Illinois Hearing Society

1 North Old State Capitol Plaza, Suite 410
Springfield, IL 62701

Dockets Management Staff
Food and Drug Administration (FDA)
Docket No. FDA-2021-N-0555

Dear FDA,

We are writing about your proposed rules regarding OTC hearing aids. While we applaud the intent to offer a self-service, less costly alternative to those who have mild hearing loss, as the Illinois Hearing Society we would like to offer some important comments and suggestions on some of your proposed rules for these OTC "hearing aids." We feel making these changes would prevent confusion, curtail hearing damage, and prevent financial harm to Illinoisians with hearing loss.

In your proposed rules, you refer to retailers that sell OTC devices as 'dispensers.' The Illinois Hearing Society membership is comprised of individuals that have studied and tested for the position as a licensed dispenser or board-certified hearing instrument specialist. The State of Illinois enacted the Hearing Instrument Consumer Protection Act to safeguard Illinoisians when purchasing hearing aids. Illinois Law defines "Hearing care professional" as a person who "is a licensed audiologist, a licensed hearing instrument dispenser, or a licensed physician."

The Illinois Insurance Code mandates certain insurance policies offer coverage for hearing instruments and related services (assessments, selection, adjusting, fitting and maintain) at $2,500 per hearing aid every 2 years. This is another Illinois law that references "hearing care professional" as a person who is a "licensed hearing instrument **dispenser**, licensed audiologist or a licensed physician." There are 8 citations in the Illinois Compiled Statutes concerning hearing instrument "**dispenser**."

Please change the terms "dispenser" and "dispensing" in your rules (Section 800.30) to "seller" or "vendor" or "selling". In Illinois, the term dispenser & dispensing refers not only to the sale of a professional hearing aid, but also insinuates the connected ***professional services*** involved with the purchase of a hearing aid. These services are hearing assessment, recommendations, selection, dispensing, fitting, adapting, and maintaining of the professional hearing aid. It is our understanding that OTC sellers are only doing just that – selling. It is then up to the buyer to self-service the device. Changing OTC term "dispenser," or "dispensing" to 'seller' or 'selling' would prevent consumer confusion regarding OTC and hearing aids here in Illinois.

In your rules for OTC hearing aids (Section 801.430 (e) (4) and (e) (5)), it directs manufacturers to measure frequency response bandwidth against the ANSI/CTA- 2051 PSAP standard which is for non-medical consumer electronics. Traditional professional hearing aid

measurements rely on the ANSI/ASA S3.22 2014 standard which is for medical devices. The average consumer may be misled and could believe the standards are comparable when in fact, they are not. Since both OTC and professional hearing aids are to help compensate for impaired hearing, both devices should be measured by the **same standard** to avoid a misperception or invalid comparison of the devices by consumers.

While your rules detail the frequency response bandwidth for OTC manufacturers, they detail no other specs or limitations for OTC hearing aids. In the Illinois statutes, hearing instruments or hearing aids are wearable instruments or devices designed to help or compensate impaired hearing requires this for instruments or devices that can provide more than 15 dB full on gain via a 2cc coupler at any frequency from 200 through 600 cycles per second.

No gain nor coupler measurements are set forth in your rules for OTC products. Illinois Law defines the gain and coupler as well as frequency limits for professional hearing aid medical devices. OTC products that promise better hearing without explicit labeling especially for output limits and gain limits and comparable frequency standards along with mandated volume controls could prevent permanent hearing damage for consumers. Please add this mandate for inclusion on OTC devices (volume control) and upon their labels (detailed measurements.)

In Illinois, every dispenser must provide a User Instructional Brochure supplied by the manufacturer which contains information mandated by you – the FDA. The sale of a hearing instrument costing $50 or more must include the receipt or a contact pertaining to the transaction. This must also include the dispenser's name, license number, business address, phone number, manufacturer's name and model and serial number of the hearing aid. All hearing instruments offered for sale in Illinois must also be accompanied by a 30-business day return privilege (from date of delivery). Under your rules, there is no mandatory return period for OTC hearing aids. This is in direct opposition to the very reason OTC devices are available to save money rather than squander it.

Illinois' Hearing Instrument Consumer Protecting Act safeguards Illinois consumers and gives them assurance, safety and confidence when purchasing hearing aids in the state of Illinois so please consider our comments and suggestions as you finalize your rules.

Thank you for your consideration in this matter.