FDA Approves First Game-Based Therapy Device for Kids With ADHD

The nondrug is intended to improve the ability of children to pay attention, stay focused and control their behavior.

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An estimated 4 million children between ages 6 and 11 have attention-deficit hyperactivity disorder (ADHD). A common disorder characterized by inattentiveness, hyperactivity and impulsiveness, ADHD interferes with functioning or development.

To address these issues, the Food and Drug Administration (FDA) recently approved the marketing of EndeavorRx, the first prescription-only game-based device, according to an agency news release.

EndeavorRx is specifically for children ages 8 to 12 with primarily inattentive or combined-type ADHD who have demonstrated an attention issue. (Combined-type ADHD is the most common type of ADHD and is characterized by inattention, high levels of activity and a lack of behavioral control.)

The game measures attention function improvements via computer-based testing and is intended for use in conjunction with other treatments for ADHD symptoms, including clinician-directed therapy, medication and educational programs.

“The EndeavorRx device offers a nondrug option for improving symptoms associated with ADHD in children and is an important example of the growing field of digital therapy and digital therapeutics,” said Jeffrey Shuren, MD, JD, director of the FDA’s Center for Devices and Radiological Health. “The FDA is committed to providing regulatory pathways that enable patients’ timely access to safe and effective innovative digital therapeutics.”

EndeavorRx is the first game-based therapy approved for marketing authorization by the FDA for any condition. Before granting marketing authorization, the FDA reviewed data from multiple studies that included more than 600 children. These studies evaluated whether participants’ attention function improved according to a series of assessment tools.

No serious adverse events were associated with playing the game, however, commonly reported side effects included frustration, headache, dizziness, emotional reaction and aggression.

For related coverage, read “Can Lack of Sleep Increase the Risk of Mental Health Problems in Kids?” and “Ride On!,” which details how cycling can help schoolkids struggling with ADHD.

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