

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.75

Relating to: Removing FDA approved cannabidiol from schedule V and excluding from Schedule I

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the rule is to remove U.S. Food and Drug Administration approved cannabidiol from Schedule V and exclude from Schedule I.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

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 Δ 9-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 marijuana 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 Δ 9-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.

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.

Pursuant to s. 961.11 (4g), Stats., the Controlled Substances Board took affirmative action to similarly treat 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 ch. 961, Stats. by 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.

The Affirmative Action order, dated June 23, 2020, took effect on June 29, 2020 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

961.11 (1) 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.

961.11(4g) Notwithstanding sub. (4), if cannabidiol is rescheduled or deleted as a controlled substance under federal law, the controlled substances board shall similarly treat cannabidiol 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 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.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

25 hours

6. List with description of all entities that may be affected by the proposed rule:

Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

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. Epidiolex is the only Federal Drug Administration approved drug product.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

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Authorized Signature

July 10, 2020

Date Submitted