Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:

Over-the-Counter (OTC) Hearing Aids, Proposed Rule
Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs), Draft Guidance

December 07, 2021

Over-the-Counter (OTC) Hearing Aids Proposed Rule
and
Personal Sound Amplification Products (PSAPs) Draft Guidance

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Proposed Rule and Draft Guidance

- **Proposed Rule: Establishing Over-the-Counter Hearing Aids**
  - www.federalregister.gov/documents/2021/10/20/2021-22473/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

- **Draft Guidance: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products

- **Some Acronyms We'll Use Frequently:**
  - **OTC** = Over-the-Counter
  - **PSAP** = Personal Sound Amplification Product

Learning Objectives

- Identify current landscape of hearing aid regulations
- Summarize proposed rule for over-the-counter hearing aids
- Summarize distinctions between hearing aids and PSAPs outlined in the draft guidance
- Identify where and how to provide written comments on PR and draft guidance

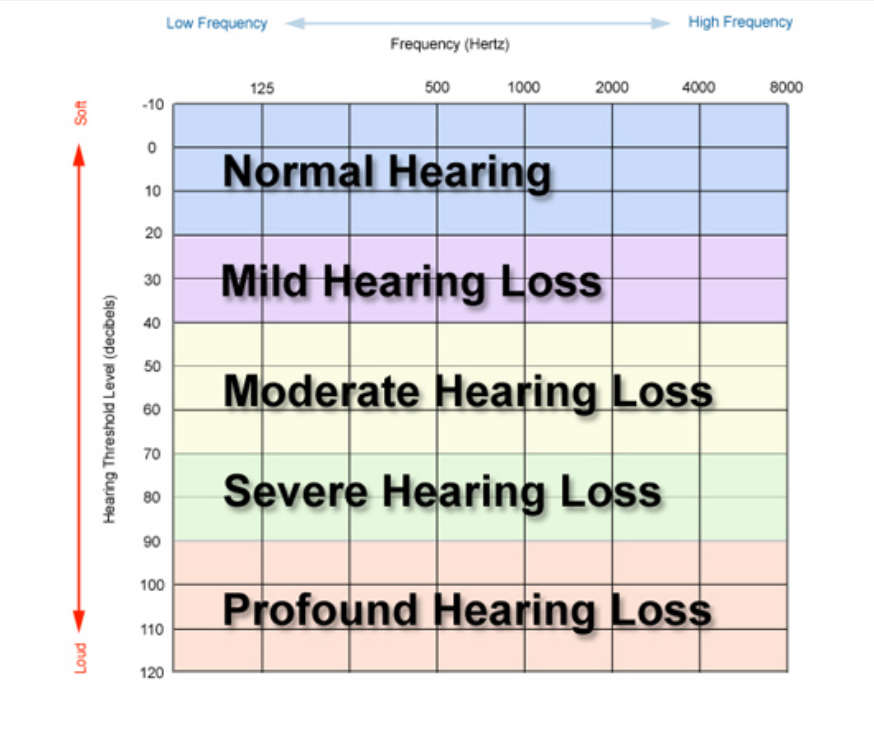
Current Landscape of Hearing Aid Regulations

Hearing Aid Use

- **About 28.8 million US adults could benefit from hearing aid (HA) use**[1]
- **Low rate of usage among adults**[1]
  - ≥ 70yr old, < 30% have ever used HAs
  - < 70 yr old, ~16% have ever used HAs
- **Barriers to HA usage**
  - Stigma
  - Cost/Value
  - Federal and state regulations

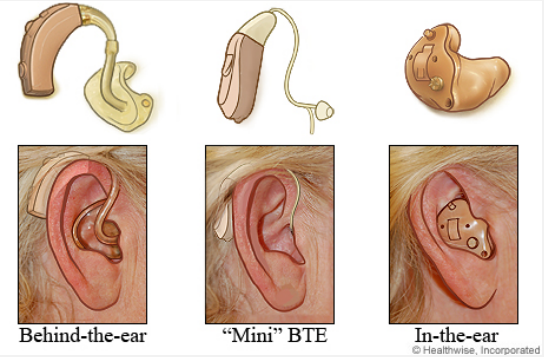
1 **NIH Quick Statistics About Hearing:** www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

Devices to Treat Hearing Loss

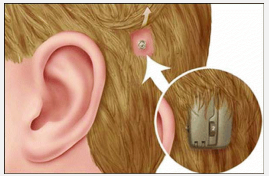


Hearing Aids:

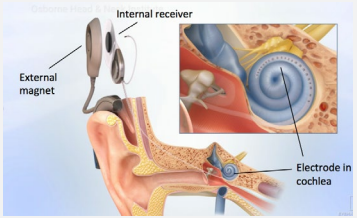
- **Air-Conduction**
- Bone-Conduction



Implantable hearing aids



Cochlear Implants



Current Regulations

- **Air-conduction hearing aids**
  - Air-conduction hearing aid [21 CFR 874.3300(b)(1)]
  - Wireless air-conduction hearing aid [21 CFR 874.3305]
  - Self-fitting air-conduction hearing aid [21 CFR 874.3325]

- **Most air-conduction hearing aids**
  - are currently **not** prescription devices
  - but are subject to certain federal restrictions

Current Regulations (cont.)

- **Labeling requirements (21 CFR 801.420)**
- **Conditions for sale (21 CFR 801.421)**
  - Medical evaluation within 6 months of dispensing
  - Waiver allowed for users 18 year and older
  - Record keeping requirements
  - Regulatory flexibility for certain conditions for sale provided through FDA Guidance "Condition for Sale of Air-Conducting Hearing Aids"

www.fda.gov/regulatory-information/search-fda-guidance-documents/immediately-effect-guidance-document-conditions-sale-air-conduction-hearing-aids

Current Regulations (cont.)

- **Additional regulations in some U.S. States**
  - Testing requirements
  - Medical evaluation
  - Restrictions on internet/mail order sales
  - Licensing requirements for dispensers

Proposed Rule for Over-The-Counter Hearing Aids

Ian Ostermiller, JD
Policy Advisor
Office of Policy

Goals of FDA's Proposals

- Maintain reasonable assurance of safety and effectiveness
- Implement § 709 of FDARA, new § 520(q) of the FD&C Act
- Establish regulatory requirements for OTC hearing aids
- Address preemption of State requirements under FDARA
- Realign current regulations for consistency

FDARA = FDA Reauthorization Act of 2017
FD&C Act = Federal Food, Drug, and Cosmetic Act

FDARA § 709 Requirements

- **Must establish OTC category that includes:**
  - Requirements to provide reasonable assurance of safety and effectiveness of OTC hearing aids
  - Output (volume) limits appropriate for OTC hearing aids
  - Appropriate labeling, including “conspicuous statement” that the device is only intended for people age 18 and older
  - Conditions for sale of OTC hearing aids

- **Must finalize updated PSAP guidance with final rule**

Strategy for Proposal

- **Update "rules of the road" for air-conduction hearing aids**
- **We are <u>not</u> creating a device type unique to OTC devices**
  - This proposal is not for a device clearance or approval
  - Devices already on the market could use the OTC lane
- **To market hearing aids as OTC**
  - Existing devices would likely need at least labeling updates
  - A 510(k) could be required, depending on specifics of changes
  - Other requirements would apply too, e.g., registration and listing

Proposed Regulations

21 CFR 800.30 – OTC Hearing Aids

- Scope
- Definitions
- Labeling
- Output limits
- Electroacoustic performance
- Design requirements
- Condition for sale
- Effect on state laws

21 CFR 801.422 – ℞ Hearing Aids

- Scope
- Definitions
- Labeling

(Prescription Use)

OTC Hearing Aids: Proposed Technical and Performance Specifications

Vasant Dasika, PhD
Biomedical Engineer
OHT1/OPEQ

Maximum Output Limit
21 CFR 800.30(d)

- OSPL90 shall not exceed
  - **115 dB SPL**, or
  - **120 dB SPL, with both input-controlled compression and volume control**

- **Rationale**: Maximum output should be neither too high, nor too low, and achieve both:
  - **Safety:** by reducing risk to residual hearing via an appropriately set upper limit
  - **Effectiveness:** by providing sufficient dynamic range and allowing adequate amplification for mild to moderate hearing loss

Electroacoustic Performance
21 CFR 800.30(e)

- **Total harmonic distortion plus noise**: ≤ 5%
- **Self-generated noise**: ≤ 32 dB SPL
- **Latency**: ≤ 15 ms
- **Frequency response bandwidth**: ≤ 250Hz to ≥ 5kHz
- **Frequency response smoothness**
  - no undue peaks/troughs in frequency response

Design Requirements
21 CFR 800.30(f)

- **Insertion depth**
  - Hearing aid design shall limit insertion of eartip to no deeper than bony-cartilaginous junction of external auditory canal
- **Use of atraumatic materials**
  - Eartip material of an OTC hearing aid shall be atraumatic
- **Proper physical fit**
  - Design shall enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit
- **Tools, tests, or software**
  - Through tools, tests, or software, shall permit lay user to control device and customize it to user's hearing needs

Hearing Aids and PSAPs: Distinctions Outlined in Draft Guidance

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Director, Division of Dental and ENT Devices
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Regulatory Requirements

- **Hearing Aid**
  - Intended to aid persons with or compensate for hearing impairment
  - Meets definition of a device, per § 201(h) of FD&C Act
  - Subject to applicable device requirements under FD&C Act and FDA regulations

- **Personal Sound Amplification Product (PSAP)**
  - Intended for non-hearing-impaired consumers to amplify sounds in certain environments and
  - Not intended to aid persons with or compensate for hearing impairment
  - Does not meet definition of a device, per § 201(h) of FD&C Act

Radiation Health Requirements

- Both are electronic products that emit sound
- FDA regulates electronic products that emit sound through the authorities provided by the Radiation Control for Health and Safety Act of 1968 (now incorporated into the FD&C Act)

- **PSAP Manufacturers responsibilities include:**
  - Report defects
  - Comply with the requirements to repurchase, repair, or replace electronic products
  - Report accidental radiation occurrences

Examples Where PSAPs Are Used

- Hunting (listening for prey)
- Bird watching
- Listening to lectures with a distant speaker
- Listening to soft sounds difficult for normal hearing individuals to hear

Distinction Between Hearing Aids and PSAPs

- FDA considers **intended use** of each product to determine if it is a device or solely an electronic product
- Product's intended use refers to "objective intent" (21 CFR 801.4) of those legally responsible for labeling
- May, for example, be shown by the design or composition of an article, or by written or oral claims or statements in any:
  - label and labeling
  - advertising
  - promotion of a product by or on behalf of a firm

Examples of Explicit/Implicit Claims

- For users with certain types or severity of hearing loss/impaired hearing
- In situations that are typically associated with and indicative of hearing loss/impaired hearing
- Alternative to a hearing aid
- Information conveyed to user to optimize product to their hearing loss/impaired hearing profile

➢ These would generally cause a PSAP to be a medical device (hearing aid)

Providing Comments on Proposed Rule and Draft Guidance

A Note about Draft Guidances

- You may comment on any guidance at any time
  - see 21 CFR 10.115(g)(5)
- Please submit comments on draft guidance before closure date
  - to ensure that FDA considers your comment on a draft guidance before we work on final guidance

Submit Comments to Dockets by: January 18, 2022

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  - Docket: FDA-2021-N-0555 (www.regulations.gov/docket/FDA-2021-N-0555)
- **Draft Guidance: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products
  - Docket: FDA-2020-D-1380 (www.regulations.gov/docket/FDA-2020-D-1380)

→ Submit separately to each docket
→ Online or by mail to designated docket

Summary

- Hearing aids have an extensive history of use and FDA regulation
- Proposed rule serves to create requirements to provide reasonable assurance of safety and effectiveness for over-the-counter hearing aids
- Proposes design, technical and performance requirements
- As draft guidance discusses, intended use helps to guide whether a product is a hearing aid (medical device) or a PSAP (not a medical device)


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Let's Take Your Questions

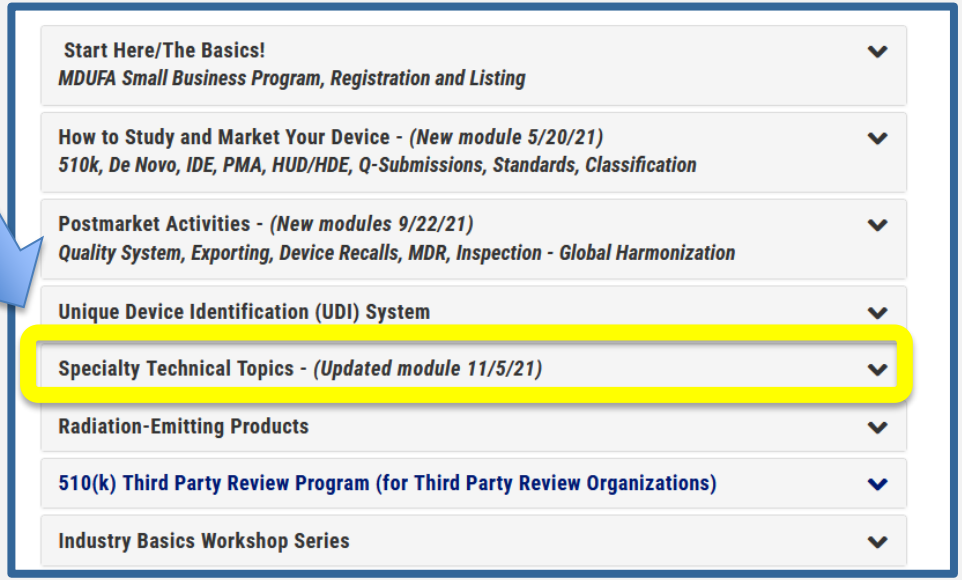
- **To Ask a Question:**
  1. Please "Raise Your Hand"
  2. Moderator will Announce Your Name to Invite You to Ask Your Question
  3. Unmute yourself when called

- **When Asking a Question:**
  - Announce your first name only (no last names or businesses)
  - Ask 1 question only; Keep question short
  - No questions about specific submissions or data-specific

- **After Question is Answered:**
  - Please mute yourself again
  - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn:**
  - www.fda.gov/Training/CDRHLearn



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