



FILED IN OFFICE
HART SUPERIOR COURT
2019 OCT -2 AM 10:28
Frankie H. Gray
FRANKIE H. GRAY, CLERK

Drug Enforcement Administration

DEA Headquarters

@DEAHQ

September 27, 2018

Contact: National Media Affairs Office

Phone Number: (202) 307-7977

FOR IMMEDIATE RELEASE

FDA-approved drug Epidiolex placed in schedule V of Controlled Substance Act

WASHINGTON - The Department of Justice and Drug Enforcement Administration today announced that Epidiolex, the newly approved medication by the Food & Drug Administration, is being placed in schedule V of the Controlled Substances Act, the least restrictive schedule of the CSA.

In June 2018, the FDA announced it approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older.

Epidiolex contains cannabidiol (CBD), a chemical constituent of the cannabis plant (commonly referred to as marijuana). The CBD in Epidiolex is extracted from the cannabis plant and is the

first FDA-approved drug to contain a purified extract from the plant.

“DEA will continue to support sound and scientific research that promotes legitimate therapeutic uses for FDA-approved constituent components of cannabis, consistent with federal law,” said Acting DEA Administrator Uttam Dhillon. “DEA is committed to continuing to work with our federal partners to seek ways to make the process for research more efficient and effective.”

“The FDA is committed to advancing scientific research and drug development programs that properly evaluate the active ingredients contained in marijuana,” said FDA Commissioner Scott Gottlieb, M.D. “Adequate and well-controlled clinical studies supported Epidiolex’s approval, so prescribers can have confidence in the drug’s uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes. The FDA will continue to support rigorous scientific research on the potential medical uses of marijuana-derived products and stand ready to work with product developers who are interested in bringing patients safe and effective, high quality products.”

Marijuana and CBD derived from marijuana remain against the law, except for the limited circumstances that it has been determined there is a medically approved benefit. In those instances, such as here, the drug will be made appropriately available to the public for medical use.

###

<https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act>