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January 14, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: "Medical Devices; Ear, Nose, and Throat Devices; Establishment of Over-the-Counter Hearing Aids" Proposed Rule; 86 *Fed. Reg.* 58150-58191; Docket No. FDA-2021-N-0555

Dear Sir or Madam:

The Consumer Healthcare Products Association[1] ("CHPA") submits these comments in response to the U.S. Food and Drug Administration's ("FDA's" or the "Agency's") proposed rule to establish a category for over-the-counter ("OTC") hearing aids and to make related amendments to the regulatory framework for hearing aids ("Proposed Rule").[2] For more than 141 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medical products. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

CHPA applauds the Agency's efforts to create a regulatory category for OTC hearing aids to improve patient access for hearing aids, and to implement the hearing aid provisions of the FDA Reauthorization Act of 2017 ("FDARA"). CHPA agrees with FDA that hearing loss affects a large number of individuals in the United States and "can have a significant impact on communication, social participation, and overall health and quality of life," that there remain barriers likely to impede the use of hearing aids in hearing-impaired individuals, and that the creation of a regulatory category for OTC hearing aids will "improve access to hearing aid technologies for Americans."[3]

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[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[2] FDA, Medical Devices; Ear, Nose, and Throat Devices; Establishment of Over-the-Counter Hearing Aids, Proposed Rule, 86 *Fed. Reg.* 58150-58191 (Oct. 20, 2021). Accessed from https://www.govinfo.gov/content/pkg/FR-2021-10-20/pdf/2021-22473.pdf on January 12, 2022.

[3] 86 *Fed. Reg.* at 58151.

While CHPA fully supports FDA's creation of a regulatory category of OTC hearing aids, CHPA believes that there are important areas of the Proposed Rule that require clarification as the Agency moves to finalizing the Proposed Rule, including: (A) the scope of legacy and wireless OTC hearing aids that could meet the requirement to include "tools, tests and software" in proposed 21 CFR § 800.30 but would not be considered self-fitting as defined in proposed 21 CFR § 874.3305(b)(3); (B) how OTC hearing aids will obtain their 510(k) exempt status after finalization of the Proposed Rule, and whether additional action is required either by FDA or by industry; and (C) application of the package labeling requirements to OTC hearing aids in small packaging with limited available labeling space on the package.

A. Scope of OTC Hearing Aids

One key area that CHPA believes should be clarified in the final rule is the scope of hearing aids that are eligible to be marketed as OTC hearing aids under proposed 21 CFR § 800.30 but are not considered self-fitting hearing aids under proposed 21 CFR § 874.3305(b)(3), and how device manufacturers should determine when an OTC hearing aid meets the definition of a self-fitting hearing aid.

Proposed 21 CFR § 800.30(a) defines an OTC hearing aid as an air-conduction hearing aid that "through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss."[4] "Tools, tests, or software" are further defined as "components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device's output, to meet the user's hearing needs."[5]

While air conduction hearing aids are currently classified under several different classification regulations, the Proposed Rule would realign the regulations for hearing aids to include all air-conduction hearing aids, including "legacy" hearing aids, wireless hearing aids, and self-fitting hearing aids, in the same classification regulation (proposed 21 CFR § 874.3305). Proposed 21 CFR § 874.3305(b)(1) defines legacy hearing aids as those that are not wireless or self-fitting and classifies legacy hearing aids as class I, 510(k) exempt. Proposed 21 CFR § 874.3305(b)(2) defines a wireless hearing aid as a hearing aid that "incorporates wireless technology in its programming or use" and classifies wireless hearing aids that are not self-fitting as class II, 510(k) exempt. In proposed 21 CFR § 874.3305(b)(3), a self-fitting hearing aid is defined as a hearing aid that "incorporates technology, including software, that allows users to program their hearing aids." This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and

[4] *Id.* at 58177.
[5] *Id.*

settings."[6] Proposed 21 CFR § 874.3305(b)(3) classifies self-fitting hearing aids as Class II subject to 510(k) requirements.

By using different terminology ("tools, test or software") in the criteria for OTC hearing aids in proposed 21 CFR § 800.30(a) and in the definition of "self-fitting" hearing aids in proposed 21 CFR § 874.3305(b)(3), the Proposed Rule could be read as suggesting that any air-conduction hearing aid that meets the requirements of proposed 21 CFR § 800.30, including legacy and wireless hearing aids, could be an OTC hearing aid. For example, the definition of a self-fitting hearing aid refers to technology that permits a user to "independently derive" and customize settings. The definition of "tools, tests, or software," on the other hand, only refers to customization, and FDA explains in the Proposed Rule that the tools, test, or software could include, for example, a user-adjustable volume or tone control, a feature to set preset listening programs manually, or interactive software for self-selecting, testing, and fitting.[7] This suggests that the "tools, tests, or software" to allow a user to control and customize their OTC hearing aid to their needs may not necessarily be the same as technology that meets the definition of a self-fitting hearing aid within proposed 21 CFR § 874.3305(b)(3). However, it remains unclear when technology would provide sufficient customization to meet the criteria for OTC marketing under proposed 21 CFR § 800.30 but would not be viewed as self-fitting.

Accordingly, CHPA requests that FDA clarify what the difference is between self-fitting hearing aids and OTC hearing aids with tools, tests and software that are customizable but are not considered "self-fitting." That is, FDA should explain what kinds of tools, tests or software that allow a user to customize the hearing aid to the user's hearing needs are not considered self-fitting technology. A clear delineation between OTC self-fitting hearing aids and OTC legacy and wireless hearing aids is critical given that under the Proposed Rule, self-fitting hearing aids would require clearance of a 510(k) premarket notification whereas non-self-fitting air-conduction hearing aids (*i.e.*, legacy hearing aids and wireless hearing aids under proposed 21 CFR § 874.3305(b)(1) and (2)) would not. In order to comply with premarket requirements, where applicable, manufacturers must be able to determine whether an OTC hearing aid would meet the definition of self-fitting. Clear definitions that allow for the differentiation between self-fitting hearing aids requiring a 510(k) premarket notification and 510(k)-exempt legacy and wireless hearing aids are necessary to ensure consistency and fairness across manufacturers.[8]

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[6] *Id.* at 58190.
[7] *Id.* at 58165.
[8] In FDA's webinar on the Proposed Rule, FDA indicated that manufacturers that have questions about how their OTC hearing aid would be classified could request a meeting with FDA. CHPA appreciates the opportunity to obtain FDA feedback on the appropriate regulatory pathway for an OTC hearing aid through the Pre-Submission process, but is concerned that a lack of clear definitions could trigger significant use of the Pre-Submission process and thereby create unnecessary resource burdens on FDA and delays for industry. Further, deferring guidance on the scope of these classifications to case-by-case advice through the Pre-Submission process does not provide uniform guidance to industry to ensure regulatory clarity and consistency. FDA

B. 510(k) Exemption for Legacy and Wireless OTC Hearing Aids

In addition to defining the scope of legacy and wireless hearing aids that could meet the criteria for OTC hearing aids, FDA should clarify the regulatory pathway for such OTC hearing aids. As noted above, proposed 21 CFR § 874.3305(b) classifies legacy hearing aids as class I, 510(k) exempt and wireless hearing aids (that are not self-fitting) as class II, 510(k) exempt. Therefore, CHPA understands that FDA intends for both legacy and wireless OTC hearing aids to be exempt from the 510(k) premarket notification requirement. CHPA would like to clarify whether OTC legacy and wireless hearing aids will automatically be 510(k) exempt upon issuance of the final hearing aid rule, or whether additional action is required (either by FDA or industry) to implement the 510(k) exemption.

FDARA directed FDA to establish a category of OTC hearing aids, and to "make findings under section 510(m) of the Federal Food, Drug, and Cosmetic Act" (FD&C Act) to determine whether OTC hearing aids require the submission of a 510(k) premarket notification to provide reasonable assurance of safety and effectiveness. In the Proposed Rule, however, FDA does not clearly state whether legacy and wireless OTC hearing aids will require the submission of a 510(k) premarket notification. CHPA understands that FDA views the exemption process under section 510(m) of the FD&C Act as unnecessary because wireless air conduction hearing aids are already 510(k) exempt. In this context, FDA states that by "realigning the regulations by sound conduction mode," the Agency is "not proposing to reclassify any device or change the exemption status under section 510(m)(2) of the FD&C Act for premarket notification for any device type."[9] Rather, FDA states, "wireless air conduction hearing aids regulated under § 874.3305 would continue to be class II exempt, subject to the limitations of exemption in § 874.9 . . ."[10] Likewise, FDA confirms that legacy hearing aids (currently class I, 510(k) exempt) would continue to be exempt from the 510(k) requirement.[11] This suggests that FDA intends for OTC legacy and wireless hearing aids to be exempt from 510(k) premarket review.

However, it is unclear how these OTC hearing aids will obtain their 510(k) exempt status after finalization of the Proposed Rule, and whether additional action is required either by FDA or by industry. FDA states in the Proposed Rule that "modifications to hearing aids, including labeling changes, to comply with the Proposed OTC Hearing Aid Controls may exceed the limitations of exemption, for example because the device was formerly intended for use by healthcare professionals only."[12] This could be read as suggesting that OTC legacy and wireless

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webinar held on December 7, 2021. Archived recording accessed from https://www.youtube.com/watch?v=Kv3YnMSV4n8 on January 14, 2022.

[9] 86 *Fed. Reg.* at 58171.

[10] *Id.*

[11] *See id.* (". . . legacy and wireless air-conduction hearing aids are exempt from section 510(k) subject to the limitations of exemption, and we are not proposing to alter the exemption status of such devices.").

[12] 86 *Fed. Reg.* at 58172.

hearing aids would have a different intended use than the currently 510(k) exempt legacy and wireless hearing aids, thereby exceeding the limitations of the exemption and requiring a new 510(k).[13] In this case, a manufacturer of an OTC legacy hearing aid or OTC wireless hearing aid would need to submit a 510(k) premarket notification for the hearing aid. Once an OTC legacy hearing aid under 21 CFR § 874.3305(b)(1) and an OTC wireless hearing aid under 21 CFR § 874.3305(b)(2) are found substantially equivalent to currently marketed legacy and wireless hearing aids, respectively, the cleared OTC indications would then expand the scope of the 510(k) exemption for legacy and wireless hearing aids to include an OTC intended use. This means that subsequent OTC legacy and wireless hearing aids would no longer exceed the limitations of the 510(k) exemption and would not require 510(k) clearance.

As such, this process seemingly requires one manufacturer of an OTC legacy hearing aid and one manufacturer of an OTC wireless hearing aid to submit a 510(k) to expand the 510(k) exemption for legacy and wireless hearing aids to include an OTC intended use. But once one manufacturer has done so, manufacturers of subsequent OTC legacy and wireless hearing aids would benefit from the expanded scope of the 510(k) exemption for these devices. Given that the Proposed Rule newly creates the categories of OTC legacy and OTC wireless hearing aids, this approach would seem to create a process whereby an individual manufacturer will be responsible for initiating the expansion of the scope of the 510(k) exemption, creating an unlevel playing field and a disincentive to file the first 510(k) for an OTC hearing aid.

CHPA requests that FDA clarify whether this outcome is intended, or whether there is an alternative process the Agency intends to follow for creating a 510(k) exempt status for both legacy and wireless OTC hearing aids.

C. Package Labeling Requirements

The Proposed Rule includes a number of labeling statements that would be required on the outside packaging for an OTC hearing aid (proposed 21 CFR § 800.30(c)(1)). However, many OTC hearing aids may be relatively small devices (such as the size of current "ear bud" style headphones) that would typically be packaged in compact, small packaging. In such cases, the space for labeling statements on the outside packaging may be limited and a manufacturer's ability to increase the packaging purely to meet labeling requirements may be constrained by state laws regulating product packaging as well as environmental concerns. CHPA recommends that FDA consider whether all the labeling statements specified in proposed 21 CFR § 800.30(c)(1) are necessary to appear on the device packaging directly (as opposed to being made available electronically via QR code or other link on the packaging). FDA should also address how compliance with the outside package labeling requirements

[13] *See* § 874.9; *see also* 63 *Fed. Reg.* 59222, 59224 (Nov. 3, 1998) ("FDA believes that any additional indication for use for an exempt classification device type (i.e., an indication not previously cleared) is considered a different intended use and does not meet the limitations on exemptions, and therefore, requires a new premarket notification.").

can be achieved for OTC hearing aids in small form factors and corresponding small package sizes with limited available space for labeling.

CHPA thanks FDA for the efforts to create a regulatory category for OTC hearing aids to improve patient access for hearing aids. Please do not hesitate to contact us if you have any questions about our comments.

Respectfully Submitted,

Marcia D. Howard, Ph.D., CAE

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