

ASX MARKET RELEASE

Nuheara petitions US FDA for OTC Hearing Act to be expedited

HIGHLIGHTS

- Nuheara has petitioned US FDA Commissioner for OTC Hearing Aid Act to be expedited.
- OTC Act designed to unlock more affordable and accessible hearing health care.
- Regulations for OTC hearing device has been charged to FDA to complete within three years
- OTC Hearing Aid has accessibility and affordability intentions that will be met with IQbuds Boost.

15 February 2018 – Perth, Australia

Nuheara Limited (**ASX: NUH**) ("Company" or "Nuheara") has directly petitioned the US Food and Drug Administration (FDA) Commissioner, Scott Gottlieb MD, to request the acceleration of the FDA's implementation of the Over-the-Counter (OTC) Hearing Aid Act of 2017. Nuheara has also encouraged the FDA to consider a set of standards already prepared by the US Consumer Technology Association (CTA) that would regulate OTC hearing devices.

In reply, William Maisel MD from the FDA's Center for Devices and Radiological Health, which has responsibility for the regulation of hearing aids stated, "We are committed to implementing the legislation through a deliberative, transparent process, informed by notice and comment rulemaking as required by law...We share your [Nuheara's] enthusiasm for the tremendous potential of the legislation to increase access and quality of life for hearing impaired Americans."

The OTC Act will drive a new era in hearing health for millions of people in the USA who experience mild to moderate hearing loss. The AARP (American Association of Retired Persons) estimates the population of hearing challenged people in USA at over 30 million and only 20% are using hearing aids (this is mainly due to cost).

The major impact of this law is that hearing aids will be able to be sold directly to the consumer without a prescription from a doctor, which would allow individuals to purchase hearing aids similarly to the way they would purchase reading glasses at a pharmacy. However, before OTC hearing aids can be sold, the FDA is required to develop standards and develop a plan to regulate OTC hearing aids within three years.

It is this three-year time frame that Nuheara has sought to expedite. Commenting on the petition, Nuheara CEO, Justin Miller said, "we are already providing significant hearing accessibility benefits to consumers with our game changing products, which will soon include IQbuds Boost™. As it stands, IQbuds Boost™ will be the only product on the market that adheres to the OTC Act requirements with

its features and functionality: the inbuilt hearing test that generates a personal profile, the automatic device calibration to the personal profile, and of course the increased hearing profile.”

“We are as one with the FDA on our mutual objective to provide more assessible and affordable hearing health care. We have the solution with IQbuds Boost.”

- ENDS -

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About Nuheara

Nuheara is a global leader in Intelligent Hearing: smart personal hearing devices that enhance and amplify human experiences. Nuheara has developed proprietary and multi-functional intelligent hearing technology that augments a person’s hearing and facilitates cable free connection to smart devices. Nuheara is based in Perth, Australia and has offices in San Francisco and New York, USA. Nuheara 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. IQbuds™ are now sold in major consumer electronics retailers and professional hearing clinics around the world. The Company’s mission is to improve people’s lives by allowing them to seamlessly listen, communicate, and connect to their physical and digital worlds.

Learn more about Nuheara: www.nuheara.com.