

April 15, 2014

TO: FDA Division of Compliance
Office of Surveillance and Compliance
US Food and Drug Administration
MPN IV Building, Room 146
7519 Standish Place
Rockville, MD 20855-2773

FR: Daniel Berke, HIS
President, NJAHP
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**RE: Complaint iHEAR Medical Web-Enabled Hearing Aid System
iHear Medical Marketing Online Hearing Tests and Hearing Aid Fitting and
Programming Without Evaluation and Proper Fitting by Licensed Hearing
Health Professionals.**

The New Jersey Association of Hearing Health Professionals (NJAHP) is gravely concerned about iHear Medical's (www.ihearmedical.com) plans to launch entirely web-based hearing aid system that will enable consumers to test their hearing in an uncontrolled-setting online and then purchase hearing aids without evaluation and proper fitting by licensed hearing health professionals. iHear Medical is currently raising money for this ill-advised program on a website called www.indiegogo.com with the intention of launching the product this summer.

The public is best-served by adherence to Federal and State law that require consumers to receive a hearing evaluation and be fitted and dispensed a hearing aid only by a properly-licensed hearing aid specialist. Purchasing hearing aid over the internet based on an uncalibrated and unreliable online hearing test without personal and continued involvement by a hearing health professional places consumers at risk serious risk for— missed pathology; purchasing a hearing aid unnecessarily; purchasing a less than optimal device; incurring further hearing damage due to an improperly programmed device; and little to no consumer protections or support/counseling services.

The FDA classifies hearing aids as Class I medical devices and has recognized that there are certain "red flags" that indicate potentially serious medical conditions and these "red flags" can only be identified through a comprehensive case history, physical examination of the individual with hearing loss, and thorough hearing examination. iHear Medical's hearing aid program flies in the face of these FDA recommendations by issuing hearing aids based on an online hearing test without care and guidance by hearing health professionals.

Hearing loss may be the symptom of a condition that cannot be detected through the use of an on-line hearing test such as acoustic neuroma, Meniere's disease, or obstruction of the external ear canal. Nor can an online hearing test appropriately capture the nature of the hearing loss, which may be sensorineural (cochlear and/or neural damage), or conductive

(obstruction, perforation, or bone-related), or mixed. Therefore, hearing loss screenings require, by necessity, a visual examination of the ear by properly-licensed professionals and comprehensive hearing evaluations.

NJAHHP encourages the FDA to look into the questionable patient hearing health care delivery model currently being marketed by iHear Medical, as it is not in the best interest of consumers and poses serious risks to their health and safety.