

SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Placement of FDA-Approved Cannabidiol Drugs Containing No More Than 0.1% Tetrahydrocannabinols in Schedule V for Controlled Substances

WHEREAS, pursuant to S.C. Code Section 44-53-160(C), the South Carolina Board of Health and Environmental Control (Board) shall add a substance as a controlled substance if the Federal government has so designated; and

WHEREAS, on June 25, 2018, the Food and Drug Administration (“FDA”) approved Cannabidiol 100 mg/ml solution, tradename Epidiolex (“Epidiolex”) as a prescription drug for the treatment of seizures associated with Lennox-Gastaut Syndrome or Dravet Syndrome; and

WHEREAS, pursuant to federal law, Epidiolex is a prescription medication that may not be dispensed without a prescription; and

WHEREAS, on September 28, 2018, the Administrator of the Federal Drug Enforcement Administration (the “DEA”) issued a final order amending Regulation 21 C.F.R. §1308.15 to place FDA-approved drugs that contain cannabidiol derived from cannabis and containing no more than .1 percent tetrahydrocannabinols, including Epidiolex and any future FDA-approved generic versions of such formulation made from cannabis, in Schedule V. Federal Register, Volume 83, Number 189, pp. 48950-48953; and

WHEREAS, the Federal Controlled Substances Act, 21 U.S.C. § 812(b) requires the following findings for a drug to be placed in Schedule V: (A) the drug has a low potential for abuse relative to the drugs or other substances in Schedule IV; (B) the drug has a currently accepted medical use in treatment in the United States; and (C) abuse of the drug may lead to limited physical dependence or psychological dependence relative to drugs or other substances in Schedule IV. The DEA conducted its own review and determined that FDA-approved drugs that contain CBD derived from cannabis and containing no more than .1 percent tetrahydrocannabinols, including Epidiolex and any future FDA-approved generic versions of such formulation made from cannabis, met the criteria for placement in Schedule V because a review of available data showed such drugs have a low potential for abuse relative to other drugs or substances in Schedule IV; have been or will be approved by FDA for the medical use in treatment in the United States; and have a limited potential for physical or psychological dependence relative to drugs or other substances in Schedule IV.

THEREFORE, the Board of Health and Environmental Control adopts the federal scheduling and amends Section 44-53-270 by adding and designating into Schedule V of the South Carolina Controlled Substances Act: A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.



Mark R. Elam, Chairman
S.C. Board of Health and Environmental Control

October 12, 2018
Columbia, South Carolina