STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING	:	AFFIRMATIVE ACTION
PROCEEDINGS BEFORE THE	:	ORDER OF THE
CONTROLLED SUBSTANCES BOARD	:	CONTROLLED SUBSTANCES BOARD

FINDINGS

1. On June 5, 2020, the Department of Justice, Drug Enforcement Administration provided a letter to the Controlled Substances Board indicating that as a result of the Agricultural Improvement Act of 2018, the Federal Drug Administration approved drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

2. The Agricultural Improvement Act of 2018 defines the term "hemp" to "mean the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol (also known as Δ9-THC) concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 1639o.). The Agricultural Improvement Act of 2018 also amended the Controlled Substances Act by excluding "hemp" from the definition of marihuana under 21 U.S.C. § 802 (16) and the listing of tetrahydrocannabinols under 21 U.S.C. § 812 (c).

3. The prescription drug product Epidolex is a cannabis derivative with a Δ9-THC concentration of not more than 0.3% on a dry weight basis. Therefore, as a result of the Department of Justice, Drug Enforcement Administration letter and the Agricultural Improvement Act, the drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

4. The Department of Justice, Drug Enforcement Administration intends to issue a final rule to conform with the Agricultural Improvement Act of 2018 that would formally remove drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols from schedule V.

5. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11 (1), (1m), (1r) and (2) or s. 961.21 and omitting the notice of proposed rule making, removing drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols as a schedule V controlled substances and excluding these drug products from schedule I.

ORDER

Pursuant to s. 961.11 (4g), Stats., the Controlled Substances Board by affirmative action similarly treats drug products approved by the U.S. Food and Drug Administration that contain

cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols under chapter 961, Stats. creating the following:

CSB 2.75 Exclusion of Approved Cannabidiol Drugs from schedule I. (1) Section 961.14 (4) (t) 4., Stats., is created to read:

961.14 (4) (t) 4. A drug product in finished dosage formulation that has been approved by the United States food and drug administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.
(2) Section 961.22 (7) is repealed.

This order shall take effect on June 29, 2020 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated June 23, 2020

Doug Englebert, Chair
Controlled Substances Board