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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: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products: Guidance for Industry and FDA Staff; 86 *Fed. Reg.* 58192-58193; Docket No. FDA-2020-D-1380

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("CHPA") submits these comments in response to the U.S. Food and Drug Administration's ("FDA's" or the "Agency's") Draft Guidance for Industry and FDA Staff "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products" ("Draft Guidance").[2,3] For more than 141 years, CHPA has served as a vital advocate for the consumer healthcare products industry.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 over-the-counter (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 clarify the applicable requirements for hearing aid devices and personal sound amplification products (PSAPs). With the creation of a regulatory category for OTC hearing aids under the Agency's OTC hearing aid proposed rule ("Proposed Rule"),[4] clear delineation for both industry and consumers between OTC hearing aids subject to the requirements of the Proposed

[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[2] FDA, Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability, 86 *Fed. Reg.* 58192 (Oct. 20, 2021). Accessed from https://www.govinfo.gov/content/pkg/FR-2021-10-20/pdf/2021-22612.pdf on January 12, 2022.

[3] FDA, Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff. Accessed from https://www.fda.gov/media/87330/download on January 12, 2022.

[4] FDA, Medical Devices; Ear, Nose, and Throat Devices; Establishment of Over-the-Counter Hearing Aids, Proposed Rule, 86 *Fed. Reg.* 58150-58190 (Oct. 20, 2021). Accessed from https://www.govinfo.gov/content/pkg/FR-2021-10-20/pdf/2021-22473.pdf on January 12, 2022.

Rule, when finalized, and PSAPs not subject to FDA's medical device regulations will be particularly critical.

To ensure appropriate regulation of products intended to aid individuals with impaired hearing or compensating for hearing loss, CHPA recommends that FDA revise the Draft Guidance to further clarify when the design or technology of a product may be evidence that the product has such an intended use and is subject to regulation as a hearing aid device. This is consistent with FDA's intended use regulation in 21 C.F.R. § 801.4, which states that "intended use" refers "to the objective intent of the persons legally responsible for the labeling of an article . . . [and the] intent may be shown by such persons' expressions, ***the design or composition of the article***, or by the circumstances surrounding the distribution of the article" (emphasis added). The Draft Guidance includes this language from 21 C.F.R. § 801.4[5], but the Draft Guidance also states that the technology of hearing aids and PSAPs may be similar. Thus, the Draft Guidance is currently not clear as to when design or technology would create a hearing aid intended use and what design or technology is consistent with a PSAP intended use to amplify sounds for non-hearing-impaired consumers. This leaves open that products with technology identical to those that meet the design and performance criteria for OTC hearing aids under the Proposed Rule (*e.g.*, proposed 21 C.F.R. §§ 800.30(d)-(f)) could be marketed as PSAPs, potentially causing confusion for individuals with hearing loss as to which PSAP or OTC hearing aid products are appropriate for their use. CHPA recommends that FDA further clarify and illustrate technology and design that is consistent with a PSAP intended use for non-hearing-impaired consumers as compared to technology and design that would be indicative of an intended use for individuals with perceived mild or moderate hearing loss.

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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[5] Draft Guidance at 10 ("A product's intended use refers to the 'objective intent' of those legally responsible for the labeling of the product, which may be shown by their oral or written expressions, the design or composition of the product, or by the circumstances surrounding the distribution of the product.")

CC: ShuChen Peng, FDA Center for Devices and Radiological Health (via email to Shu-Chen.Peng@fda.hhs.gov)

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