

Notice of Rulemaking Without Public Hearing

The Controlled Substance Board will adopt the attached rule creating CSB 2.74 relating to scheduling of lemborexant, 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 2.74 relating to scheduling of lemborexant.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: s. 961.11 (1) and (4), 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 a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, 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 rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2). [s. 961.11 (4), Stats.]

Related statute or rule: s. 961.14, Stats.

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

On April 7, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing lemborexant into Schedule IV of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating lemborexant as a schedule IV controlled substance under ch. 961, Stats., based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 8, 2020 to similarly treat lemborexant under chapter 961 effective May 18, 2020 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.20 (2) (eqm), Stats., which adds lemborexant to schedule IV.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled lemborexant.

Iowa: Iowa has not scheduled lemborexant.

Michigan: Michigan has not scheduled lemborexant.

Minnesota: Minnesota has not scheduled lemborexant.

Summary of factual data and analytical methodologies:

The methodology was to schedule lemborexant to conform with the federal Controlled Substances Act.

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 608-261-2377; 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, 2021 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.74 is created to read:

CSB 2.74 Addition of Lemborexant to schedule IV. Section 961.20 (2) (eqm), Stats., is created to read:

961.20 (2) (eqm) Lemborexant.

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 2.74	
4. Subject Scheduling lemborexant	
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 April 7, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing lemborexant into Schedule IV of the federal Controlled Substances Act.	
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. In addition, it is in the best interest of Wisconsin citizens to schedule lemborexant as a controlled substance.	
16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule will be to schedule lemborexant as a schedule IV controlled substance.	
17. Compare With Approaches Being Used by Federal Government The federal government has scheduled lemborexant as a schedule IV controlled substance.	
18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Illinois: Illinois has not scheduled lemborexant.	

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Iowa: Iowa has not scheduled lemborexant.

Michigan: Michigan has not scheduled lemborexant.

Minnesota: Minnesota has not scheduled lemborexant.

19. Contact Name	20. Contact Phone Number
Jon Derenne	(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:

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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