U.S. FOOD & DRUG ADMINISTRATION

July 24, 2018

Dear Hearing Aid Manufacturer:

In section 709 of the FDA Reauthorization Act of 2017 (FDARA), Congress enacted a definition, outlined certain requirements, and set forth a process for establishing a category of over-the-counter (OTC) hearing aids and the requirements that apply to them. That statutorily mandated process provides for FDA to publish proposed regulations by August 18, 2020, to consider public comments, and then to publish final regulations within 180 days of the close of the comment period. Section 709 also includes a preemption provision stating that no state or local law can be different from, in addition to, or not identical to, the regulations that FDA will establish for OTC hearing aids under authority of FDARA.

Section 709 reflects a careful balance between consumer access to new technologies and consumer protections to assure the safety and effectiveness of OTC hearing aids. The protections include output limits, appropriate labeling, advisements about when to consult with a licensed health care practitioner, and guidance on when premarket review by FDA would be required.

Section 709 is not self-implementing, meaning that the OTC hearing aid category, as defined by FDARA section 709, does not exist until the effective date of a published final regulation. Until that time, no products that are claimed to address hearing loss are, or can claim to be, OTC hearing aids within the meaning of FDARA section 709. Currently, hearing aids continue to be restricted devices, for which sales must follow applicable federal and state requirements. FDA has published a guidance document stating that the agency will not enforce the requirement for a medical evaluation or waiver under 21 CFR 801.421, but manufacturers should be mindful of any similar state law requirements.

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV 800-638-2041 or 301-796-7100.

Sincerely,

/s/
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