

SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Placement of Brexanolone into Schedule IV for Controlled Substances

WHEREAS, pursuant to S.C. Code Section 44-53-160(C), the S.C. Board of Health and Environmental Control (Board) shall designate a substance as a controlled substance by scheduling it in accordance with an order effecting federal scheduling as a controlled substance;

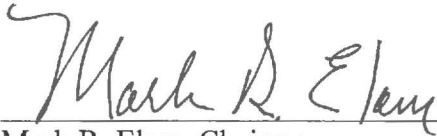
WHEREAS, on June 10, 2019, The U.S. Department of Justice, Drug Enforcement Administration (DEA), issued an interim final rule placing brexanolone and its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible in schedule IV of the federal Controlled Substance Act, effective June 17, 2019. F.R. Volume 84, Number 116, pp. 27938-27943;

WHEREAS, brexanolone is a new molecular entity with central nervous system depressant properties, and the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration have recently approved the use of brexanolone for intravenous use to treat postpartum depression (“PPD”) in adult women;

WHEREAS, according to its interim final rule, the DEA has concluded brexanolone has a low potential for abuse relative to the drugs or other substances in schedule III, a currently accepted medical use in the United States, and may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III; therefore, brexanolone should be placed in schedule IV of the federal Controlled Substances Act effective June 17, 2019; and

THEREFORE, the Board of Health and Environmental Control adopts the federal scheduling of brexanolone and amends Section 44-53-250 of the South Carolina Code of Laws by adding and designating into Schedule IV of the South Carolina Controlled Substances Act: brexanolone (3a-hydroxy-5a-pregnan-20-one) and its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible.

July 11, 2019
Columbia, SC



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