Wisconsin Department of Safety and Professional Services Division of Policy Development 4822 Madison Yards Way PO Box 8366 Madison WI 53708-8366



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Tony Evers, Governor Dawn B. Crim, Secretary

TELECONFERENCE/VIRTUAL CONTROLLED SUBSTANCES BOARD

Virtual, 4822 Madison Yards Way, 2nd Floor, Madison Contact: Christian Albouras (608) 266-2112 June 23, 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)
- **B.** Administrative Matters
 - 1. Department, Staff and Board Updates
 - 2. Board Members

C. Administrative Rule Matters – Discussion and Consideration

- 1. Scheduling Norfentanyl by Affirmative Action (2)
- 2. Deleting Federal Drug Administration (FDA) Approved Cannabidiol Drugs from the Controlled Substances Schedules by Affirmative Action (3-4)
- 3. Schedule Public Hearing for Isotonitazene and 1P-LSD for August 2020 (5)
- 4. Pending or Possible Rulemaking Projects
- **D.** Public Comments

ADJOURNMENT

NEXT MEETING: JULY 10, 2020

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, 608-266-2112.

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

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IN THE MATTER OF RULE-MAKING : AFFIRMATIVE ACTION PROCEEDINGS BEFORE THE : ORDER OF THE

CONTROLLED SUBSTANCES BOARD : CONTROLLED SUBSTANCES BOARD

<u>FINDINGS</u>

- 1. On April 17, 2020, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing norfentanyl into schedule II of the federal Controlled Substances Act. The scheduling action is effective May 18, 2020.
- 2. The Controlled Substances Board did not receive an objection to similarly treating norfentanyl as a schedule II under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating norfentanyl as a controlled substance.
- 3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.15 and omitting the notice of proposed rule making, designating norfentanyl as a schedule II controlled substance.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats norfentanyl under chapter 961, Stats. by creating the following:

CSB 2.16 Addition of norfentanyl to schedule II. (1) Section 961.16 (8) (b), Stats., is renumbered 961.16 (8) (b) (intro.) and amended to read: 961.16 (8) (b) An immediate precursor to fentanyl, including all of the following:

1. 4-anilino-N-phenethyl-4-piperidine, commonly known as ANPP.

- (2) Section 961.16 (8) (b) 2., Stats. is created to read:
- 2. N-phenyl-N-(piperidin-4-yl)propionamide, commonly known as norfentanyl.

This order shall take effect on June 29, 2020 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

| Dated | |
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| | Doug Englebert, Chair |
| | Controlled Substances Board |

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

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IN THE MATTER OF RULE-MAKING : AFFIRMATIVE ACTION PROCEEDINGS BEFORE THE : ORDER OF THE

CONTROLLED SUBSTANCES BOARD : CONTROLLED SUBSTANCES BOARD

<u>FINDINGS</u>

- 1. 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.
- 2. 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 $\Delta 9$ -THC) concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 16390.). The Agricultural Improvement Act of 2018 also amended the Controlled Substances Act by excluding "hemp" from the definition of marihuana under 21 U.S.C. § 802 (16) and the listing of tetrahydrocannabinols under 21 U.S.C. § 812 (c).
- 3. The prescription drug product Epidolex is a cannabis derivative with a $\Delta 9$ -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.
- 4. The Department of Justice, Drug Enforcement Administration intends to issue a final rule to conform with the Agricultural Improvement Act of 2018 that would formally remove 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.
- 5. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11 (1), (1m), (1r) and (2) or s. 961.21 and omitting the notice of proposed rule making, 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 as a schedule V controlled substances and excluding these drug products from schedule I.

ORDER

Pursuant to s. 961.11 (4g), Stats., the Controlled Substances Board by affirmative action similarly treats 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 under chapter 961, Stats. creating the following:

CSB 2.75 Exclusion of Approved Cannabidiol Drugs from schedule I. (1) Section 961.14 (4) (t) 4., Stats., is created to read:

961.14 (4) (t) 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) is repealed.

| This order | r shall take effect | on June 29, | 2020 to | allow for | publication | in the A | Administrative |
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| Register. | The order expire | s upon prom | nulgation | of a final | rule. | | |

| Dated | |
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| | Doug Englebert, Chair |
| | Controlled Substances Board |

Proposed Dates for August Public Hearing:

Tuesday, August 11, 2020 (Between: 1:00pm-4:00pm)

Wednesday, August 12, 2020 (Between: 1:30pm-4:00pm)

Tuesday August 18, 2020 (Between: 12:30pm-4:00pm)