STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING : PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD :

REPORT TO THE LEGISLATURE CR 24-083

I. THE PROPOSED RULE: The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA: The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The objective of the proposed rule is to add the following five synthetic cannabinoids as a schedule I controlled substance under s. 961.11 (4), Stats:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201

The Controlled Substances Board did not receive an objection to similarly listing five of the above synthetic cannabinoids as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing those 5 synthetic cannabinoids as schedule I controlled substances. The remaining synthetic cannabinoid, MMB-FUBICA, is already included in schedule I of ch. 961, Stats. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats the above 5 synthetic cannabinoids under chapter 961, Stats. by creating the following:

CSB 2.006 Adding 5 Synthetic Cannabinoids to Schedule I. (1) Section 961.14 (4) (tb) 54. to 58., Stats., are created to read:

961.14 (4) (tb) 54. Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate, commonly known as MDMB-4en-PINACA.
55. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 4F-MDMB-BUTICA or 4F-MDMB-BICA.
56. *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxaminde, commonly known as ADB-4en-PINACA.
57. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, commonly known as CUMYL-PEGACLONE or SGT-151.
58. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 5F-EDMB-PICA or 5F-EDMB-2201.

The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication in the Administrative Register and expires upon promulgation of a final rule.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing. No other public comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS: Legislative Council Staff did not make any recommendations.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

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 24-083)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.006, relating to scheduling five synthetic cannabinoids.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

Section 961.11 (1), Stats. provides that "[t]he 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."

Section 961.11(4), Stats. provides that "[i]f 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)."

Related statute or rule: s. 961.14, Stats.

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

On December 12, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 6 synthetic cannabinoids to schedule I of the federal Controlled Substances Act:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201
- MMB-FUBICA

The scheduling action was effective December 12, 2023.

Plain language analysis:

The objective of the proposed rule is to add the following five synthetic cannabinoids as a schedule I controlled substance under s. 961.11 (4), Stats:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201

The Controlled Substances Board did not receive an objection to similarly listing five of the above synthetic cannabinoids as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing those 5 synthetic cannabinoids as schedule I controlled substances. The remaining synthetic cannabinoid, MMB-FUBICA, is already included in schedule I of ch. 961, Stats. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats the above 5 synthetic cannabinoids under chapter 961, Stats. by creating the following:

CSB 2.006 Adding 5 Synthetic Cannabinoids to Schedule I. (1) Section 961.14 (4) (tb) 54. to 58., Stats., are created to read:

961.14 (4) (tb) 54. Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate, commonly known as MDMB-4en-PINACA.
55. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 4F-MDMB-BUTICA or 4F-MDMB-BICA.
56. *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxaminde, commonly known as ADB-4en-PINACA.
57. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, commonly known as CUMYL-PEGACLONE or SGT-151.
58. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 5F-EDMB-PICA or 5F-EDMB-2201.

The Affirmative Action order, dated January 24, 2024, took effect on February 5, 2024, upon publication in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: Illinois has not listed the 5 synthetic cannabinoids in this rule as schedule I controlled substances. However, they do have general requirement to include any synthetic cannabinoid that is not approved by the United States Food and Drug Administration or if approved is not dispensed according to law would be considered a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances. However, they do have general requirement to include any synthetic cannabinoid that is not approved by the United States Food and Drug Administration or included in schedules II to V [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:

The methodology was to add the 5 synthetic cannabinoids listed in this rule to Schedule I 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:

The proposed rule was posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by January 10, 2025 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.006 is created to read:

CSB 2.006 Adding 5 Synthetic Cannabinoids to Schedule I. (1) Section 961.14 (4) (tb) 54. to 58., Stats., are created to read:

961.14 (4) (tb) 54. Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3carboxamido)butanoate, commonly known as MDMB-4en-PINACA. 55. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 4F-MDMB-BUTICA or 4F-MDMB-BICA. 56. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3carboxaminde, commonly known as ADB-4en-PINACA. 57. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, commonly known as CUMYL-PEGACLONE or SGT-151. 58. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, commonly known as 5F-EDMB-PICA or 5F-EDMB-2201.

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 01/14/2025

_____ Agency <u>Douglas Inglebert</u> Chairperson

Controlled Substances Board

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis ⊠ Original	2. Date 11/20/24	
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.006		
4. Subject Scheduling 5 Synthetic Cannabinoids		
5. Fund Sources Affected	6. Chapter 20, Stats. Appropriations Affected	
□ GPR □ FED □ PRO □ PRS □ SEG □ SEG-S	s. 20.165 (1) (g) and (hg)	
7. Fiscal Effect of Implementing the Rule		
No Fiscal Effect Increase Existing Revenues	☐ Increase Costs ☐ Decrease Costs	
Indeterminate Decrease Existing Revenues	Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply)		
State's Economy		
	c Utility Rate Payers	
— — —	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).		
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)?		
$\square \text{ Yes } \square \text{ No}$		
11. Policy Problem Addressed by the Rule		
The objective of the proposed rule is to add the following five synthetic cannabinoids as a schedule I controlled		
substance under s. 961.11 (4), Stats:		
• MDMB-4en-PINACA		
 4F-MDMB-BUTICA or 4F-MDMB-BICA 		
• ADB-4en-PINACA		
CUMYL-PEGACLONE or SGT-151		
• 5F-EDMB-PICA or 5F-EDMB-2201		
The Controlled Substances Board did not receive an objection to similarly listing five of the above synthetic		
cannabinoids as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the		
federal register of the final order listing those 5 synthetic cannabinoids as schedule I controlled substances. The		
remaining synthetic cannabinoid, MMB-FUBICA, is already included in schedule I of ch. 961, Stats.		
 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 will be posted on the Department's website for 14 days to solicit public comment on economic impact,		
including how the proposed rules may affect businesses, local government units, and individuals.		
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)		
DSPS estimates a total of \$3,455.00 in one-time costs for implementing this rule. The estimated funds support the		

equivalent of 0.1 limited term employee to undertake tasks such as rule drafting, legal research and review, preparation

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

for prosecution/informational resolution, and investigation of CSB referrals. The one-time costs cannot be absorbed in the currently appropriated agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is that the federal and state controlled substances acts will be uniform to avoid stakholder confusion.

16. Long Range Implications of Implementing the Rule

The long range implications of implementing the rule are that the following will be Schedule I controlled substances in Wisconsin:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201

17. Compare With Approaches Being Used by Federal Government

On December 12, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 6 synthetic cannabinoids to schedule I of the federal Controlled Substances Act:

- MDMB-4en-PINACA
- 4F-MDMB-BUTICA or 4F-MDMB-BICA
- ADB-4en-PINACA
- CUMYL-PEGACLONE or SGT-151
- 5F-EDMB-PICA or 5F-EDMB-2201
- MMB-FUBICA

The scheduling action was effective December 12, 2023.

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

Illinois: Illinois has not listed the 5 synthetic cannabinoids in this rule as schedule I controlled substances. However, they do have general requirement to include any synthetic cannabinoid that is not approved by the United States Food and Drug Administration or if approved is not dispensed according to law would be considered a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances. However, they do have general requirement to include any synthetic cannabinoid that is not approved by the United States Food and Drug Administration or included in schedules II to V [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not included the 5 synthetic cannabinoids listed in this rule as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

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