

US OTC HEARING AID MARKET TO OPEN FOR NUHEARA

Nuheara Limited (**ASX: NUH**) (**Company** or **Nuheara**), transforming the way people hear by creating smart and affordable hearing solutions, welcomes the US Food and Drug Administration's landmark final ruling, establishing a regulatory category for over-the-counter (OTC) Hearing Aids in the United States.

In a world first, and most significantly for Nuheara, the ruling allows hearing aids within the OTC category to be sold directly to consumers in stores or online without a medical exam or fitting by an audiologist. There is now a 60-day enactment period until the commencement of OTC hearing aid consumer retail sales are allowed, anticipated for mid-October 2022.

The US FDA received over 1,000 public comment submissions on the proposed rule change. The majority of submissions reflected that American people and healthcare professionals agreed on the significant positive impact that OTC hearing aids could have.

The public comments also revealed, as expected, that the dominant hearing aid manufacturers strongly opposed the proposed rule, including using industry-funded "astroturf" campaigns intended to distort public opinion. Despite the incumbent hearing aid manufacturers' efforts to jeopardise such an important ruling, the FDA formally ruled in favour of the OTC category for hearing aids.

This historical rule change will forever upend the hearing aid industry and unlock historical barriers to entry for the estimated 38 million Americans who experience some hearing loss. Currently in the US, hearing aids are sold at an average cost of US\$4,726 per pair and can be as much as US\$10,000 or more per pair through licensed audiologist and licensed hearing aid retailers. Now, with the ability for those with perceived mild to moderate hearing loss to purchase OTC, this cost could come down lower than US\$1,000 per pair of hearing aids.

Nuheara's Co-Founder and Managing Director, Justin Miller states:

"In one sweep, the FDA has revolutionised the way people can access hearing aids in the US. The FDA hasn't just created an extra OTC category, it has completely overhauled the categorisation of all hearing aids into two categories: OTC and prescription.

"We have been patiently waiting for, and anticipating, these guidelines for five years. Changing the hearing landscape through accessibility and affordability is why we set out on this journey eight years ago. This ruling is in complete alignment with Nuheara's strategy and one which the company has been focused on over the last 18 months.

"Nuheara's five years of Direct-To-Consumer (DTC) and traditional retail sales experience places us at the forefront to lead the way with OTC offerings. This new OTC ruling, along with our experience, our technology, and our clinical

trial, have placed us in the prime position of being able to deliver more accessible and affordable hearing devices to those in the US that need it most.”

US-based Nuheara CEO John R. Luna said:

“The US hearing aid market is forever changed with this OTC hearing aid final rule publication. We’re very excited in the knowledge that the US consumer could very soon be making the decision to self-care, self-fit with affordable non-prescriptive hearing aids available over-the-counter in traditional retail and online.

“This historic change will save consumers with perceived mild-to-moderate hearing loss thousands of dollars on a pair of hearing aids.

“Nuheara is well positioned with our OTC hearing aids (pending FDA clearance), through our trademark license agreement with HP Inc. that will be initially available at Best Buy retail stores in the US. OTC hearing aids will become a significant part of Nuheara’s future as we continue to innovate to bring new hearing products to market.”

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AUTHORISED BY:

Justin Miller
Managing Director and CEO
Nuheara Limited

INVESTOR AND MEDIA ENQUIRIES:

Ronn Bechler, Market Eye
Email: ronn.bechler@marketeye.com.au
Phone: + 61 400 009 774

ABOUT NUHEARA

Nuheara is a global leader in smart hearing technology which change people’s lives by enhancing the power to hear. As a global pioneer in Hearable products, Nuheara developed proprietary, multi-functional, personalised intelligent hearing devices that augments a person’s hearing. Nuheara is headquartered in Perth, Australia and was the first consumer wearables technology company to be listed on the Australian Stock Exchange (ASX).

In 2016, the Company released its revolutionary wireless earbuds, IQbuds, which allow consumers to augment their hearing according to their personal hearing preferences and connect hands free with their voice-enabled smart devices. In 2020 Nuheara released its third-generation hearable the IQbuds² MAX. In 2021, Nuheara transformed its operations to include medical device manufacturing for its hearing aid products to meet global demand for mild to moderate hearing loss. Nuheara products are now sold Direct to Consumer (DTC) and in major consumer electronics retailers, professional hearing clinics, pharmacies, and speciality retailers around the world. In April 2022, Nuheara submitted an FDA 510(k) for its self-fit hearing aid and signed a worldwide trademark licensing agreement with HP Inc.

The Company’s mission is to transform the way people hear by creating smart hearing solutions that are both accessible and affordable. For further information, please visit <https://www.nuheara.com/>.