August 31, 2023

Speech-Language Pathology and Audiology
and Hearing Aid Dispensers Board
State of California
Department of Consumer Affairs
1601 Response Road, Suite 260
Sacramento, CA 95815

Sent via email to: speechandhearing@dca.ca.gov

Re: Petition for Exemption from Federal Preemption, Hearing Aids
Docket Number FDA-2013-P-0615

Dear Board Members and Staff:

We are writing in response to the application requesting exemption from Federal preemption for State medical device requirements (the Application) submitted by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board (the Board). The Application was dated May 30, 2012, and was filed by the U.S. Food and Drug Administration (FDA) on June 4, 2012. It requested exemptions for State requirements respecting the sale of hearing aids as they might relate to former Federal requirements, specifically former 21 CFR §§ 801.420 and 801.421.* However, the applicable Federal requirements for hearing aids have changed since the Board submitted the Application, and the bases for the requested exemption are no longer in effect. As such, FDA has determined that the Application is moot.

The applicable Federal requirements changed as a result of the final rule that FDA issued to establish a regulatory category for over-the-counter (OTC) hearing aids, which took effect on October 17, 2022 (87 FR 50698, Aug. 17, 2022). In addition to establishing new requirements for OTC hearing aids, the final rule included the removal of labeling requirements for restricted hearing aids, § 801.420; the repeal of conditions for sale for restricted hearing aids, § 801.421; and the establishment of labeling requirements for prescription hearing aids, 21 CFR § 801.422 (see 87 FR at 50755).

As we explained in the proposed rule, the removal and repeal of §§ 801.420 and 801.421, respectively, rendered the previous exemption decisions regarding hearing aids inapplicable (see 86 FR at 58170, Oct. 20, 2021), and we continued this reasoning in the final rule in response to comments (see 87 FR at 50738). Because the previous exemption decisions relating to State requirements for hearing aids became inapplicable, we finalized the removal of the corresponding regulations under 21 CFR

* The links lead to the regulations in effect on August 17, 2022, prior to their removal and repeal.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

part 808 that codified those previous exemptions decisions (see 87 FR at 50762). We note, however, that we retained previous exemption decisions for a California law that did not relate solely to hearing aids (see 21 CFR § 808.55).

The Application from the Board refers to the same regulations, the removal and repeal of which rendered the previous exemption decisions inapplicable. As such, because the Federal requirements prompting the Application are no longer in effect, the changes effected by the final rule therefore render the Application moot.

We also note that the requirements for OTC hearing aids, as distinct from restricted or prescription hearing aids, affect the Federal-State relationship for requirements on hearing products. We explained in the proposed and final rules that section 709(b)(4) of the FDA Reauthorization Act of 2017 ("FDARA") (Pub. L. 115-52, 131 Stat. 1067) provides for Federal preemption specific to OTC hearing aids that is different from the general rule for preemption of device requirements under section 521 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C. § 360k) (see 86 FR at 58166 and 87 FR at 50736, so explaining). The final rule codified this provision under 21 CFR § 800.30(h). As a result of the preemption provision specific to OTC hearing aids, FDA is unable to grant exemptions, or continue in effect any previously granted exemptions, under section 521 of the FD&C Act for State or local requirements that are within the scope of the more-specific preemption provision under section 709(b)(4) of FDARA.

As explained above, the changes in Federal requirements have rendered the Board's Application moot. Therefore, please consider this letter the final response to the Application.

If you have any questions about this response, you may contact FDA's Intergovernmental Affairs Staff at IGA@fda.hhs.gov.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.08.31 11:55:37 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and
Radiological Health