STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 20-077)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.75, relating to removing FDA approved cannabidiol from schedule V and excluding FDA approved cannabidiol from schedule I.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 961.14 and 961.22, Stats.

Statutory authority: s. 961.11 (1) and (4) (g), Stats.

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

If cannabidiol or nabiximols is rescheduled or deleted as a controlled substance under federal law, the controlled substances board shall similarly treat cannabidiol or nabiximols under this chapter as soon as practically possible but no later than 30 days from the date of publication in the federal register of a final order rescheduling or deleting cannabidiol or nabiximols or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h). The board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r), and (2) or s. 961.13, 961.15, 961.17, 961.19, or 961.21, a final rule, for which notice of proposed rule making is omitted, rescheduling or deleting cannabidiol or nabiximols. [s. 961.11 (4g), Stats.]

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:

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.

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).

The prescription drug product Epidiolex 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.

On August 21, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register 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 from schedule V.

Plain language analysis:

The Controlled Substances Board took affirmative action on June 23, 2020 to similarly treat U.S. Food and Drug Administration approved cannabidiol under chapter 961 effective June 29, 2020 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule repeals s. 961.22 (7), Stats., removing Food and Drug Administration approved cannabidiol from Schedule V.

In addition, this rule creates s. 961.14 (4) (t) 4., Stats., creating an exception from Schedule I (under tetrahydrocannabinols) for an FDA approved cannabidiol derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. This exception is created so that the repeal of FDA approved cannabidiol from Schedule V does not revert these substances to inclusion in Schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois does not schedule Food and Drug Administration approved cannabidiol.

Iowa: Iowa schedules Food and Drug Administration approved cannabidiol as Schedule V controlled substances.

Michigan: Michigan does not schedule Food and Drug Administration approved cannabidiol.

Minnesota: Minnesota does not schedule Food and Drug Administration approved cannabidiol.

Summary of factual data and analytical methodologies:

The methodology was to remove cannabidiol from scheduling in schedule V and to exempt it from reverting into schedule I in light of the DEA's recent treatment of this drug.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule schedules a drug and does not have an effect on small business. The rule draft was posted for 14 days on the department website to solicit economic impact comments from businesses. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Jon Derenne, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-266-0955; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Jon Derenne, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by January 14, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.75 is created to read:

CSB 2.75 Exclusion of Approved Cannabidiol Drugs from schedule I and deleting from schedule V. (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), Stats., is repealed.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated _____ _____

Chair