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(4) In any medical condition for which there is no proof of safety and effectiveness.

(5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

(d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-hour-day exposure of industrial workers as recommended by the American Conference of Governmental Industrial Hygienists.

(e) The method and apparatus specified in 40 CFR part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section.

§ 801.417 Chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in §2.125 of this chapter.

[43 FR 11318, Mar. 17, 1978]

§ 801.420 Hearing aid devices; professional and patient labeling.

(a) Definitions for the purposes of this section and §801.421. (1) Hearing aid means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) Ear specialist means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) Dispenser means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) Audiologist means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) Sale or purchase includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) Used hearing aid means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered “used” merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) Label requirements for hearing aids. Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A “+” symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) Labeling requirements for hearing aids—(1) General. All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with §801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(1) An illustration(s) of the hearing aid, indicating operating controls, user
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adjustments, and battery compart-
ment.
(ii) Information on the function of all
controls intended for user adjustment.
(iii) A description of any accessory
that may accompany the hearing aid, e.g.,
accessories for use with a tele-
vision or telephone.
(iv) Specific instructions for:
(a) Use of the hearing aid.
(b) Maintenance and care of the hear-
ing aid, including the procedure to fol-
low in washing the earmold, when re-
placing tubing on those hearing aids
that use tubing, and in storing the
hearing aid when it will not be used for
an extended period of time.
(c) Replacing or recharging the bat-
teries, including a generic designation
of replacement batteries.
(v) Information on how and where to
obtain repair service, including at least
one specific address where the user can
go, or send the hearing aid to, to ob-
tain such repair service.
(vi) A description of commonly oc-
curring avoidable conditions that could
adversely affect or damage the hearing
aid, such as dropping, immersing, or
exposing the hearing aid to excessive
heat.
(vii) Identification of any known side
effects associated with the use of a
hearing aid that may warrant con-
sultation with a physician, e.g., skin
irritation and accelerated accumula-
tion of cerumen (ear wax).
(viii) A statement that a hearing aid
will not restore normal hearing and
will not prevent or improve a hearing
impairment resulting from organic
conditions.
(ix) A statement that in most cases
infrequent use of a hearing aid does not
permit a user to attain full benefit
from it.
(x) A statement that the use of a
hearing aid is only part of hearing ha-
bilitation and may need to be supple-
mented by auditory training and in-
spection in lipreading.
(xi) The warning statement required
by paragraph (c)(2) of this section.
(xii) The notice for prospective hear-
ing aid users required by paragraph
(c)(3) of this section.
(xiii) The technical data required by
paragraph (c)(4) of this section, unless
such data is provided in separate label-
ing accompanying the device.
(2) Warning statement. The User In-
structional Brochure shall contain the
following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a
prospective hearing aid user to consult
promptly with a licensed physician (prefer-
ably an ear specialist) before dispensing a
hearing aid if the hearing aid dispenser de-
termines through inquiry, actual observa-
tion, or review of any other available in-
formation concerning the prospective user, that
the prospective user has any of the following
conditions:
(i) Visible congenital or traumatic deform-
ity of the ear.
(ii) History of active drainage from the ear
within the previous 90 days.
(iii) History of sudden or rapidly progres-
sive hearing loss within the previous 90 days.
(iv) Acute or chronic dizziness.
(v) Unilateral hearing loss of sudden or re-
cent onset within the previous 90 days.
(vi) Audiometric air-bone gap equal to or
greater than 15 decibels at 500 hertz (Hz),
1,000 Hz, and 2,000 Hz.
(vii) Visible evidence of significant ceru-
men accumulation or a foreign body in the
ear canal.
(viii) Pain or discomfort in the ear.
Special care should be exercised in select-
ing and fitting a hearing aid whose max-
imum sound pressure level exceeds 132 deci-
bels because there may be risk of impairing
the remaining hearing of the hearing aid
user. (This provision is required only for
those hearing aids with a maximum sound
pressure capability greater than 132 decibels
(dB).)

(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 per-
son with a hearing loss have a medical eval-
uation by a licensed physician (preferably a
physician who specializes in diseases of the
ear) before purchasing a hearing aid. Li-
censed physicians who specialize in diseases
of the ear are often referred to as
otolaryngologists, otologists or
otorhinolaryngologists. The purpose of med-
ical evaluation is to assure that all medi-
cally treatable conditions that may affect
hearing are identified and treated before the
hearing aid is purchased.
Following the medical evaluation, the phy-
sician will give you a written statement that
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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.

(4) Technical data. Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard “Specification of Hearing Aid Characteristics,” ANSI S3.22–2003 (Revision of ANSI S3.22–1996) (Includes April 2007 Erratum). The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005–3993, or are available for inspection at the Regulations Staff, CDRH (HFZ–215), FDA, 1350 Piccard Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).
(ii) Frequency response curve.
(iii) Average saturation output (HF-Average SSPL 90).
(iv) Average full-on gain (HF-Average full-on gain).
(v) Reference test gain.
(vi) Frequency range.
(vii) Total harmonic distortion.
(viii) Equivalent input noise.
(ix) Battery current drain.
(x) Induction coil sensitivity (telephone coil aids only).
(xi) Input-output curve (ACG aids only).
(xii) Attack and release times (ACG aids only).

(5) Statement if hearing aid is used or rebuilt. If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) Statements in User Instructional Brochure other than those required. A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

(i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and
§ 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 requirement. 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:

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 specializes 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]