

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 2.98, relating to Excluding [18 F]FP-CIT.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, 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. 961.16, Stats.

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

On November 21, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [18 F]FP-CIT from schedule II of the federal Controlled Substances Act. The scheduling action is effective December 21, 2022.

Plain language analysis:

This rule excludes [18 F]FP-CIT from schedule II.

The Controlled Substances Board did not receive an objection to similarly excluding [18 F]FP-CIT from schedule II under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order removing [18 F]FP-CIT as a schedule II controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat [18 F]FP-CIT under ch. 961, Stats. by creating the following:

CSB 2.98 Excluding [18 F]FP-CIT from schedule II. Section 961.16 (2) (b), Stats., is amended to read:

961.16 (2) (b) Coca leaves and any salt, compound, derivative, or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [123I]Ioflupane is and [18 F]FP-CIT are excluded from this paragraph. The following substances and any of their salts, esters, isomers, and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023 to allow for 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 excluded [18 F]FP-CIT from their schedule II controlled substances list [720 Illinois Compiled Statutes 570/206].

Iowa: Iowa has not excluded [18 F]FP-CIT from their schedule II controlled substances list [Iowa Administrative Code s. 124.206].

Michigan: Michigan has not excluded [18 F]FP-CIT from their schedule II controlled substances list [Michigan Compiled Laws s. 333.7214].

Minnesota: Minnesota has not excluded [18 F]FP-CIT from their schedule II controlled substances list [Minnesota Statutes 152.02 (3)].

Summary of factual data and analytical methodologies:

This rule excludes [¹⁸F]FP-CIT from schedule II 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 excludes [¹⁸F]FP-CIT from schedule II which will not have any effect on small business.

Fiscal Estimate and 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.

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; telephone 608-267-7139; 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 March 8, 2024, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.98 is created to read:

CSB 2.98 Excluding [¹⁸F]FP-CIT from schedule II. Section 961.16 (2) (b), Stats., is amended to read:

961.16 (2) (b) Coca leaves and any salt, compound, derivative, or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [¹²³I]Ioflupane ~~is~~ and [¹⁸F]FP-CIT are excluded from this paragraph. The following substances and any of their salts, esters, isomers, and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

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)