The FDA & Hearing Aids

The FDA regulates the sales of hearing aids and implantable devices. In their recent “Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” issued on: February 25, 2009, the FDA provided the regulatory definition of hearing aids:

21 CFR 874.3300 Hearing Aid

(a) Identification. A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400).

(b) Classification. (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9.

(2) Class II for the bone-conduction hearing aid.

All hearing aids must comply with specific requirements regarding patient and professional labeling identified in 21 CFR 801.420. This regulation includes specific labeling requirements for the hearing aid device itself (e.g., device model, serial number, date of manufacture) as well as the content of the User Instructional Brochure that must be provided to potential hearing aid recipients (e.g. technical data, “Warning to Hearing Aid Dispenser” statement).

Additionally, all hearing aids must comply with the required conditions for sale, as stated in 21 CFR 801.421. A prospective hearing aid user must provide to the hearing aid dispenser a written statement from a licensed physician that the prospective user has been medically evaluated and is a candidate for a hearing aid. This evaluation must occur within 6 months prior to the date of purchase of the hearing aid. If 18 years of age or older, the prospective user may waive this requirement for medical evaluation provided that the prospective user signs a waiver statement under the conditions outlined in this regulation. Children (age less than 18 years) are not eligible for a waiver.

Finally, the hearing aid dispenser must retain records of all medical evaluation statements and waivers for a period of three years after dispensing of the hearing aid.
These regulatory conditions for sale were established to encourage prospective users to receive proper medical evaluation and treatment for treatable causes of hearing loss. The hearing aid classification regulation specifically excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400). Therefore, they are not subject to these regulatory requirements for labeling and conditions for sale.

For questions regarding regulatory requirements for hearing aid devices, please contact the Branch Chief for Ear, Nose, and Throat Devices at 240-276-4242.

http://www.fda.gov/cdrh/ode/guidance/1696.html

_The FDA’s website includes a number of different documents regarding hearing aids and hearing devices, as follows:_

**Index of CDRH Web Documents**

**Hearing Aids**
- Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products
- Guidance for Industry; Noise Claims in Hearing Aid Labeling; Final
- Implantable Middle Ear Hearing Device; Guidance for Industry and FDA

**Hearing Devices**
- Brain stem implant to restore some hearing when tumors damage the cranial hearing nerves
- Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA
- FDA Approves New Implantable Hearing Device
- FDA Plans to Strengthen Hearing Aid Rules
- Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products
- Implantable Middle Ear Hearing Device; Guidance for Industry and FDA
- Message Sent Loud and Clear to Hearing Aid Marketer
- Nucleus ® 24 Auditory Brainstem Implant System
- On the Teen Scene: Enjoy, Protect, the Best Ears of Your Life
- Straight Talk from FDA About Hearing Loss and Hearing Aids
- Testing of Hearing Aid Interference from Digital Cellular Telephones

This list and with links to the original documents can be found on the FDA website at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/topicindex/topindx.cfm?alpha=h or use http://tinyurl.com/6joc