PROPOSED RULE ESTABLISHING OVER-THE-COUNTER (OTC) HEARING AIDS

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ASHA American Speech-Language-Hearing Association

This side-by-side comparison is intended to summarize the recommendations put forth in the consensus paper drafted by the hearing care associations (ASHA, AAA, ADA, & IHS) in 2018 and the FDA-proposed regulations released in October 2021. ASHA submitted comments to the FDA on January 13, 2022, urging them to consider several revisions that would strengthen and ensure consumer safety and device efficacy.

	HEARING CARE ASSOCIATIONS PAPER	FDA-PROPOSED REGULATIONS
INTENDED USERS	Individuals 18 y/o + with self-perceived mild to moderate hearing loss (defined as thresholds of 26 - 55 dB HL for product design requirements)	Individuals 18 y/o + with self-perceived mild to moderate hearing loss; functional descriptors of mild to moderate hearing provided
DEFINITION OF OTC HEARING AIDS	Name the new category of devices "Self-Fit Over-the-Counter Hearing Devices"	Category labeled as "Over-the-Counter Hearing Aids;" they may be "self-fit" but this not a requirement
OUTPUT LIMIT; GAIN REQUIREMENTS	Peak OSPL90 no greater than 110dB SPL; 25 dB gain limit	Max OSPL90 limit of 115 dB SPL or 120 dB SPL if device is equipped with a volume control & input controlled compression; no gain requirement
DESIGN REQUIREMENTS	Input-controlled compression; volume control; only instant-fit eartips should be used	Input-controlled compression & volume control acknowledged as beneficial but NOT required; earpiece must use atramuatic materials and sit no deeper than the bony-cartiaginous junction of ear canal.
LABELING OUTSIDE THE BOX	Recognition of intended use/usage; important notice about hearing loss being a medical condition best addressed in consultation with a licensed professional	Warning against use in people younger than 18; symptoms of mild to moderate hearing loss; advice of availability of professional services; "red flag" conditions that require medical care; weblink and telephone number for information; notice of manufacturer's return policy
LABELING INSIDE THE BOX	Strong warning against use in children; user instructional brochure with direction on how to identify lack of benefit and what to do	Warning against use in people younger than 18; "red flag" conditions that require medical care; warning about pain from device placement; cautions about hearing protection and excessive sound output; advice to seek professional services; note about user expectations; note about reporting adverse effects to FDA; information about use and care of devices; technical data
RISK CLASSIFICATION	Same risk classification as hearing aids: Class I – non-wireless, Class II – wireless, manufacturer should be required to undergo 510(k) process	Class I - legacy air-conduction hearing aids and Class II -wireless air-conduction hearing aids are exempt from 510(k) process; Class II self-fitting air-conduction hearing aids are not 510(k) exempt; prescription devices would no longer be restricted devices
CONSUMER PROTECTION	Return and refund policies; protection against unsubstantiated and false claims	Not proposing to federally mandate a return policy for OTC devices; however, state or local requirements for returns would likely continue to apply; protections against misbranding under FD&C Act - violations subject to enforcement action