

FDA Regulation of Hearing Aids

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Presentation Outline

- Overview of risk-based regulatory approach for devices
- Hearing aid regulations
 - Labeling
 - Conditions for sale
- Recent developments
 - PCAST, NASEM reports
 - FDA Workshop: “Streamlining GMPs for Hearing Aids”
 - Immediately in Effect Guidance re: medical evaluation/waiver regulation
- Future Directions

Definition of a Medical Device



- Intended to diagnose, cure, mitigate, treat or prevent a disease/condition, or
- Intended to affect the structure or function of the body, and
- Does not achieve intended use through chemical action or metabolism



Definition of Hearing Aid

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.

(21 CFR 801-420)

Personal Sound Amplification Products (PSAPs)

- No formal regulatory definition
- PSAPs are intended to amplify environmental sound for *non-hearing impaired* consumers for use in a variety of listening situations (e.g. hunting, bird watching, listening to distant sounds)
- PSAPs do **NOT** meet the regulatory definition for a medical device and are not subject to medical device regulations

The Diversity of Medical Devices



Regulatory Process for Devices

Medical Device Amendments of 1976 to the FD&C Act:
Created a tiered, ***risk-based*** classification with regulatory requirements gauged to risks:

Class	Risk	Regulatory Requirements
Class I	Low	General Controls (most exempt from marketing application)
Class II	Moderate	General Controls and Special Controls
Class III	High	General Controls and Premarket Approval (PMA)

Regulatory Classification for Hearing-Related Devices

Class	Risk	Example
Class I	Low	Air-conduction hearing aid
Class II	Medium	Wireless air-conduction hearing aid (Class II exempt) Transcutaneous air-conduction hearing aid Bone-conduction hearing aid Bone-anchored hearing aid Tinnitus masker
Class III	High	Cochlear implant Implantable middle ear hearing device Auditory brainstem implant

21 CFR 874.3300 Hearing Aid

Class I: General Controls

- Prohibition of adulterated or misbranded devices
- GMPs
- Registration of manufacturing facilities and listing of device types
- Record keeping
- Repair, replacement, refund
- Premarket notification [510(k)]: most Class I devices now exempted



21 CFR 874.3305 Wireless air-conduction hearing aid

Class II: General controls plus Special Controls

- Special Controls
 - Appropriate analysis/testing should validate EMC and safety of exposure to nonionizing radiation
 - Design, description, and performance data should validate wireless technology functions
 - Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation
- Exempt from Premarket Notification



- Most air conduction hearing aids are not prescription devices,

BUT

- Hearing aids are **restricted** by regulation with respect to **device labeling** (21 CFR 801.420) and **conditions for sale** (21 CFR 801.421).

Patient/Professional Labeling (21 CFR 801.420)

- User Instructional Brochure
 - Instructions for use, expectations
 - “Warning to Hearing Aid Dispensers”—red flag signs and symptoms
 - “Important Notice for Prospective Hearing Aid Users”
 - Technical performance data (ANSI S3.22-2003)

Hearing Aid Regulations (cont'd): Conditions for Sale (21 CFR 801.421)

- Medical evaluation by a licensed physician within the preceding 6 months prior to dispensing
- Waiver of medical evaluation possible for users ≥ 18 years
 - Sign statement acknowledging that medical evaluation is in his/her best health interest
 - Dispenser may not actively encourage waiver
 - Opportunity to review User Instructional Brochure
- Record keeping (3 years)

Preamble to Hearing Aid Regulations (1977)

“The Commissioner emphasizes...that the medical evaluation requirement is based upon the recognition that an unnecessary or partially effective hearing aid may be substituted for primary medical or surgical treatment, thus depriving the patient of ...appropriate medical diagnosis and care resulting in a detriment to health.”

Recent Developments

- President's Council of Advisors on Science and Technology (PCAST) Report: "Aging America & Hearing Loss: Imperative of Improved Hearing Technologies" (October, 2015)
- Recommendations for FDA included:
 - Create a new class of hearing aids for sale over-the-counter for mild to moderate age-related hearing loss
 - Exempt this class of hearing aids from Quality Systems regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer electronics industry
 - Rescind the 2013 draft hearing aid/PSAP guidance and allow PSAPs to make claims about their technological capabilities

Recent Developments (cont'd)

- FDA public workshop: "Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids" (April 21, 2016)
- Received comments/recommendations on:
 - GMPs versus other quality/performance standards
 - FDA regulations and barriers to hearing aid access
 - Consumer perspective
 - Self-diagnosing and self-treating mild to moderate hearing loss

Recent Developments (cont'd)

- National Academies of Sciences, Engineering, and Medicine (NASEM) Report: “Hearing Health Care for Adults: Priorities for Improving Access and Affordability” (June 2, 2016)
- Included recommendations for FDA:
 - Remove the medical evaluation/waiver requirement
 - Ensure consumers receive information about the medical conditions of hearing loss through user instructional brochures
 - Establish a new category of over-the-counter (OTC) wearable hearing devices that can assist adults with mild to moderate hearing loss

Recent Developments (cont'd)

- NASEM's recommendations for FDA (cont'd):
 - Retain a guidance document (2009 or revised version of 2013 guidance) on PSAPs clarifying that they are not to be offered/promoted for hearing loss, but are subject to the electronic product provisions of the Food, Drug, and Cosmetic Act

Recent Developments (cont'd)

- “Immediately in Effect Guidance Document: Labeling and Conditions for Sale for Non-Prescription Hearing Aids” (December 10, 2016)
 - FDA will not enforce medical evaluation/waiver requirement for ≥ 18 yr
 - Labeling regulation still enforced
- Senators Warren and Grassley introduced the “Over-the-Counter Hearing Aid Act of 2017” to allow hearing aids that are intended to be used by adults to compensate for mild to moderate hearing impairment to be sold over the counter

Future Directions

- Consider creating a category of OTC hearing aids that could deliver new, innovative and lower-cost products directly to consumers without requirement for a credentialed dispenser
- Continue co-sponsorship of ongoing activities related to NAS study
 - Solicit input from stakeholders on NAS recommendations regarding OTC hearing aids: June 9, 2017 NAS Open Public Meeting
- Finalize guidance clarifying regulatory requirements for hearing aids vs. PSAPs

Questions?

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