

FDA approves first brain wave test for ADHD

July 15 2013

US regulators on Monday approved the first brain wave test for attention deficit hyperactivity disorder, saying it may improve the accuracy of diagnoses by medical experts.

Cases of ADHD are on the rise in the United States, as are the number of prescriptions for stimulants doled out to young people who appear to have difficulty concentrating or controlling impulses.

The new <u>test</u>, known as the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System, measures <u>electrical impulses</u> given off by neurons in the brain.

A 15-20 minute test calculates the ratio of certain brain wave frequencies known as theta and beta waves in children age six to 17.

"The theta/beta ratio has been shown to be higher in children and adolescents with ADHD than in children without it," the US Food and Drug Administration said.

"Diagnosing ADHD is a multistep process based on a complete medical and psychiatric exam," cautioned Christy Foreman, director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health.

"The NEBA System along with other clinical information may help <u>health care providers</u> more accurately determine if ADHD is the cause



of a behavioral problem."

The FDA said the test "can help confirm an ADHD diagnosis" or help decide if further treatment should focus on "other medical or behavioral conditions that produce symptoms similar to ADHD."

The FDA approved the device after a reviewing it as a new and "low- to moderate-risk medical device."

Studies supplied by the manufacturer evaluated 275 patients using both the NEBA system and other standard protocols for diagnosing ADHD which include behavioral questionnaires, behavioral and IQ testing and physical exams.

An independent review found the device "aided clinicians in making a more accurate diagnosis of ADHD when used in conjunction with a clinical assessment for ADHD, compared with doing the <u>clinical</u> <u>assessment</u> alone," the FDA said.

The device is made by NEBA Health in Augusta, Georgia.

ADHD is believed to occur in five to 10 percent of US children. A recent analysis of US government data by the New York Times found that as many as one in five teenage boys is diagnosed with the disorder.

A study in the journal Pediatrics last year found a 46 percent rise in ADHD prescriptions from 2002 to 2010.

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