

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.65

Relating to: Scheduling of FDA approved cannabidiol drugs

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 schedule US Food and Drug Administration approved cannabidiol as Schedule V controlled substance. The Controlled Substances Board determines the scheduling of US Food and Drug Administration approved cannabidiol as Schedule V controlled substances is in the best interest of the citizens of Wisconsin.

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 September 28, 2018, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing US Food and Drug Administration approved cannabidiol into Schedule V of the federal Controlled Substances Act. The scheduling action was effective September 28, 2018.

Pursuant to s. 961.11 (4g), Stats., the Controlled Substances Board took affirmative action to similarly treat US Food and Drug Administration approved cannabidiol under ch. 961, Stats. by creating the following:

CSB 2.65 Addition of approved cannabidiol drugs to schedule V. Section 961.22 (7), Stats., is created to read:

961.22 (7) APPROVED CANNABIDIOL DRUGS. 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.

The Affirmative Action order, dated October 9, 2018, took effect on October 15, 2018 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 :

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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

November 9, 2018

Date Submitted