OTC
Draft Regulation

FDA Framework

- FDA is amending and proposing to establish a new regulatory framework as it relates to hearing aids.
- Two categories of Categories of Hearing Aids
  - Prescription Hearing Aids
  - OTC Hearing Aids
  - Device type classifications would not be changed
- PSAP Draft Regulations were also released with the OTC Regulation

FDA's Proposal| What FDA is Proposing

FDA is proposing to establish OTC hearing aid category plus make all other hearing aids "prescription devices."

OTC Hearing Aids

FDA is proposing to establish regulatory controls, that if met, would allow Class I and Class II hearing aids to be sold OTC:

- OTC devices intended for individuals with perceived mild-to-moderate hearing loss.
- Subject to technical requirements, performance criteria, and labeling rules.
- "Self-fitting" OTC devices subject to 510(k) and clinical studies.
- Licensed hearing care professionals do not need to be involved but are permitted to sell, dispense, and support OTC hearing aids.

Prescription Hearing Aids

FDA is proposing to treat non-OTC hearing aids as "prescription hearing aids" that would need to be prescribed by hearing care professional licensed under state law.

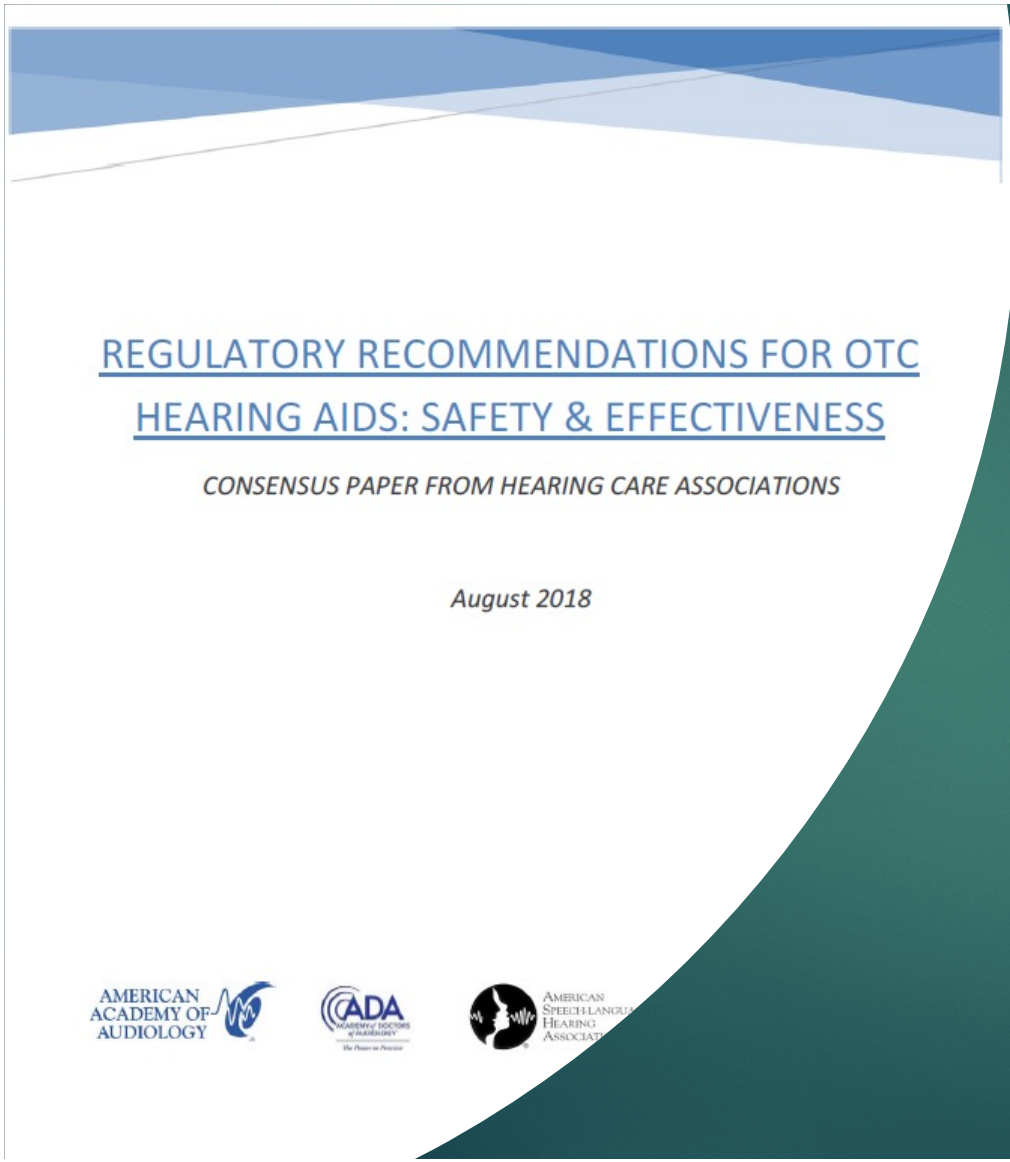
- Today, hearing aids are treated as "restricted" medical devices that are subject to conditions of sale, use, and distribution.
- This realignment would not affect the device class or premarket notification exemption status of any existing device.
- FDA is proposing to allow licensed hearing care professionals, including hearing aid specialists, to prescribe hearing aids.

PSAP Guidance

FDA also released new PSAP guidance:

- FDA is proposing to maintain the same distinction between "hearing aids" and "PSAPs" based on intended use (hearing aids are intended to compensate for hearing loss whereas PSAPs are intended to amplify sounds for persons with normal hearing).
- FDA will not treat "PSAPs" as medical devices. However, if PSAPs are advertised in a way that explicitly or implicitly claims the product is intended to treat hearing loss or is an alternative to a hearing aid, it will be treated as a "medical device" and FDA will enforce its proposed regulation.

Associations Consensus Paper Recommendations



August 14th Major Milestone: Consensus Paper Released

5 Key Points

1. **Recommendation 1**: FDA to establish **product requirements** appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment. In particular, the Working Group recommends that: a) the **2 cc coupler HFA full on gain, as measured at an input level of 50 dB SPL per ANSI S3.22-2014, is 25 dB** or lower; and b) **the peak (or maximum) 2 cc coupler OSPL90, per ANSI S3.22-2014, is not greater than 110 dB SPL**, in combination with input compression and volume control. In addition, the use of instant-fit ear-tips is encouraged.

2. **Recommendation 2:** FDA to define concise, **outside-of-the-box labeling** appropriate for medical devices sold over-the-counter. This should include **recognition of intended use / usage** and an important notice for the prospective users about **hearing loss being a medical condition best addressed in consultation with a licensed professional**.

3. **Recommendation 3:** FDA to define comprehensive, **inside-the-box labeling** including a strong warning that the device is not intended for children under the age of 18. Additionally, inside-the-box should include a User Instructional Manual with direction to the consumer on how to identify lack of benefit and what to do.

amplifon

5 Key Points (con't)

4. Recommendation 4: FDA to name the new category as "*Self-Fit Over-the-Counter Hearing Devices*" and to maintain for such category the same risk classification as air conduction hearing aids – i.e. Class I for non-wireless devices and Class II (exempt) for wireless OTC hearing devices. Additionally, the Working Group strongly recommends that any 510(k) exemptions be limited to devices that have received a first-time FDA marketing authorization (a 510(k) clearance). The initial OTC air conduction hearing devices should be required to undergo the 510(k) processes.

5. Recommendation 5: FDA, in coordination with the FTC, to establish strong consumer protection laws (e.g. return and refund policies, unsubstantiated and false claims, …) and put in place adequate processes and resources to enforce them, especially in the first years of introduction of the new category.

amplifon

Minimum Product Specifications

Maximum OSPL90: ≤110 dB SPL	HFA-FOG: ≤25 dB	Frequency Response: Lower 250 Hz to equal or great than 5 kHz
Response Smooth: ≥12 dB/ octave rule	EIN: ≤30 dB Maximum	Harmonic Distortion: Current ANSI recommendations
Latency: Less than 15msec	Volume Control: Yes	Compression: Input compression (minimum)
Battery: Type_____ disposable or rechargeable	Battery Life: ____ current drain or _____Hours	RF Immunity: M2/T2 (if available)

FDA's Proposal| OTC Proposal vs. Consensus Recommendations

		FDA Proposal	Consensus Recommendation
1	Product Requirements – Max Output	▪ Peak output of 115 dB SPL; or ▪ If device incorporates input-controlled compression and user-adjustable volume control, peak output of 120 dB SPL.	▪ Peak output of 110 dB SPL measured at 2 cc coupler OSPL90, per ANSI S3.22-2014.
	Product Requirements – Gain limit	▪ No gain limitation	▪ HFA full on gain, at an input level of 50 dB SPL, is 25 dB or lower.
2	Outside the box labelling	▪ Proposed outside-of-the-box labeling includes recognition of intended use, device usage, and a notice to prospective users about HL being a medical condition best addressed in consultation with a licensed professional.	▪ Define concise, outside-of-the-box labeling appropriate for mild-to-moderate HL. ▪ This should include recognition of intended use, device usage, and a notice to prospective users about HL being a medical condition best addressed in consultation with a licensed professional.
3	Inside the box labelling	▪ Proposed inside-the-box labeling includes a strong warning that the device is not intended for children under the age of 18, strong warnings on how to use device, identify lack of benefit, when to consult a professional, and how to report adverse events to the FDA.	▪ Define comprehensive, inside-the-box labeling including a strong warning that the device is not intended for children under the age of 18. ▪ Additionally, inside-the-box should include a User Instructional Manual with direction to the consumer on how to identify lack of benefit and what to do.
4	Risk classification	▪ Maintains same risk classification as air-conduction hearing aids (Class I) and wireless air-conduction hearing aids (Class II). ▪ Requires new "self-fitting" OTC devices to obtain 510(k) premarket clearance and complete clinical study.	▪ Maintain same risk classification as air-conduction hearing aids (Class I) and wireless air-conduction hearing aids (Class II). ▪ Require new OTC devices to obtain 510(k) premarket clearance.
5	Consumer protection	▪ Establishes strong consumer protections, including allowing existing state return/refund policies to apply to OTC hearing aids.	▪ Establish strong consumer protection laws (e.g. return and refund policies, unsubstantiated and false claims, …) and put in place adequate processes and resources to enforce them..

FDA OTC Regulation

- The draft regulation utilized the ANSI/CTA 2051 standard proposed by the Consumer Technology Association 2017 which was developed for PSAP's
- The Associations Consensus Paper was not referenced in the regulation
- There was not a standard or definition for Mild or Moderate hearing loss noted
- Regulations noted in this regulation preempts State regulations regarding hearing aids

FDA's Proposed OTC Regulation | Timeline and What to Expect

Status of FDA's Regulatory Process

Steps of FDA's Regulatory Process		Expected Timing
NPRM	FDA Publishes Draft Regulation	**Oct. 20**
Public Comment	Public Comment Period Ends • 90-day public comment period	**Jan. 18, 2022**
Final Regulation	FDA Publishes Final Regulation • FDA allowed up to 180 days to publish final regulation after public comment ends.	**July 2022**
Effective Date	Final Regulation Takes Effect • Final regulation takes effect 60 days after publication	**September 2022**
Market Opens	First Device on the Market • 510(k) exempt devices • Devices subject to 510(k) + clinical study (i.e. new self-fitting OTC hearing aids)	**Sep '22-Apr '23** • **Sep. '22** • **Feb-Apr '23**

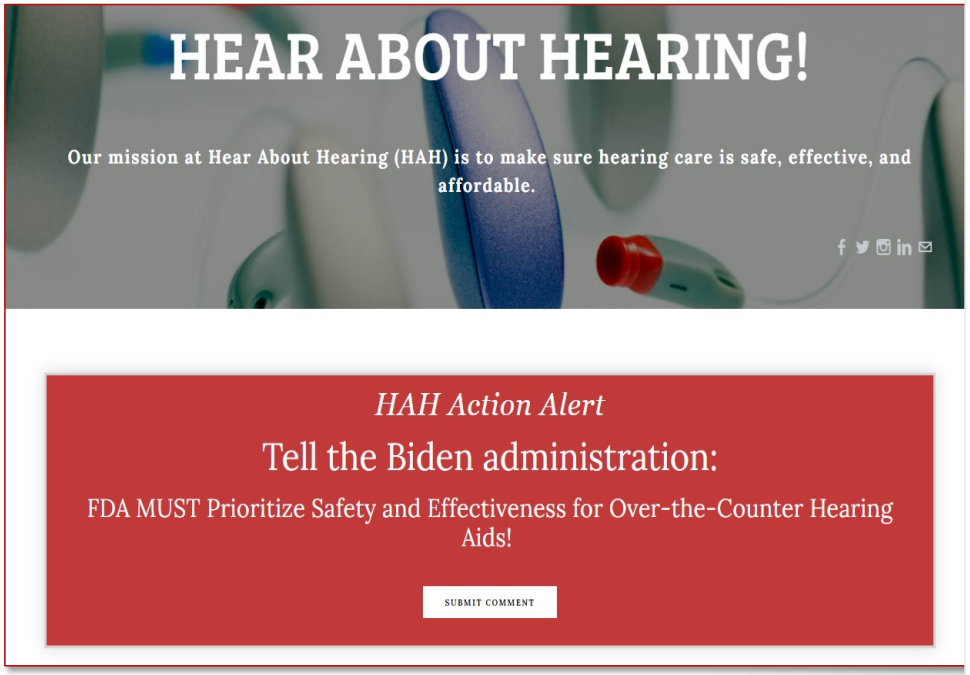
FDA's Public Comment Period

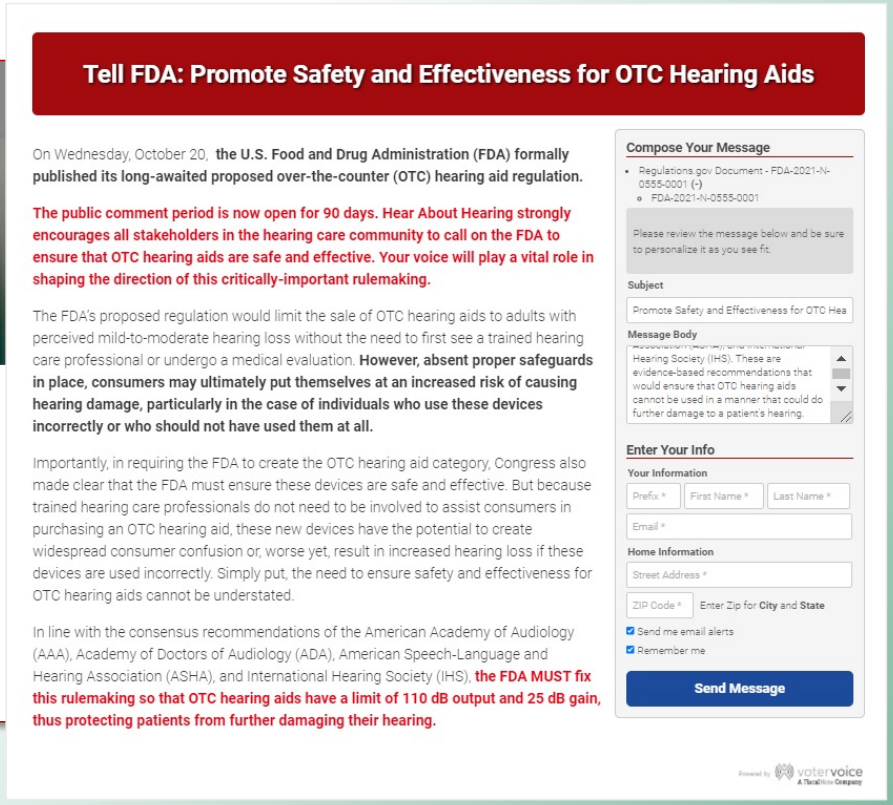
Recommend submit written comments to the FDA urging adoption of the consensus policy recommendations developed ADA, AAA, ASHA and IHS to ensure OTC devices are "safe and effective."

amplifon

Public Comment Period |

Hear About Hearing **is a non-partisan site which enables individuals to submit comments directly to the FDA during the public comment period through the website integrating VoterVoice comment writing functionality.**





www.hearabouthearing.org

Panel Discussion

amplifon