STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD : NOTICE OF PROPOSED RULE-MAKING : OF THE CONTROLLED SUBSTANCES : BOARD ADOPTING RULES

NOTICE IS HEREBY GIVEN that pursuant to ss. 961.11 (1) and 961.16, Stats., and interpreting ss. 961.11 (1) and 961.16, Stats., and according to the procedure set forth in s. 227.16 (2) (e), Stats., the Controlled Substances Board will adopt the following rule as proposed in this notice, without public hearing unless, within 30 days after publication of this notice, the Controlled Substances Board is petitioned for a public hearing by 25 natural persons who will be affected by the rule; a municipality which will be affected by the rule; or an association which is representative of a farm, labor, business or professional group which will be affected by the rule.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes interpreted:
Sections 961.11 (1) and 961.16, Stats.

Statutory authority:
Sections 961.11 (1) and 961.16, Stats.

Explanation of agency authority:

The Controlled Substances Board is authorized by s. 961.11 (1) Stats., to add substances to or delete or reschedule substances listed under schedule II, in s. 961.16, Stats., pursuant to the rule-making procedures of ch. 227, Stats.

Related statute or rule:
21 CFR Sec. 1308.12 (d) (5)

Plain language analysis:

By final rule of the Drug Enforcement Administration (DEA), adopted effective June 4, 2007, lisdexamfetamine was classified as a schedule II controlled substance under the federal Controlled Substances Act (CSA). Lisdexamfetamine has not been so scheduled under the Wisconsin Controlled Substances Act in ch. 961, Stats. The objective of this proposed rule-making is to bring the treatment of this drug into conformity with that at the federal level.

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 recordkeeping requirements regarding procuring, prescribing and dispensing of such drugs. This is because certain drugs, like lisdexamfetamine, have a greater likelihood of abuse, addiction and adverse consequences to patient health if utilized inappropriately, than do other drugs.

Lisdexamfetamine is also known by the trade name Vyvanse TM and has the DEA Drug Code 1205. It will be marketed as a prescription drug product for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The DEA found reason to classify Lisdexamfetamine, including its salts, isomers, and salts of isomers, as a schedule II drug based on the following findings:

(1) Lisdexamfetamine has a high potential for abuse;

(2) Lisdexamfetamine has a currently accepted medical use in treatment in the United States; and

(3) Abuse of lisdexamfetamine may lead to severe psychological or physical dependence.

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

21 CFR Sec. 1308.12 (d) (5)
Lisdexamfetamine has been classified as a schedule II controlled substance in the federal Controlled Substances Act since June 4, 2007. This regulation change will make Wisconsin regulations consistent with the federal CSA.

Comparison with rules in adjacent states:

Illinois: Not scheduled. Provisions relating to permit authorization application requirements and renewal: Federal registration is required before activity can occur. Illinois grants an "independent activity" license that expires on December 31 of even-numbered years. A registered person who fails to renew before the expiration date of the registration must apply for a new registration. The registration expires on the date specified. Section 3100, Illinois Rules.

Iowa: Schedule II Controlled Substance. House File 2167, Sec. 2. Provisions relating to permit authorization application requirements and renewal: Iowa's regulations identify who must register and include application requirements. A $100 late renewal fee is assessed if there is a failure to remit payment by the first day of the month following expiration. Grounds for revocation, suspension and denial are specified. Section 657, Iowa Administrative Code.

Michigan: Not scheduled. Provisions relating to permit authorization application requirements and renewal: Michigan requires a research license. Rules deal separately with personal training for euthanasia, thefts and diversion, storage, employees and records. Chapter 338, Michigan Rules.

Minnesota: As of March 8, 2010, Minnesota classified lisdexamfetamine as a schedule II controlled substance.

Summary of factual data and analytical methodologies:

The Wisconsin Controlled Substances Board reviewed the federal rule summary and supplemental information for the scheduling of this substance, and agrees with the conclusions therein regarding the potential for abuse.

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

Since there is no anticipated impact on small business from this rule, no additional compliance, bookkeeping, reporting, recordkeeping or professional skills are required.

Section 227.137, Stats, requires an "agency" to prepare an economic impact report before submitting the proposed rule-making order to the Wisconsin Legislative Council. The Department of Regulation and Licensing is not included as an "agency" in this section.

Anticipated costs incurred by private sector:

The department finds that this rule has no significant fiscal effect on the private sector.

Fiscal estimate:

There is no fiscal impact on the department.

Effect on small business:

These proposed rules will not have any significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at hector.colon@wisconsin.gov, or by calling (608) 266-8608.

Agency contact person:

Pamela Haack, Department of Regulation and Licensing, Division of Board Services, 1400 East Washington Avenue, Room 116, P.O. Box 8935, Madison, Wisconsin 53708-8935. Telephone: (608) 266-0495. Email: pamela.haack@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Pamela Haack, Department of Regulation and Licensing, Division of Board Services, 1400 East Washington Avenue, Room 116, P.O. Box 8935, Madison, Wisconsin 53708-8935, or by email at pamela.haack@wisconsin.gov. Comments

must be received on or before October 15, 2010 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.35 is created to read:

CSB 2.35 Addition of lisdexamfetamine to schedule II. (1) Section 961.16 (5) (e) is created to read:

Section 961.16 (5) (e) lisdexamfetamine, commonly known as "Vyvanse TM."

(END OF TEXT OF RULE)
