Comparison of FDA Reauthorization Act of 2017 (FDARA) with FDA Propose Rule on Regulation of Over-the-Counter Hearing Aids

Technical Specifications & Characteristics for Over-the-Counter Hearing Aids As outlined in the FDAR	FDAR	FDA Proposed Rule
Air conduction device or wireless air conduction device	√	√
Intended for over 18 consumer	√	√
Compensates for perceived mild to moderate hearing loss	√	No proposed gain range - not targeted at mild to moderate hearing loss, despite evidence-based fitting algorithms that clearly provide gain ranges
Tools, tests or software allows the user to control the OTC HA and customize it to the user's hearing needs	√	Silent on minimum suggested self-fitting methods
Tools may use wireless technology	√	√
May include tests for self-assessment of hearing loss	√	No guidance in this area
Available without the supervision, prescription or other order, involvement, or intervention of a licensed person	√	√
Available through in-person transactions, mail, or online	√	√
Exempt from 801.420 and 802.421 of Title 21	√	√
Establishes a category of OTC HAs	√	Does not establish a category of OTC HAs. An OTC HA can be either a class 1 or 2 devices, similar to devices traditionally prescribed and fit by a licensed professional.
Provides reasonable assurances of the safety and efficacy of OTC HAs	√	Defaults to the CTA 2051-2017 (ANSI) Personal Sound Amplification Performance Criteria. This standard is specifically designed for a consumer product not intended for individuals with hearing loss and not intended for full time use (situational).

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Establishes or adopts output limits appropriate for the OTC HAs	√	Recommends limits of 115 and 120 dB SPL and, despite data to the contrary, defers to users knowing when to turn down the VC or remove the devices when sounds are harmful
Includes requirements for appropriate labeling	√	Includes a variety of outside and inside of the box labeling. but does not include a warning that outputs are known to damage hearing. The labeling does not identify that optimal hearing health includes a hearing test by a licensed professional prior to exploring amplification options.
Labeling - how to report adverse events	√	√
Labeling of any conditions or contraindications	√	√
Labeling - advisements to consult promptly with a licensed physician	√	√
Determines whether OTC HAs require a report under section 510(k) to provide reasonable assurance of safety and effectiveness	√	Language is unclear as to whether or not all OTC HAs will report under section 510(k). As indicated in the bill, this is a mechanism for safety and effectiveness.
Indicates that no state or local government shall establish or continue in effect any law, regulation or order, or other requirement specifically applicable to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of the OTC HAs	√	In the absence of establishing a category of devices, language suggests the preemption of all state and local rules regulating all hearing aids - beyond the scope of the legislation.
Updates and finalizes the draft guidance "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products	√	√

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