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**TELECONFERENCE/VIRTUAL  
CONTROLLED SUBSTANCES BOARD  
Virtual, 4822 Madison Yards Way, Madison  
Contact: Christian Albouras (608) 266-2112  
August 18, 2020**

*The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions and deliberations of the Board.*

**AGENDA**

**1:00 P.M.**

**OPEN SESSION – CALL TO ORDER – ROLL CALL**

- A. Adoption of Agenda (1-2)**
- B. Approval of Minutes of July 10, 2020 (3-5)**
- C. Introductions, Announcements and Recognition – Discussion and Consideration**
- D. Administrative Matters – Discussion and Consideration**
  - 1. Department, Staff and Board Updates
  - 2. Board Members
- E. Public Hearing on Clearinghouse Rule 20-022 Relating to Scheduling MMB-FUBICA and 4F-MDMB-BINACA (6-16)**
  - 1. Review and Respond to Clearinghouse Report and Public Hearing Comments
- F. Public Hearing on Clearinghouse Rule 20-023 Relating to Scheduling Isotonitazene and 1P-LSD (17-25)**
  - 1. Review and Respond to Clearinghouse Report and Public Hearing Comments
- G. Administrative Rule Matters – Discussion and Consideration**
  - 1. Scope CSB 2.77 Relating to Scheduling Flualprazolam (26-29)
  - 2. Pending or Possible Rulemaking Projects
- H. Discussion and Consideration of Items Received After Preparation of the Agenda:**
  - 1. Introductions, Announcements, and Recognition
  - 2. Administrative Matters
  - 3. Election of Officers
  - 4. Appointment of Liaisons and Alternates
  - 5. Delegation of Authorities
  - 6. Informational Items
  - 7. Division of Legal Services and Compliance (DLSC) Matters
  - 8. Education and Examination Matters
  - 9. Credentialing Matters

10. Practice Matters
11. Legislative and Policy Matters
12. Administrative Rule Matters
13. Liaison Reports
14. Appearances from Requests Received or Renewed
15. Speaking Engagements, Travel, or Public Relations Requests, and Reports
16. Consulting with Legal Counsel

I. Public Comments

J. Open Session Items Noticed Above Not Completed in the Initial Open Session

**ADJOURNMENT**

**NEXT MEETING: SEPTEMBER 11, 2020**

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED  
WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer at 608-266-2112 or the Meeting Staff at 608-266-5439.

**CONTROLLED SUBSTANCES BOARD  
MEETING MINUTES  
JULY 10, 2020**

**PRESENT:** Subhadeep Barman, Yvonne Bellay, Doug Englebert, Leonardo Huck, Peter Kallio, Sandy Koresch, John Weitekamp

**EXCUSED:** Alan Bloom

**STAFF:** Christian Albouras, Executive Director; Jameson Whitney, Board Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Megan Glaeser, Bureau Assistant; Daniel Betekhtin; Bureau Assistant, and other DSPS Staff

**CALL TO ORDER**

Doug Englebert, Chairperson, called the meeting to order at 9:34 a.m. A quorum was confirmed with seven (7) board members present.

**ADOPTION OF AGENDA**

**MOTION:** Peter Kallio moved, seconded by Leonardo Huck, to adopt the Agenda as published. Motion carried unanimously.

**APPROVAL OF MINUTES**

**May 8, 2020 & June 23, 2020**

**MOTION:** Peter Kallio moved, seconded by Leonardo Huck, to adopt the Minutes of May 8, 2020 and June 23, 2020 as published. Motion carried unanimously.

**PRESCRIPTION DRUG MONITORING PROGRAM (PDMP) UPDATE**

*ePDMP New Prescribing Metrics Notification*

**MOTION:** Subhadeep Barman moved, seconded by Peter Kallio, the board recommends that staff implement the metric notification be provided when Prescribers have not reviewed their prescriber metrics in the past 90 days. Motion carried unanimously.

**MOTION:** Sandy Koresch moved, seconded by John Weitekamp, to create a workgroup to determine metric notification thresholds and to appoint Peter Kallio, Subhadeep Barman, Doug Englebert and John Weitekamp as members. Motion carried unanimously.

**Update on VA and APRIS Impact**

**MOTION:** Peter Kallio moved, seconded by Sandy Koresch, to delegate to the Metrics Work Group to work with Department staff to analyze and assess the appropriateness of the VHA PDMP integration pilot program as proposed by

Appriss, and delegates authority to the chair (Doug Englebert) of the Work Group to make decisions regarding the program. Motion carried unanimously.

### **ADMINISTRATIVE RULE MATTERS**

#### **Adopt CR 19-156 (CSB 4) Relating to Operation of Prescription Drug Monitoring Program**

**MOTION:** Subhadeep Barman moved, seconded by Peter Kallio, to approve the Adoption Order for Clearinghouse Rule 19-156 (CSB 4), relating to the operation of Prescription Drug Monitoring Program. Motion carried unanimously.

#### **Adopt CR 19-157 (CSB 3) Relating to Special Use Authorizations**

**MOTION:** Yvonne Belay moved, seconded by Subhadeep Barman, to approve the Adoption Order for Clearinghouse Rule 19-157 (CSB 3), relating to Special Use Authorizations. Motion carried unanimously.

#### **Scope: CSB 2.73, Relating to Scheduling Cenobamate**

**MOTION:** Peter Kallio moved, seconded by Sandy Koresch, to approve the Scope Statement revising CSB 2.73, relating to scheduling Cenobamate, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

#### **Scope: CSB 2.74, Relating to Scheduling Lemborexant**

**MOTION:** Subhadeep Barman moved, seconded by John Weitekamp, to approve the Scope Statement revising CSB 2.74, relating to scheduling Lemborexant, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

#### **Scope: CSB 2.75, Relating to FDA Approved Cannabidiol**

**MOTION:** Sandy Koresch moved, seconded by Subhadeep Barman, to approve the Scope Statement revising CSB 2.75, relating to FDA Approved Cannabidiol, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on

the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

**Scope: CSB 2.76, Relating to Scheduling Norfentanyl**

**MOTION:** Subhadeep Barman moved, seconded by Yvonne Bellay, to approve the Scope Statement revising CSB 2.76, relating to scheduling Norfentanyl, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

**CSB 2.71, Relating to Scheduling Lasmiditan**

**MOTION:** Peter Kallio moved, seconded by Leonardo Huck, to approve the preliminary rule draft of CSB 2.71, relating to scheduling Lasmiditan, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

**ADJOURNMENT**

**MOTION:** Peter Kallio moved, seconded by Subhadeep Barman, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:48 a.m.

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 30 July 2020 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 18 August 2020	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Public Hearing on Clearinghouse Rule 20-022 relating scheduling MMB-FUBICA and 4F-MDMB-BINACA a. Review and respond to Clearinghouse Report and Public Hearing comments	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Hold Public Hearing at 1:00 p.m.  Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.			
11) <span style="float: right;">Authorization</span> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="width: 60%;"><i>Sharon Henes</i></div> <div style="width: 35%; text-align: right;"><i>7/30/20</i></div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <span>Signature of person making this request</span> <span>Date</span> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <span>Supervisor (if required)</span> <span>Date</span> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <span>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</span> <span>Date</span> </div>			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN  
CONTROLLED SUBSTANCES BOARD

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

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PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.70, relating to scheduling MMB-FUBICA and 4F-MDMB-BINACA.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** s. 961.14, Stats.

**Statutory authority:** ss. 961.11 (1) and (4m), 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.)

The controlled substances board, by rule and without regard to the requirements of sub. (1m), may schedule a controlled substance analog as a substance in schedule I regardless of whether the substance is substantially similar to a controlled substance in schedule I or II, if the board finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under 21 USC 355. Upon receipt of notice under s. 961.25, the board shall initiate scheduling of the controlled substance analog on an emergency basis under this subsection. The scheduling of a controlled substance analog under this subsection expires one year after the adoption of the scheduling rule. With respect to the finding of an imminent hazard to the public safety, the board shall consider whether the substance has been scheduled on a temporary basis under federal law or factors under sub. (1m) (d), (e) and (f), and may also consider clandestine importation, manufacture or distribution, and, if available, information concerning the other factors under sub. (1m). The board may not promulgate a rule under this subsection until it initiates a rule-making proceeding under subs. (1), (1m), (1r) and (2) with respect to the controlled substance analog. A rule promulgated under this subsection lapses upon the conclusion of the rule-making proceeding initiated under subs. (1), (1m), (1r) and (2) with respect to the substance. (s. 961.11 (4m), Stats.)

**Related statute or rule:** s. 961.14, Stats.

**Plain language analysis:**

This rule schedules MMB-FUBICA and 4F-MDMB-BINACA as Schedule I controlled substances.

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

MMB-FUBICA and 4F-MDMB-BINACA are not currently scheduled under the Controlled Substances Act.

**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 scheduled MMB-FUBICA and 4F-MDMB-BINACA as controlled substances.

**Iowa:** Iowa has not scheduled MMB-FUBICA and 4F-MDMB-BINACA as controlled substances.

**Michigan:** Michigan has not scheduled MMB-FUBICA and 4F-MDMB-BINACA as controlled substances.

**Minnesota:** Minnesota has not scheduled MMB-FUBICA and 4F-MDMB-BINACA as controlled substances.

**Summary of factual data and analytical methodologies:**

Based upon the Green County District Attorney’s request for emergency scheduling and the finding of an imminent hazard to the public safety, the Controlled Substances Board decided to schedule MMB-FUBICA and 4F-MDMB-BINACA. In making the findings of imminent hazard to the public safety, the Controlled Substances Board considered the following factors: the history and current pattern of abuse; the scope, duration and significance of abuse; and the risk to the public health.

**Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:**

The rule schedules two synthetic drugs as Schedule I controlled substances which will not have any 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:**

Sharon Henes, 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 Sharon Henes, 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 at or before the public hearing to be held on August 18, 2020 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. CSB 2.70 is created to read:

**CSB 2.70 Scheduling 4F-MDMB-BINACA and MMB-FUBICA.** Section 961.14 (4) (tb) 38m. and 43m., Stats., are created to read:

*961.14 (4) (tb) 38m. Methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, commonly known as 4F-MDMB-BINACA or 4F-MDMB-BUTINACA.  
43m. Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methylbutanoate, commonly known as MMB-FUBICA or AMB-FUBICA*

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.

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(END OF TEXT OF RULE)

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<b>1. Type of Estimate and Analysis</b> <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	<b>2. Date</b> 30 June 2020
<b>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)</b> CSB 2.70	
<b>4. Subject</b> Scheduling MMB-FUBICA and 4F-MDMB-BINACA	
<b>5. Fund Sources Affected</b> <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	<b>6. Chapter 20, Stats. Appropriations Affected</b>
<b>7. Fiscal Effect of Implementing the Rule</b> <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	
<b>8. The Rule Will Impact the Following (Check All That Apply)</b> <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 <b>(if checked, complete Attachment A)</b>	
<b>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).</b> \$0.00	
<b>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)?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<b>11. Policy Problem Addressed by the Rule</b> The Green County District Attorney's Office requested emergency scheduling of MMB-FUBICA and 4F-MDMB-BINACA. The Controlled Substances Board made a determination on an imminent hazard to the public.	
<b>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.</b> This rule was posted for economic comments and none were received.	
<b>13. Identify the Local Governmental Units that Participated in the Development of this EIA.</b> None.	
<b>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)</b> This rule will not have a fiscal or economic impact.	
<b>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule</b> MMB-FUBICA and 4F-MDMB-BINACA will be schedule I controlled substances.	
<b>16. Long Range Implications of Implementing the Rule</b> MMB-FUBICA and 4F-MDMB-BINACA would be treated as schedule I controlled substances.	
<b>17. Compare With Approaches Being Used by Federal Government</b> The federal government has not scheduled MMB-FUBICA and 4F-MDMB-BINACA.	
<b>18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)</b> Our surrounding states have not scheduled MMB-FUBICA and 4F-MDMB-BINACA.	
<b>19. Contact Name</b> Sharon Henes	<b>20. Contact Phone Number</b> 608-358-4617

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

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

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

**ATTACHMENT A**

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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)

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

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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

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5. Describe the Rule's Enforcement Provisions

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

- Yes    No
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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Scott Grosz**  
*Clearinghouse Director*

**Anne Sappenfield**  
*Legislative Council Director*

**Margit S. Kelley**  
*Clearinghouse Assistant Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE **20-022**

AN ORDER to create CSB 2.70, relating to scheduling MMB-FUBICA and 4F-MDMB-BINACA.

Submitted by **CONTROLLED SUBSTANCES BOARD**

07-10-2020 RECEIVED BY LEGISLATIVE COUNCIL.

08-04-2020 REPORT SENT TO AGENCY.

MSK:BL

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES  NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES  NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES  NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS  
[s. 227.15 (2) (e)]

Comment Attached YES  NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES  NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL  
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES  NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES  NO



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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Scott Grosz**  
*Clearinghouse Director*

**Anne Sappenfield**  
*Legislative Council Director*

**Margit Kelley**  
*Clearinghouse Assistant Director*

### CLEARINGHOUSE RULE 20-022

#### Comments

**[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]**

#### **2. Form, Style and Placement in Administrative Code**

In SECTION 1 of the proposed rule, the text of the created provisions should be shown without italics.

#### **5. Clarity, Grammar, Punctuation and Use of Plain Language**

In s. 961.14 (4) (tb) 43m., a period should be inserted at the end of the sentence.

**From:** [Kelley, Margit S - LEGIS](#)  
**To:** [Henes, Sharon - DSPS](#)  
**Cc:** [Grosz, Scott A - LEGIS](#)  
**Subject:** CHR 20-022  
**Date:** Wednesday, August 5, 2020 7:37:26 AM

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Hi Sharon,

It occurred to me that the comment in CHR 20-022 about using plain text, rather than italics, was in the context of how the text would appear in the statutes. Instead, the CSB rule is identifying what would be added to the statutes, and the italics are in the context of how that's identified in the rule.

In other words, we understand that CSB will be keeping italics in that context, for the final rule. We'll try to catch that in the future.

Thanks!



**Margit Kelley**

Senior Staff Attorney, Wisconsin Legislative Council  
608.504.5717 | [margit.kelley@legis.wisconsin.gov](mailto:margit.kelley@legis.wisconsin.gov)  
One East Main Street, Suite 401, Madison, WI 53703

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 30 July 2020 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 18 August 2020	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Public Hearing on Clearinghouse Rule 20-023 relating scheduling Isotonitazene and 1P-LSD a. Review and respond to Clearinghouse Report and Public Hearing comments	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Hold Public Hearing at 1:00 p.m.  Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.			
11) <span style="float: right;">Authorization</span> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="width: 60%; border-bottom: 1px solid black; padding-bottom: 5px;"><i>Sharon Henes</i></div> <div style="width: 35%; border-bottom: 1px solid black; padding-bottom: 5px; text-align: center;">7/30/20</div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <span>Signature of person making this request</span> <span>Date</span> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <span>Supervisor (if required)</span> <span>Date</span> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <span>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</span> <span>Date</span> </div>			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN  
CONTROLLED SUBSTANCES BOARD

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

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PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.72, relating to scheduling isotonitazene and 1P-LSD.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** s. 961.14, Stats.

**Statutory authority:** ss. 961.11 (1) and (4m), 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.)

The controlled substances board, by rule and without regard to the requirements of sub. (1m), may schedule a controlled substance analog as a substance in schedule I regardless of whether the substance is substantially similar to a controlled substance in schedule I or II, if the board finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under 21 USC 355. Upon receipt of notice under s. 961.25, the board shall initiate scheduling of the controlled substance analog on an emergency basis under this subsection. The scheduling of a controlled substance analog under this subsection expires one year after the adoption of the scheduling rule. With respect to the finding of an imminent hazard to the public safety, the board shall consider whether the substance has been scheduled on a temporary basis under federal law or factors under sub. (1m) (d), (e) and (f), and may also consider clandestine importation, manufacture or distribution, and, if available, information concerning the other factors under sub. (1m). The board may not promulgate a rule under this subsection until it initiates a rule-making proceeding under subs. (1), (1m), (1r) and (2) with respect to the controlled substance analog. A rule promulgated under this subsection lapses upon the conclusion of the rule-making proceeding initiated under subs. (1), (1m), (1r) and (2) with respect to the substance. (s. 961.11 (4m), Stats.)

**Related statute or rule:** s. 961.14, Stats.

**Plain language analysis:**

This rule schedules isotonitazene and 1P-LSD as Schedule I controlled substances.

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

Isotonitazene and 1P-LSD are not currently scheduled under the Controlled Substances Act.

**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 scheduled isotonitazene or 1P-LSD as controlled substances.

**Iowa:** Iowa has not scheduled isotonitazene or 1P-LSD as controlled substances.

**Michigan:** Michigan has not scheduled isotonitazene or 1P-LSD as controlled substances.

**Minnesota:** Minnesota has not scheduled isotonitazene or 1P-LSD as controlled substances.

**Summary of factual data and analytical methodologies:**

Based upon the Walworth County District Attorney's request for emergency scheduling, additional information from the Milwaukee Medical Examiner and the finding of an imminent hazard to the public safety, the Controlled Substances Board decided to schedule isotonitazene. Based upon the Calumet County District Attorney's request for emergency scheduling and the finding of an imminent hazard to the public safety, the Controlled Substances Board decided to schedule 1P-LSD. In making the findings of imminent hazard to the public safety, the Controlled Substances Board considered the following factors: the history and current pattern of abuse; the scope, duration and significance of abuse; and the risk to the public health.

**Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:**

The rule schedules two synthetic drugs as Schedule I controlled substances which will not have any 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:**

Sharon Henes, 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 Sharon Henes, 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 at or before the public hearing to be held on August 18, 2020 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. CSB 2.72 is created to read:

**CSB 2.72 Scheduling of isotonitazene and 1P-LSD.** Section 961.14 (2) (pe) and (4) (jm), Stats., are created to read:

*961.14 (2) (pe) Isotonitazene.*

*961.14 (4) (jm) 1-propionyl-lysergic acid diethylamide, commonly known as 1P-LSD.*

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.

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(END OF TEXT OF RULE)

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<b>1. Type of Estimate and Analysis</b> <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	<b>2. Date</b> 30 June 2020
<b>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)</b> CSB 2.72	
<b>4. Subject</b> Scheduling isotonitazene and 1P-LSD	
<b>5. Fund Sources Affected</b> <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	<b>6. Chapter 20, Stats. Appropriations Affected</b>
<b>7. Fiscal Effect of Implementing the Rule</b> <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	
<b>8. The Rule Will Impact the Following (Check All That Apply)</b> <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 <b>(if checked, complete Attachment A)</b>	
<b>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).</b> \$0.00	
<b>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)?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<b>11. Policy Problem Addressed by the Rule</b> The Walworth County District Attorney's Office requested emergency scheduling of isotonitazene. The Milwaukee Medical Examiner provided additional information involving recent overdose cases, including deaths, involved isotonitazene in Milwaukee, Walworth and Jefferson Counties. The Calumet County District Attorney's Office requested emergency scheduling of 1P-LSD. The Controlled Substances Board made a determination on an imminent hazard to the public.	
<b>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.</b> This rule was posted for economic comments and none were received.	
<b>13. Identify the Local Governmental Units that Participated in the Development of this EIA.</b> None	
<b>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)</b> This rule will not have a fiscal or economic impact.	
<b>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule</b> Isotonitazene and 1P-LSD will be schedule I controlled substances.	
<b>16. Long Range Implications of Implementing the Rule</b> Isotonitazene and 1P-LSD would be treated as a schedule I controlled substances.	
<b>17. Compare With Approaches Being Used by Federal Government</b> The federal government has not scheduled isotonitazene and 1P-LSD.	
<b>18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)</b> Our surrounding states have not scheduled isotonitazene and 1P-LSD.	

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

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19. Contact Name

Sharon Henes

20. Contact Phone Number

608-358-4617

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

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

**ATTACHMENT A**

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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)

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

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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

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5. Describe the Rule's Enforcement Provisions

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

- Yes     No
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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Scott Grosz**  
*Clearinghouse Director*

**Anne Sappenfield**  
*Legislative Council Director*

**Margit S. Kelley**  
*Clearinghouse Assistant Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE **20-023**

AN ORDER to create CSB 2.72, relating to scheduling isotonitazene and 1P-LSD.

Submitted by **CONTROLLED SUBSTANCES BOARD**

07-10-2020 RECEIVED BY LEGISLATIVE COUNCIL.

08-05-2020 REPORT SENT TO AGENCY.

SG:BL

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES  NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES  NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES  NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS  
[s. 227.15 (2) (e)]

Comment Attached YES  NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES  NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL  
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES  NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES  NO

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 30 July 2020 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 18 August 2020	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Rule Matters 1. Scope CSB 2.77 Relating to Scheduling Flualprazolam 2. Pending or Possible Rulemaking Projects	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		<i>07/30/20</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

# STATEMENT OF SCOPE

## Controlled Substances Board

**Rule No.:** CSB 2.77

**Relating to:** Scheduling Flualprazolam

**Rule Type:** Both Permanent and Emergency

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

The Controlled Substances Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare.

The Controlled Substances Board has received information from the Milwaukee Medical Examiner's Office, Dane County Medical Examiner's Office, Jefferson County Sheriff's Department, Monona Police Department, Jackson Police Department and Jefferson Police Department indicating recent overdose cases, including deaths, that have involved flualprazolam. In at least one of the deaths, the only substance was flualprazolam.

Flualprazolam is an analog of alprazolam (a schedule IV controlled substance), differing in chemical composition by the presence of a fluorine atom.

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

The objective of the proposed rule is to schedule flualprazolam as a controlled substance.

### 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:

Flualprazolam is an analog of alprazolam (a FDA approved schedule IV controlled substance), differing in chemical composition by the presence of a fluorine atom. Flualprazolam is a benzodiazepine synthesized and patented in 1970s for research purposes but was never marketed as a medicine. Flualprazolam is not used clinically.

The onset of action due to flualprazolam is reported to be 10-20 minutes after oral use with a duration of action of 6-14 hours. Flualprazolam depresses the central nervous system resulting in sedation, reduced anxiety, and loss of consciousness. Flualprazolam is similar to alprazolam which has demonstrably greater abuse liability compared to diazepam, especially for those with a personal or family substance use disorder history.

The World Health Organization released a critical review report on flualprazolam in October 2019. On March 4, 2020, the United Nations Commission on Narcotic Drugs placed flualprazolam under international control as a Schedule IV. Delaware added several benzodiazepines, including flualprazolam, to Schedule IV due to the serious potential for abuse. Flualprazolam is on several states' law enforcement watchlists or alerts.

In 2019 and 2020, there has been an increased prevalence of flualprazolam in the United States. Law enforcement officers and medical examiners have provided information to the Controlled Substances Board indicating this substance is implicated in Wisconsin overdose cases, including those resulting in death.

Public health concerns are similar to other benzodiazepines which are higher potency with a relatively fast time of onset. When flualprazolam is combined with opioids, this contributes to increased overdose through benzodiazepine-potentiated opioid-induced respiratory depression. In addition, flualprazolam causes disinhibition and sedation that impair driving. There have been reports of intentionally counterfeit alprazolam product containing flualprazolam entering the drug supply chain in other states.

Flualprazolam has a fast onset of action and similarities to alprazolam and has a relatively high dependence liability.

The Controlled Substances Board considered the following factors in making the determination to add flualprazolam to the controlled substance schedules in ch. 961, Stats.:

- The actual or relative potential for abuse.
- The scientific evidence of its pharmacological effect.
- The state of current scientific knowledge regarding the substance.
- The history and current pattern of abuse.
- The scope, duration and significance of abuse.
- The risk to the public health.
- The potential of the substance to produce psychological or physical dependence liability.
- Whether the substance is an immediate precursor of a substance already controlled under ch. 961, Stats.

The Controlled Substances Board makes a finding that flualprazolam has a potential for abuse.

The alternative to scheduling flualprazolam as a controlled substance is for it to remain as a substance that is not treated as a controlled substance in Wisconsin. Alprazolam is not a schedule I controlled substance, therefore, a prosecution involving flualprazolam can not be commenced under Wisconsin's analog law (s. 961.25, Stats).

#### **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.

(1m) In making a determination regarding a substance, the board shall consider the following:

- (a) The actual or relative potential for abuse;
- (b) The scientific evidence of its pharmacological effect, if known;
- (c) The state of current scientific knowledge regarding the substance;
- (d) The history and current pattern of abuse;
- (e) The scope, duration and significance of abuse;
- (f) The risk to the public health;
- (g) The potential of the substance to produce psychological or physical dependence liability; and
- (h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

(1r) The controlled substances board may consider findings of the federal food and drug administration or the drug enforcement administration as prima facie evidence relating to one or more of the determinative factors.

(2) After considering the factors enumerated in sub. (1m), the controlled substances board shall make findings with respect to them and promulgate a rule controlling the substance upon finding that the substance has a potential for abuse.

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

60 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:**

The federal government has not scheduled flualprazolam as a controlled substance.

**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. This rule is not likely to have a significant economic impact on small businesses.

**Contact Person:** Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

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Authorized Signature

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Date Submitted