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Food and Drug Administration,
Department of Health and Human Services, Rm 1-23
12420 Parklawn Dr.
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under the Code of Federal Regulations, Title 21, Volume 8. Cite: 21CFR801.420 Subpart H—Special Requirements for Specific Devices, Section 801.420 Hearing aid devices; professional and patient labeling, and Section 801.421 Hearing Aid Devices; conditions for sale to request that the Commissioner of Food and Drugs 1) revoke Section 801.421 in its entirety; 2) revoke all references to 801.421 in Section 801.420; and 3) replace the language in 801.421 (c) (3) in its entirety with the new language proposed in this petition.

A. Action requested

The petitioner requests the following: 1) revocation of Subpart H Section 801.421 (of Part 801 - - Labeling) in its entirety; 2) revocation of all references to 801.421 in Section 801.420; and 3) replacement of the language in 801.421 (c) (3) in its entirety with the new language proposed in this petition.

1. The petitioner requests that the following be revoked in its entirety:

PART 801—Labeling
Subpart H—Requirements for Specific Devices
Section 801.421 Hearing Aid devices; conditions for sale.

(a) "Medical evaluation requirements-- (1) General. Except as provided in paragraph (a) (2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a) (1) of this section, provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement:

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I have been advised by ------- ------- (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specialized in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) Opportunity to review User Instructional Brochure. Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure

(c) Availability of User Instructional Brochure. (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) Recordkeeping. The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) Exemption for group auditory trainers. Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

[42 FR 9296, Feb. 15, 1977]

2. The petitioner requests that all references to 801.421 be removed from Part 801 – Labeling, Subpart H—Requirements for Specific Devices, Section 801.420 Hearing Aid devices; professional and patient labeling.

3. The petitioner requests that the language in paragraph (c) (3) Availability of User Instruction Brochure in PART 801—Labeling, Subpart H—Requirements for Specific Devices, Section 801.420 Hearing Aid devices; professional and patient labeling be replaced by the text in this petition. Paragraph (c) (3) of the current regulation 801.420 states:

(3) Notice for prospective hearing aid users. The User Instructional Brochure shall contain the following notice:

Important Notice for Prospective Hearing Aid Users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

The petitioner requests that the language in (c) (3) above be replaced by the following:

(3) Notice for prospective hearing aid users. Upon request by an individual who is considering the purchase of a hearing aid, a seller shall, with respect to any hearing aid that s/he sells, provide a copy of the User Instructional Brochure for the hearing aid, in person, by mail, or prominently displayed on a website, or provide the name and address or website information of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

If the prospective hearing aid user is 18 years of age or older, a prospective hearing aid purchaser shall be given a copy of the following information in person, by mail, or prominently displayed on a website.

- **A hearing aid will not restore normal hearing and will not prevent progressive hearing loss, and will not improve the underlying causes of organic hearing loss.**
- **Some hearing loss is caused by conditions that can be medically corrected. The following signs indicate the need for medical evaluation by a licensed physician, preferably a physician who specializes in diseases of the ear:**
  1. **Congenital or traumatic deformity of the ear**
  2. **Pain or discomfort in the ear**
  3. **History of active drainage from the ear within the part 90 days**
  4. **History of sudden or rapidly progressing hearing loss**
  5. **Unilateral hearing loss or a difference in hearing between ears in the past 90 days**
  6. **Excessive earwax**
  7. **Foreign body in the ear canal**
  8. **Acute or chronic dizziness**

Children with hearing loss

A child with a hearing loss should be directed to a physician for a medical evaluation and to an audiologist for evaluation and rehabilitation, since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

B. Statement of grounds

Current FDA regulation that requires medical evaluation (or waiver for prospective hearing aid users 18 years of age and older) is unnecessary. A comparable policy would be to deny prospective users of eyeglasses the right to purchase reading glasses at a retail business unless they were first evaluated by a physician, preferably one who specializes in diseases of the eye, to obtain medical clearance for their purchase, or unless they sign a waiver.

The operative principle that separates over-the-counter drugs or devices from those that require prescription by a physician is whether misuse of that drug or device can cause harm to the user. The wrong prescription drug may be dangerous to a particular patient. The potential harm from direct purchase of a hearing aid without medical evaluation is negligible.

Consumers are permitted to take aspirin instead of seeing a professional when something hurts, even though pain is sometimes an indication of a life-threatening medical condition. Experience has taught us that the vast majority of people can make intelligent decisions with regard to reading glasses and aspirin. If they overlook a serious problem, they can subsequently consult medical personnel if poor vision or pain persists or worsens. Likewise, medications such as Sudafed and Claritin that were once prescription-only are now available over the counter, presumably because FDA concluded that the benefits of reduced cost and increased availability of these drugs outweighed any risks involved in allowing the consumer to decide when the use of these drugs was warranted.

The present FDA regulation that requires a medical evaluation or a waiver in lieu of medical evaluation is unnecessarily restrictive and is contrary to precedents created by other products, most notably, eyeglasses. If reading glasses can be sold over-the-counter without a requirement to see an eye-care professional to rule out glaucoma or other diseases or conditions, then a rule that regulates the sale of hearing aids appears unjustified.

Only five percent of hearing loss in adults can be improved through medical or surgical treatment. The vast majority of Americans (95%) with hearing loss can treat their hearing loss with hearing aids. (National Center on Hearing Assessment and Management, 2003) They have sensorineural hearing loss for which medical treatment is not useful. Many of these persons could benefit from some form of mild-gain amplification some of the time. Even though many of these persons do not obtain the services of hearing professionals, some find other ways to purchase devices to help them hear better--from sources where little or no regulation is imposed (e.g., Radio Shack personal amplifiers, or hearing-aid-type devices available through magazines, catalogs, newspaper ads, mail order and the Internet). Sporting goods stores and specialty catalogs sell hearing devices that are clearly hearing aids, but the purchasers of these devices are not required to obtain medical clearance or sign a waiver.

Most states have laws that restrict the sale of hearing aids. In states with licensure, registration or certification for hearing aid dispensers, only licensed hearing professionals can sell hearing aids. Some state laws require that the waiver of medical evaluation contain the exact language that is contained in 801.421(a) (2)(iii) of the Code of Federal Regulations.

> I have been advised by ------- ------- (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specialized in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

The FDA has not decreed that a consumer's best health interest is served by having a medical evaluation prior to the purchase of any device other than a hearing aid. To impose this restriction on hearing aid sales is not warranted.

The revocation of Section 801.421 would necessitate amending Section 801.420 to delete references to the medical evaluation and waiver; however, many of the labeling requirements in Section 801.420 for the User Instructional Brochure will preserve important consumer information and technical data. Much of the information in these sections, including the warnings, may be beneficial to the hearing aid purchaser. It is the petitioner's request only to eliminate any and all references to the required medical evaluation and waiver in Section 801.421, so that prospective hearing aid users would not be required to obtain medical evaluation or sign a waiver in order to purchase a hearing aid.

This Citizen Petition was encouraged by Secretary Tommy Thompson's regulatory reform initiative released December 26, 2001 (Henneghan, 2001). Secretary Thompson is quoted as stating:

> "We will listen carefully to the people affected by our regulations—including both patients and providers. When appropriate, we will change these requirements to make them more effective and efficient, and we will work with the Congress to change specific provisions in the law that may lead to unnecessary and excessive regulatory burdens."

Expected opposition to revocation of 21CFR801.421

Among those who oppose revoking and changing the current regulation are some hearing professionals and the leadership of their professional organizations. Their position has been that the current hearing aid regulation is necessary to ensure the health and safety of the prospective hearing aid user. Some of these persons advocate placing additional barriers in the path toward obtaining a hearing aid, arguing for amending the regulation so that it requires a comprehensive audiological evaluation performed by an audiologist in addition to a medical examination.

Opposition to this petition may also come from some physicians, particularly those who specialize in diseases of the ear, and the leadership of their professional organizations. The position of the opposing physicians has been that hearing loss is a medical condition that can only be diagnosed by a physician (Holt, 2002). This group maintains that the requirement of a medical evaluation prior to the purchase of a hearing aid ensures that there is no potentially harmful underlying pathology that requires medical or surgical intervention.

C. Environmental impact

No known environmental impact will result from the revocation and amendment of these sections.

D. Economic Impact

A statement of economic impact is not included, as per Section 10.20 and 10.30 (D) of the Citizen Petition filing instructions.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Gail Gudmundsen

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References

Henneghan, Martha (2001) HHS Press Release--Advisory Committee on Regulatory Reform. www.hhs.gov/news.

Holt, G.R. (2002), AAO-HNS leader criticizes article by Fabry. *Hearing Journal, 55(8),* 52.

National Center on Hearing Assessment and Management (2003), as sited by Self Help for the Hard of Hearing (SHHH) www.shhh.org.