

Notice of Rulemaking Without Public Hearing

The Controlled Substance Board will adopt the attached rule creating CSB 2.75 relating to removing FDA approved cannabidiol from schedule V and excluding FDA approved cannabidiol from schedule I, without public hearing under the procedure set forth in s. 961.11(4), Stats.

Submittal of Written Comments

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 on or before January 14, 2021 to be included in the record of rule-making proceedings.

Initial Regulatory Flexibility Analysis

The proposed rule will not have an effect on small businesses, as defined under s. 227.114 (1).

Agency Small Business Regulatory Coordinator

Daniel Hereth, (608) 267-2435, Daniel.Hereth@wisconsin.gov

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

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 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 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.

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.

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)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date November 12, 2020
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.75	
4. Subject Removing FDA approved cannabidiol from scheduling	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected
7. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the Rule 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. This rule removes FDA approved cannabidiol from the Wisconsin drug schedules and creates an exception within Schedule V.	
12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. The rule was posted on the department's website for 14 days to solicit economic impact comments from businesses, business sectors, associations representing business, local governmental units, and individuals. No comments were received.	
13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.	
14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred) No impact.	
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion.	
16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule will be to remove Food and Drug Administration approved cannabidiol from Schedule V.	
17. Compare With Approaches Being Used by Federal Government	

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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).

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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.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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.

19. Contact Name

Jon Derenne

20. Contact Phone Number

(608) 266-0955

This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
 - Less Stringent Schedules or Deadlines for Compliance or Reporting
 - Consolidation or Simplification of Reporting Requirements
 - Establishment of performance standards in lieu of Design or Operational Standards
 - Exemption of Small Businesses from some or all requirements
 - Other, describe:
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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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