STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

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 IIII 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-hydroxybutyic 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.