



Carol Roessler
STATE SENATOR

October 1, 2003

To: Member of the Senate Committee on Health, Children, Families, Aging and Long Term Care.

From: Senator Carol Roessler, Chair

Re: Clearinghouse Rule 03-057 relating to scheduling of a schedule III controlled substance under chapter 961, Stats. the Uniform Controlled Substance Act.

CR 03-057 has been referred to the Senate Committee on Health, Children, Families, Aging and Long Term Care Committee. By final rule of the Drug Enforcement Administration (DEA) adopted effective March 3, 2000, gamma-hydroxybutric acid (GHB) was classified as a schedule I and schedule III controlled substance under the federal Controlled Substance Act (CSA) pursuant to Public Law 106-172. GHB is currently only classified as a schedule I controlled substance under the Wisconsin Controlled Substance Act in Chapter 961, Wis. Stats. The objective of the rule is to bring state classification of GHB into conformity with federal law.

If you would like the Committee to hold a hearing on CR 03-057, please contact Jennifer Halbur in my office at 266-5300 by Friday October 17th, 2003.

STATE OF WISCONSIN
CONTROLLED SUBSTANCE BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 03-057)

September 30, 2003

TO: Alan J. Lasse
President of the Senate
Room 219 South, State Capital
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the CONTROLLED SUBSTANCES BOARD is submitting in final draft form rules relating to the scheduling of a schedule III controlled substance under chapter 961, Stats., the Uniform Controlled Substances Act.

If you have any questions concerning the final draft form or desire additional information, please contact Joel Garb at 261-2385

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 03-057)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.30, relating to the scheduling of a schedule III controlled substance under chapter 961, Stats., the Uniform Controlled Substances Act.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 961.11 (1) and 961.18, Wis. Stats.

Statutes interpreted: ss. 961.11 and 961.18, Wis. Stats.

By final rule of the Drug Enforcement Administration (DEA), adopted effective March 3, 2000, gamma-hydroxybutric acid (GHB) was classified as a schedule I and schedule III controlled substance under the federal Controlled Substances Act (CSA) pursuant to Public Law 106-172. GHB is currently only classified as a schedule I controlled substance under the Wisconsin Controlled Substances Act in Chapter 961, Wis. Stats. The objective of the rule is to bring state classification of GHB into conformity with federal law.

Drugs that are classified as "controlled substances" under federal and state laws are subject to higher civil and criminal penalties for their illicit possession, distribution and use. Health care providers are also subject to greater record keeping requirements respecting their obtaining, prescribing and dispensing of such drugs. This is due to the fact that certain drugs have a greater likelihood of abuse, addiction and adverse consequences to patient health if utilized inappropriately, than do other drugs. The DEA administers the CSA. In doing so, it is empowered to schedule a drug as a controlled substance. Schedule III controlled substances are listed in 21 CFR 1308.13. Section 1308.13(c)(5) lists GHB as included in that classification for any drug product containing GHB for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act. Public Law 106-172 authorized the DEA to classify GHB as a schedule I and schedule III controlled substance. This forms the basis for the DEA action. The board has been requested to initiate rulemaking to create a GHB classification which mirrors federal law to enable citizens of this state to benefit from FDA approved prescription drug products containing GHB.

TEXT OF RULE

SECTION 1. CSB 2.30 is created to read:

CSB 2.30 Addition of gamma-hydroxybutyric acid to schedule III. (1) Section 961.18 (3) (o) is created to read:

Section 961.18 (3) (o) Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal food, drug and cosmetic act:

1. Gamma-hydroxybutyric acid.

(END OF TEXT OF RULE)

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.

Dated _____

Agency _____

Chairperson
Controlled Substances Board

FISCAL ESTIMATE

The Department of Regulation and Licensing will incur \$500 in costs to print and distribute the rule change.

FINAL REGULATORY FLEXIBILITY ANALYSIS

This rule will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

**STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD**

**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 03-057
CONTROLLED SUBSTANCES BOARD : (s. 227.19 (3), Stats.)**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

None

III. FISCAL ESTIMATES:

These rules will have no significant economic impact.

IV. STATEMENT EXPLAINING NEED:

In this rule the Controlled Substances Board classifies an FDA approved prescription drug product containing gamma-hydroxybutyric acid (GHB), as a schedule III controlled substance. This results in a state classification in conformity with federal law.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on August 6, 2003. Bob Gagne, with Orphan Medical, Inc., appeared and spoke in favor of the rule change. There were no other appearances and no written comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

The recommendation suggested in the Clearinghouse Report was accepted in whole.

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

This rule will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Terry C. Anderson
Legislative Council Director

Richard Sweet
Clearinghouse Assistant Director

Laura D. Rose
Legislative Council Deputy 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 03-057

AN ORDER to create CSB 2.30, relating to the scheduling of a schedule III controlled substance under chapter 961, Stats., the Uniform Controlled Substances Act.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

06-16-2003 RECEIVED BY LEGISLATIVE COUNCIL.

07-07-2003 REPORT SENT TO AGENCY.

RS:AS



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Richard Sweet
Clearinghouse Assistant Director

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Legislative Council Deputy Director

CLEARINGHOUSE RULE 03-057

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated October 2002.]

2. Form, Style and Placement in Administrative Code

The treatment clause of s. CSB 2.08 should state that s. 961.18 (3) (o) is created because the rule is creating the entire paragraph, not just the subdivision of the paragraph. In addition, a subdivision is not typically created unless there is more than one item to list. However, it is recognized that the board may be anticipating the addition of subdivisions in the future.