Title 21 - Food and Drugs
Chapter I - Food and Drug Administration, Department of Health and Human Services
Subchapter H - Medical Devices
Part 800 - General
Subpart B - Requirements for Specific Medical Devices

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360j, 360k, 361, 362, 371. Section 800.30 also issued under Sec. 709, Pub. L. 115-52, 131 Stat. 1065-67.

§ 800.30 Over-the-counter hearing aid controls.

(a) ***Scope.*** This section specifies the requirements for over-the-counter (OTC) air-conduction hearing aids. Air-conduction hearing aids that satisfy the requirements in paragraphs (c) through (f) of this section are considered "available" over the counter as section 520(q)(1)(A)(v) of the Federal Food, Drug, and Cosmetic Act uses the term. Air-conduction hearing aids that do not meet the definition in section 520(q) of the Federal Food, Drug, and Cosmetic Act or do not satisfy the following requirements are prescription hearing aids. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation in part 874 of this chapter.

(b) ***Definitions for the purposes of this section.*** This section uses the following definitions:

Air-conduction hearing aid. An air-conduction hearing aid is a hearing aid that conducts sound to the ear through the air.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Licensed person. A licensed person is a person as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act that holds a license or degree for the diagnosis, assessment, or treatment of hearing loss; or that holds a license to sell or distribute hearing aids. A person that must meet generally applicable licensing or operating requirements such as annual health and safety inspections, provided the generally applicable licensing or operating requirement is consistent with this section and other applicable requirements under the Federal Food, Drug, and Cosmetic Act, is not a "licensed person" solely for that reason. A person that represents as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) is not a "licensed person" solely by making such representations.

Over-the-counter hearing aid. An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.

Rebuilt hearing aid. An OTC hearing aid is "rebuilt" if the manufacturer has inspected and tested the device, made any necessary modifications to ensure it meets applicable regulatory requirements, including the requirements in this section to be available OTC, and adequately reprocessed the device for the next user.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Tools, tests, or software. Tools, tests, or software are components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device's output, to meet the user's hearing needs.

Used hearing aid. A hearing aid is "used" if a user has worn it for any period of time. However, a hearing aid shall not be "used" merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is "bona fide" if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) ***Labeling.*** An OTC hearing aid shall bear all of the following in the labeling:

(1) ***Outside package labeling.*** The outside package of an OTC hearing aid shall bear all of the following:

(i) ***Warnings and other important information.*** All of the following shall appear on the outside package:

(A) (A) *Warning against use in people younger than 18.*

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

(B) ***Symptoms suggesting perceived mild to moderate hearing loss.***

This hearing aid is for adults with signs of mild to moderate hearing loss. How do you know if you have this?

- You have trouble hearing speech in noisy places
- You find it hard to follow speech in groups
- You have trouble hearing on the phone
- Listening makes you tired
- You need to turn up the volume on the TV or radio, and other people complain it's too loud

(C) ***Advice of availability of professional services.***

Some people with hearing loss may need help from a hearing healthcare professional. How do you know if you need to see one?

- You can't hear speech even if the room is quiet
- You don't hear loud sounds well, for example, you don't hear loud music, power tools, engines, or other very noisy things

If your hearing loss makes it hard to hear loud noises, this hearing aid may not be your best choice without help from a professional. If this hearing aid does not help you enough, ask for help from a hearing healthcare professional.

(D) *"Red flag" conditions.*

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

(E) *Notice of contact information.*

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] or write to [email address] or [postal address] to request a paper copy of this information and other labeling.

(F) *Notice of manufacturer's return policy.*

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

(ii) ***Statement of build condition.*** If the OTC hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(iii) ***Statement of OTC availability.*** The principal display panel shall bear the marks "OTC" and "hearing aid" with the same prominence required under § 801.61(c) of this chapter for the device's statement of identity. The device's common name on the principal display panel may satisfy all or part of this requirement to the extent the common name includes the marks.

(iv) ***Indication of battery information.*** The outside package shall indicate the type and number of batteries and whether batteries are included in the package.

(v) ***Indication of control platform.*** The outside package shall indicate whether a mobile device or other non-included control platform is required. The indication must include the type of platform and how the platform connects to the device.

(2) ***Labeling, inside the package.*** The manufacturer or distributor of an OTC hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) ***Warning against use in people younger than 18.***

WARNING: If you are younger than 18, do not use this.
You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

(B) ***"Red flag" conditions.***

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

(C) ***Warning about pain from device placement.***

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

(ii) Any additional warnings the manufacturer may include prior to the cautions and notices to users in paragraph (c)(2)(iii) of this section.

(iii) The following cautions and notices for users, which shall appear prior to any content except the cover page and the warnings under paragraphs (c)(2)(i) and (ii) of this section:

(A) ***Caution about hearing protection.***

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

(B) *Caution about excessive sound output.*

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

(C) *Caution about components lodging in ear.*

Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

(D) *Advice to seek professional services.*

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

(E) *Note about user expectations.*

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

(E) *Note about reporting adverse events to FDA.*

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

(iv) An illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(v) Information on the function of all controls intended for user adjustment.

(vi) A description of any accessory that accompanies the OTC hearing aid, including but not limited to wax guards and accessories for use with a computer, television, or telephone.

(vii) Specific instructions for all of the following:

(A) Instructions for sizing or inserting the eartip of the OTC hearing aid to prevent insertion past the depth limit and damage to the tympanic membrane.

(B) The tools, tests, or software that allow the user to control the OTC hearing aid, including self-selection and self-checking the performance of the OTC hearing aid, and customize it to the user's hearing needs, including information about properly fitting eartips.

(C) Use of the OTC hearing aid with any accompanying accessories.

(D) Maintenance and care of the OTC hearing aid, including how a lay user can clean, disinfect, and replace parts or how to seek replacements, as well as how to store the hearing aid when it will not be used for an extended period of time.

(E) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(F) Expected battery life.

(G) Any other information necessary for adequate directions for use as defined in § 801.5 of this chapter.

(viii) Identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician, referring to an ear-nose-throat doctor when preferable, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(ix) The technical specifications required by paragraph (c)(4) of this section.

(x) A description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid, including but not limited to, as applicable, ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(xi) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xii) Information on how and where to obtain repair service or replacements, including at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service or replacements.

(xiii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

(3) ***Labeling on the device.*** The labeling on an OTC hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a "+" symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the OTC hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) ***Technical specifications.*** All of the following technical specifications shall appear in the user instructional brochure that accompanies the device. You may additionally include it on the outside package:

(i) The maximum output limit value (Output Sound Pressure Level 90 (OSPL90)).

(ii) The full-on gain value, which is the gain with a 50 decibel (dB) Sound Pressure Level (SPL) pure-tone input and volume set to full on.

(iii) The total harmonic distortion value.

(iv) The self-generated noise value.

(v) The latency value.

(vi) The upper and lower cutoff frequencies for bandwidth.

(5) ***Software device labeling.*** OTC hearing aid software that is not distributed with the hearing aid or amplification platform shall meet all of the following labeling requirements. With respect to the information required under paragraphs (c)(1) through (4) of this section, the information must be provided in the software device labeling, as specified in paragraphs (c)(5)(i) through (v) of this section, rather than the locations (*e.g.*, outside package labeling) specified in paragraphs (c)(1) through (4):

(i) Prior to first use of the software or obtaining payment information for the software, whichever occurs first, the labeling must clearly and prominently present all of the following to the prospective user. For each, the labeling must remain visible until the user dismisses it or proceeds to the next step:

(A) Compatibility and minimum operating requirements for the software device.

(B) Disclosures of any fees or payments after first use or initial payment, including but not limited to any fees or payments relating to subscriptions, add-on features, or continued access to features or services. The disclosures must name and briefly describe what each fee or payment covers.

(C) The information required under paragraphs (c)(1)(i), (iii), and (v) of this section.

(ii) Prior to first use of the software, the labeling must clearly and prominently present all of the following to the prospective user:

(A) The information required under paragraph (c)(2)(i)(A) of this section, and it must remain visible until the user acknowledges it.

(B) The information required under paragraphs (c)(2)(i)(B) and (C), (c)(2)(ii), (iii), and (v), (c)(2)(vii)(B) and (G), and (c)(2)(viii) and (ix) of this section, and the information must remain visible until the user dismisses it or proceeds to the next step.

(C) All other information required under paragraph (c)(2) of this section, to the extent applicable, and the information must remain visible until the user dismisses it or proceeds to the next step.

(iii) The software device labeling must include the information required under paragraphs (c)(3)(i) and (c)(4) of this section.

(iv) All of the software device labeling must be accessible for review after acknowledgment, dismissal, or proceeding to the next step.

(v) If there are changes to any of the labeling required under paragraph (c)(5) of this section, the labeling with the changed information must be presented to the user until the user dismisses it.

(d) ***Output limits.*** The output limit for an OTC hearing aid shall be the device maximum acoustic output sound pressure level (SPL) with an acoustic coupler as described in paragraph (e)(6) of this section when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. An OTC hearing aid shall not exceed the following limits at any of the frequencies at which the device is intended to operate:

(1) ***General output limit.*** An OTC hearing aid shall not exceed an output limit of 111 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) ***Output limit for a device with activated input-controlled compression.*** An OTC hearing aid that has input-controlled compression activated shall not exceed an output limit of 117 dB SPL at any frequency.

(e) ***Electroacoustic performance limits.*** An OTC hearing aid shall perform within all of the following electroacoustic limits. Measure each electroacoustic performance characteristic using an acoustic coupler as described in paragraph (e)(6) of this section, where applicable:

(1) ***Output distortion control limits.*** Test the output distortion of the OTC hearing aid as follows to ensure that it does not exceed the limit specified in paragraphs (e)(1)(i) through (iii) of this section.

(i) The total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method:

(A) Using sine wave-based testing, measure at 70 dB SPL and 100 dB SPL; or

(B) Using a 500-hertz (Hz) one-third-octave pulsed-noise signal, measure at 67 dB SPL and 97 dB SPL.

(ii) You must measure the total harmonic distortion using a 500-Hz input tone with an analyzer that has a bandwidth at least as wide as the frequency limits of the OTC hearing aid.

(iii) You must measure the output distortion at the OTC hearing aid's maximum volume and the input sound level to the OTC hearing aid adjusted to produce the required outputs.

(2) ***Self-generated noise level limits.*** Self-generated noise shall not exceed 32 dBA. You must disable any methods that artificially lower the apparent noise floor for the measurement. Such methods would include but are not limited to auto-muting and downward expansion.

(3) ***Latency.*** Latency shall not exceed 15 ms. You must measure the latency with a method that is accurate and repeatable to within 1.5 ms.

(4) ***Frequency response bandwidth.*** The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater. You must measure the frequency response bandwidth as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

(5) ***Frequency response smoothness.*** No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak. You must measure the frequency response smoothness using values for a diffuse field and the corrected one-third-octave frequency insertion response as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

(6) ***Acoustic coupler choice.*** Where applicable, use one of the following acoustic couplers to measure electroacoustic performance:

(i) When compatible with the device design, a 2-cubic centimeter (cm^3) acoustic coupler; or

(ii) When a 2-cm^3 acoustic coupler is not compatible with the device design, an acoustic coupler that is a scientifically valid and technically equivalent alternative. You must document the rationale for using an alternative acoustic coupler.

(f) ***Design requirements.*** An OTC hearing aid must conform to all of the following design requirements:

(1) ***Insertion depth.*** The design of an OTC hearing aid shall limit the insertion of the most medial component so that, when inserted, the component is reasonably expected to remain at least 10 millimeters (mm) from the tympanic membrane.

(2) ***Use of atraumatic materials.*** The material for the eartip of an OTC hearing aid shall be atraumatic.

(3) ***Proper physical fit.*** The design of an OTC hearing aid shall enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

(4) ***Tools, tests, or software.*** The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.

(5) ***User-adjustable volume control.*** The OTC hearing aid shall have a user-adjustable volume control.

(6) ***Adequate reprocessing.*** If the OTC hearing aid is used or rebuilt, it must be adequately reprocessed for the next user prior to sale.

(g) ***Conditions for sale of an OTC hearing aid.*** The sale of an OTC hearing aid is subject to all of the following conditions:

(1) ***Age minimum.*** Sale to or for a person younger than 18 years of age is prohibited.

(2) ***Statement of OTC availability.*** Sale of an OTC hearing aid is prohibited unless its labeling bears the statement of OTC availability required under paragraph (c)(1)(iii) of this section.

(h) ***Effect on State law.*** Any State or local government requirement for an OTC hearing aid is preempted to the following extent:

(1) ***Preemption.*** No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under section 709(b) of the FDA Reauthorization Act of 2017, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

(2) ***Professional requirements*** -

(i) ***General rule.*** The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity, whether through in-person transactions, by mail, or online, shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification, or any other State or local sanction unless such requirement is generally applicable to the sale of any product or to all places of business regardless of whether they sell OTC hearing aids. However, although a State or local government may not require the order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

(ii) ***Sale of OTC hearing aids is not an exemption.*** The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids does not exempt a person from any State or local government's professional or establishment requirements that are consistent with this section.

(iii) ***Representations may create professional obligations.*** A person shall not incur specialized obligations by representing as a servicer, marketer, seller, dispenser, customer support representative, or distributor (or an equivalent description) of OTC hearing aids. However, a person representing as any other defined professional or establishment, or as a State licensed dispenser, is subject to applicable State and local requirements even if the person undertakes commercial or professional activities only in relation to OTC hearing aids.

(3) ***Private remedies.*** This section does not modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(i) ***Incorporation by reference.*** ANSI/CTA-2051, "Personal Sound Amplification Performance Criteria," dated January 2017 (ANSI/CTA-2051:2017), is incorporated by reference into this section with the approval of the Director of the Office of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Food and Drug Administration and at the National Archives and Records

Administration (NARA). Contact the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov*, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*. The material may be obtained from Consumer Technology Association (CTA), Technology & Standards Department, 1919 S Eads Street, Arlington, VA 22202; phone: 703-907-7600; fax: (703) 907-7693; email: *standards@ce.org*, website: *www.cta.tech*.

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