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WASHINGTON — US regulators have approved the first marijuana-derived drug ever to hit the US market, Epidiolex, which will be used to treat two rare and severe forms of childhood epilepsy.

Made by the British biopharma company GW Pharmaceuticals, Epidiolex uses purified cannabidiol, or CBD, which is one of more than 80 active compounds in the cannabis sativa plant, often known simply as marijuana.

"This is an important medical advance," said US Food and Drug Administration Commissioner Scott Gottlieb.

"But it's also important to note that this is not an approval of marijuana or all of its components. This is the approval of one specific CBD medication for a specific use."

The drug, authorised on Monday, is for use against Lennox-Gastaut syndrome and Dravet syndrome in patients two years of age and older, the FDA said.

Both forms of epilepsy cause severe seizures.

Dravet syndrome is a rare genetic condition that causes frequent fever-related seizures, involuntary muscle spasms and a potentially life-threatening state of continuous seizure activity requiring emergency medical care.

"Children with Dravet syndrome typically experience poor development of language and motor skills, hyperactivity and difficulty relating to others," said the FDA.

Like Dravet syndrome, Lennox-Gastaut syndrome also begins in childhood and causes multiple types of seizures. Most children affected develop learning problems, intellectual disability, delayed motor skills and need help with daily activities.

"For those living with intractable seizures caused by LGS and Dravet syndrome, Epidiolex represents a true medical advancement," said Philip Gattone, president and CEO of the Epilepsy Foundation.

"Clinical development for these rare and severe conditions is essential, and today's news brings hope for these patients and their families that a new treatment option may have the potential to help better control their seizures."

Before the drug can be made widely available, the US Drug Enforcement Administration must reclassify CBD, which is considered a Schedule 1 drug that has a high risk of abuse and no medical value because it is derived from marijuana.

A reclassification is expected within 90 days, according GW Pharmaceuticals. The drug should be available in the coming months.

Epidiolex will be marketed by Greenwich Biosciences, a subsidiary of GW Pharmaceuticals.

The European Medicines Agency is currently reviewing Epidiolex for treating seizures associated with LGS and Dravet Syndrome, with a decision on whether or not to recommend approval expected early next year.

Epidiolex's effectiveness was studied in three randomised clinical trials involving 516 patients with either Lennox-Gastaut syndrome or Dravet syndrome, comparing Epidiolex to a placebo.

Across the board, the drug was shown to be effective in cutting the frequency of seizures.

Side effects included sleepiness, sedation, lethargy, elevated liver enzymes, decreased appetite, diarrhoea, rash, weakness, insomnia, poor quality sleep and infections.

An advisory panel to the FDA recommended in April that the drug be approved.

The FDA is not required to follow the advisory panel's advice but usually does.

CBD does not cause intoxication or euphoria. That so-called "high" comes from a different compound in marijuana, known as tetrahydrocannabinol (THC). — AFP