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Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs), Draft Guidance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Over-the-Counter (OTC) Hearing Aids Proposed Rule and Personal Sound Amplification Products (PSAPs) Draft Guidance

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U.S. Food and Drug Administration
Proposed Rule and Draft Guidance

• Proposed Rule: Establishing Over-the-Counter Hearing Aids

• Draft Guidance: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products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• Summarize distinctions between hearing aids and PSAPs outlined in the draft guidance
• Identify where and how to provide written comments on PR and draft guidance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

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”

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 not 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

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(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

Srinivas “Nandu” Nandkumar, PhD
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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=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

• Proposed Rule: Establishing Over-the-Counter Hearing Aids

• Draft Guidance: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

→ 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)
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!

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