of the existing medical evaluation and waiver requirements may result in significant delays in the diagnosis and management of medically and surgically treatable causes of hearing loss. Delay in diagnosis and treatment of some of these conditions (e.g., cholesteatomas, autoimmune sensorineural hearing loss, tumors, ototoxicity, and infections) may lead to further, irreversible loss of hearing and other adverse health consequences.

### Conclusion

FDA continues to believe that the safe and effective use of hearing aids depends on the collateral measure of a medical examination to ensure that a hearing aid, rather than medical or surgical treatment, is the appropriate solution for a particular person's hearing impairment. If a patient over the age of 18 is unable or unwilling to seek a medical examination, after being advised that doing so is not in his or her best interest, that patient may utilize the waiver provision. Accordingly, your request to eliminate the medical evaluation and waiver provisions of 21 CFR 801.421 and 21 CFR 801.420 is denied.

If you have any questions regarding this letter, please contact Joseph M. Sheehan of our Regulations Staff at (301) 827-2974.

Sincerely yours,

  
Beverly Chernaik Rothstein  
Acting Deputy Director  
For Regulation and Policy  
Center for Devices and Radiological Health

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<sup>1</sup> Yueh et al., *Screening and Management of Adult Hearing Loss in Primary Care*, 289 JAMA 1976-85 (2003).