

At Academy's Urging, FDA Issues Cease and Desist Letter to hi HealthInnovations

Based on conversations between the American Academy of Audiology and the U.S. Food and Drug Administration (FDA), the FDA has issued a cease and desist letter with regard to the online hearing test offered by hi HealthInnovations. The Academy began discussions with the FDA in early November 2011 and was instrumental in the Agency's investigation of this matter.

In the letter, which may be viewed [here](#), the FDA asserts that hi HealthInnovations is in violation of the Federal Food, Drug, and Cosmetic Act, which requires marketing clearance or approval of devices by the FDA. The test is considered a device under the Act as its intended use is diagnostic in nature. The standards set forward in the Act are crafted to ensure patient safety as well as the efficacy of devices. The FDA has deemed hi HealthInnovations' lack of adherence as a violation.

“The Academy is pleased to see that our multi-faceted approach to addressing the patient safety concerns associated with the hi HealthInnovations online hearing test and online hearing aid purchase continues to be effective,” said Academy President Therese Walden. “We will persist in our efforts on all fronts to ensure our patients receive the highest quality of hearing health care.”