

SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Placement of Ganaxolone into Schedule V for Controlled Substances

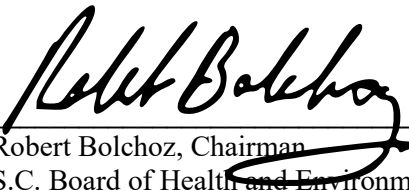
WHEREAS, pursuant to S.C. Code Section 44-53-160(C), the S.C. Board of Health and Environmental Control (Board) shall designate a substance as a controlled substance by scheduling it in accordance with an order effecting federal scheduling as a controlled substance;

WHEREAS, the U.S. Department of Justice, Drug Enforcement Administration (“DEA”), issued an interim final rule placing ganaxolone in schedule V, including its salts in schedule V of the federal Controlled Substance Act, effective June 1, 2022. F.R. Volume 87, Number 105, pp. 32991-32996;

WHEREAS, ganaxolone is a new molecular entity with central nervous system activity, and the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration have recently approved the use of ganaxolone for the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in patients two years of age and older;

WHEREAS, according to its interim final rule, the DEA has concluded ganaxolone has a low potential for abuse relative to the drugs or other substances in schedule IV, 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 V; therefore, ganaxolone should be placed in schedule V of the federal Controlled Substances Act effective June 1, 2022; and

THEREFORE, the Board of Health and Environmental Control adopts the federal scheduling of Ganaxolone and amends Section 44-53-270 of the South Carolina Code of Laws by adding and designating into Schedule V of the South Carolina Controlled Substances Act: Ganaxolone [(3 α -hydroxy-3 β -methyl-5 α -pregnan-20-one) including its salts.



Robert Bolchoz, Chairman
S.C. Board of Health and Environmental Control

June 29, 2022

Columbia, South Carolina