Federal Regulation of Hearing Aids

By Erica Campbell

There are two governing bodies that enforce federal regulations pertaining to hearing aids—the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). The FDA enforces regulations pertaining to the manufacture and sale of hearing aids, and the FTC enforces regulations that prohibit misleading sales and advertising practices (e.g., providing inaccurate information about hearing aid performance or refund policies). The most frequently referenced FDA regulations are outlined in the *Code of Federal Regulations* Title 21, Sections 801.420 and 801.421 (last revised on April 1, 2011). The FTC works to prevent fraudulent, deceptive, and unfair business practices in the marketplace, and to provide information to help consumers spot, stop, and avoid such business practices. The FTC offers specific guidance to consumers in a document titled *Sound Advice on Hearing Aids*, which is described in more detail later in this article.

Discussion of FDA Regulatory Requirements

While it is not an audiologist's responsibility to monitor a hearing aid manufacturer's compliance with the FDA regulations, it is important for audiologists to be aware of the regulatory environment affecting manufacturers as well as audiologists, and protections available to audiology patients. The following discussion sets forth the responsibilities of the parties under the FDA regulations.

Prior to the purchase of hearing aids, the dispenser must obtain a written statement, signed by a licensed physician, stating that the patient has been medically evaluated and cleared for fitting with a hearing aid. This evaluation must have taken place within the preceding six months. If the patient is 18 years of age or older, he or she may be provided the opportunity to waive the medical evaluation; however, the dispenser must inform him or her that the waiver is not in the user's best health interest. Additionally, the patient must not be actively encouraged to waive the medical evaluation.

If the patient decides to waive the medical evaluation, he or she must sign the following statement:

> I have been advised by _____ (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 specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

The patient should be advised to consult a licensed physician (preferably an ear specialist) prior to hearing aid fitting if any of the following conditions are present:

- Visible congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.
- History of sudden or rapidly progressive hearing loss within the previous 90 days.
- Acute or chronic dizziness.
- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hz, 1000 Hz, and 2000 Hz.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- Pain or discomfort in the ear.

A record of the signed medical evaluation or waiver statement

must be retained by the dispenser for a period of three years after the dispensing of the hearing aid. Exemptions from the medical evaluation and waiver include qualified schools or institutions purchasing auditory trainers (e.g., soundfield FM systems) for communicating with and educating those with hearing loss.

Prior to signing the earlier mentioned statement, the patient must be provided an opportunity to review the user instructional brochure for a hearing aid that has been or may be selected for the prospective user. This brochure should be reviewed orally, and time should be allowed for the patient to read this as well. If the brochure is not available, the patient should be provided the name and address of the manufacturer or distributor of the brochure in order to obtain a copy.

The user instructional brochure provided by the manufacturer shall include the following components to the extent they are applicable to the particular requirements and characteristics of the hearing aid:

- Hearing aid illustration, controls, user adjustments, and battery compartment.
- Information on control functions.
- Accessory descriptions (e.g., for use with the television or phone).
- Hearing aid use instructions.
- Maintenance and care of the aid.
- Replacing or recharging batteries.
- How to obtain repair service (including at least one specific address to obtain service).
- Description of conditions to avoid (e.g., dropping aid or exposing to excessive heat).
- Side effect identification that may warrant consultation with physician (e.g., skin irritation).
- Statement that the aid will not restore normal hearing and will not prevent or improve a hearing

impairment resulting from organic conditions.

- Statement that infrequent usage does not permit them to attain full benefit.
- Statement that use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

The user instructional brochure should 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.
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> 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.
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> 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.
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> 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.
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> 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.
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> Children with Hearing Loss: In addition to seeing a physician for a medical evaluation, a child with 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.

A warning statement to hearing aid dispensers must also be in the brochure listing the red flags requiring the conditions that should prompt a physician referral as listed earlier (e.g., acute or chronic dizziness, audiometric air-bone gaps, etc.).

Technical data pertaining to the performance of the hearing aid can either be provided in the user brochure or in separate labeling that accompanies the device, including SSPL 90 curve, frequency response curve, HF-Average SSPL 90, HF-Average full-on gain, reference test gain, frequency range, total harmonic distortion, equivalent input noise, battery drain, induction

ALSO OF INTEREST
Joint Statement on Consumer-Administered Hearing Tests and Direct-to-Consumer Hearing Aid Sales
Visit www.audiology.org and search keywords "direct-to-consumer" or use the QR code to view the document on your mobile device.

coil sensitivity, and attack and release times.

Hearing aids must be clearly and permanently labeled with the name of the manufacturer, model name or number, serial number, and year of manufacture. Additionally a "+" symbol must be used as a label to indicate correct battery insertion unless it is physically impossible to insert the battery in the reversed position. If the patient is purchasing a used or rebuilt hearing aid, this must be stated on the aid's packaging as well as on a tag that is physically attached to the hearing aid.

It should also be noted that trial periods are not regulated by the federal government but are typically specified by the individual state. Many states require a 30-day trial period, but you will need to check with your own state's applicable licensure law(s) or related state regulations. Additionally, the state may provide guidelines on what to include in the hearing aid contract (i.e., if the hearing aid is used or reconditioned, provider's license number, make and model of hearing aid).

For a complete listing of the above regulations, visit www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfcfr/CFRSearch.cfm, then type "801.420" or "801.421" in the Title21 Part. Section box.

Discussion of FTC Guidance

The FTC, also known as the Bureau of Consumer Protection, works to combat deceptive business practice and consumer fraud. The agency provides information for the consumer directed at guiding them through the process of obtaining a hearing aid. A description of the types of hearing loss and the differences between hearing health-care professionals are outlined. The FTC breaks down the components of a purchase agreement and key elements that the potential user should be attuned to, including the trial and warranty period, purchase cost, and options of future loaner devices.

The FTC provides a description of the parts of a hearing aid, as well as comparisons between a hearing aid and a personal sound amplification product. Recommendations are set forth for seeking the use of a hearing aid over the latter to expedite diagnosis and any potential treatable conditions. Additionally, direction is offered on how to locate a hearing health-care professional, offering several types of hearing aid manufacturers to select from. For more information, review the FTC document titled *Sound Advice on Hearing Aids*, which can be found at www.ftc.gov/bcp/edu/pubs/consumer/health/hea10.shtm.

To report deceptive business practices or other types of consumer fraud, contact the FTC at www.ftc.gov/complaint or call 1-877-382-4357 (TTY: 1-866-653-4261).

Current Issues

The recent advent of hearing aid sales made over the Internet has raised many questions about the compliance and enforcement of FDA regulations in this forum. The most notable issue pertains to the insurance companies United Healthcare and hi HealthInnovations (UHC/HI) who have begun offering online hearing tests and the online purchase of hearing aids. Without the involvement of a hearing health-care professional, concerns regarding patient health and safety are at the forefront.

The FDA has been made aware of these issues through the advocacy of the Academy, as well as other professional organizations and hearing health-care professionals, and has issued a statement citing that the sale of hearing aids over the Internet must comply with the "spirit" of the medical evaluation. The FDA has requested that Academy members forward information to them when members learn of Internet sites that allow consumers to make hearing aid purchases by simply checking a box to waive the medical evaluation. The FDA states that it will investigate each reported Internet site to determine if the waiver follows the requirements of *Code of Federal Regulations* Title 21 as discussed previously. To report concerns regarding the sale of hearing aids over the Internet, you can send an e-mail to webcomplaints@ora.fda.gov. Additional FDA guidance, "Buying Medical Devices and Diagnostic Tests Online," can be found on the FDA Web site at www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/BuyingMedicalDevicesandDiagnosticTestsOnline/default.htm.

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NOTE: At the time of publication, the Academy learned that the FDA issued a cease and desist letter with regard to the online hearing test offered by UHC/HI. In the letter, the FDA asserts that UHC/HI is in violation of the Federal Food, Drug, and Cosmetic Act, which requires marketing clearance or approval of devices by the FDA. Please see the Academy's Web site for the most up-to-date news on this topic.