SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Placement of Daridorexant 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, the U.S. Department of Justice, Drug Enforcement Administration ("DEA"), issued an interim final rule placing daridorexant in schedule IV, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers is possible within the specific chemical designation, in schedule IV of the federal Controlled Substance Act, effective April 7, 2022. F.R. Volume 87, Number 67, pp. 20313-20318;

WHEREAS, daridorexant 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 daridorexant for use as a treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance;

WHEREAS, according to its interim final rule, the DEA has concluded daridorexant 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, daridorexant should be placed in schedule IV of the federal Controlled Substances Act effective April 7, 2022; and

THEREFORE, the Board of Health and Environmental Control adopts the federal scheduling of daridorexant 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: Daridorexant [(S)-2-(5-chloro-4-methyl-1Hbenzo[d]imidazol-2-yl)-2- methylpyrrolidin-1-yl](5-methoxy-2- (2H-1,2,3-triazol-2- yl)phenyl) methanone including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers is possible within the specific chemical designation.

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

May 5, 2022
Columbia, South Carolina