CR 84-97

CERTIFICATE

RECEIVER

SEP 2 0 1984 Revisor of Statutes Bureau

STATE OF WISCONSIN

) SS

CONTROLLED SUBSTANCES BOARD)

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

12-1-824

I June L. Dahl, Ph.D., Chairman and custodian of the official records of said Board, do hereby certify that the annexed rule, relating to the transfer of Sufentanil from Schedule I to Schedule II of the Uniform Controlled Substances Act was duly approved and adopted by this Board on August 16, 1984.

I further certify that said copy has been compared by me with the original on file in this Board and that the same is a true copy thereof, and of the whole of such original.

> IN TESTIMONY WHEREOF, I have hereunto set my hand at the State Capitol in the city of Madison, this 17th day of September, A.D., 1984.

June L. Dahl, Ph.D., Chairman

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ORDER OF THE CONTROLLED SUBSTANCES BOARD CREATING RULES

Revisor of Statutes Bureau

Relating to rescheduling of sufentanil, a controlled substance, in Chapter 161, the Uniform Controlled Substances Act.

Analysis prepared by the Controlled Substances Board:

According to state law, s. 161.11(4), Stats., if any substance is designated, rescheduled, or deleted as a controlled substance under federal law, the Controlled Substances Board shall take similar action to control the substance, unless it objects.

On May 25, 1984, the Drug Enforcement Administration published a notice (49 FR 22074) transfering sufentanil, a narcotic anesthetic agent, from schedule I to schedule II of the federal controlled substances act (CSA). The DEA took this action following receipt of notice from the Department of Health and Human Services (DHHS) recommending that sufentanil be rescheduled from schedule I to schedule II because a New Drug Application (NDA) for sufentanil has been approved by the Food and Drug Administration. Sufentanil is therefore safe and effective for use in medical treatment in the United States. The factors considered by the Department of Health and Human Services in its scientific and medical evaluation of sufentanil included (49 FR 10274):

- (a) The actual or relative potential for abuse;
- (b) The scientific evidence of its pharmacological effect, if known:

(c) The state of current scientific knowledge regarding the substance;

- (d) The history and current pattern of abuse;
- (e) The scope, duration and significance of abuse;
- (f) The risk to the public health;

(g) The potential of the substance to produce psychic or physical dependence liability; and

(h) Whether the substance is an immediate precursor of a

substance already controlled under this chapter.

Based on the DHHS scientific and medical evaluation, the Drug Enforcement Administration found that:

- 1) Sufentanil has a currently accepted medical use in treatment in the United States.
- 2) Sufentianil has a high pobential for abuse.
- 3) Abuse of sufentanil may lead to severe psychological or physical dependence.

These findings are consistent with placement of sufentanil in schedule II of the CSA.

The Controlled Substances Board has reviewed the Department of Health and Human Services' scientific and medical evaluation and the Drug Enforcement Administration findings. The Controlled Substances Board concurs with and adopts the findings of the Department of Health and Human Services and the Drug Enforcement Administration, and is adopting CSB 2.16 to reschedule sufentanil from schedule I to schedule II of the Wisconsin Uniform Controlled Substances Act.

While the Board has in the past and may in the future exercise authority to require a different level of control over a substance than does the federal government, the Board has no reason to differ with the placement of sufentanil in schedule II of the Uniform Controlled Substances Act at this time.

Therefore, pursuant to the authority vested in the Controlled Substances Board by s. 161.11(4), Stats., the Board hereby creates CSB 2.16, Wis. Adm. Code, as follows:

Chapter CSB 2.16 Transfer of Sufentanil from schedule I to schedule II.

SECTION 1. Section 161.14(2)(xg), Stats., is repealed.

SECTION 2. Section 161.16(3)(y), Stats., is created to read:

(y) Sufentanil

This order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register.

Dated: _____ September 17, 1984

June &. Dahl, Ph.D., Chairman Controlled Substances Board



State of Wisconsin \ DEPARTMENT OF HEALTH AND SOCIAL SERVICES

CONTROLLED SUBSTANCES BOARD - 1 WEST WILSON STREET P.O. BOX 7851 MADISON, WISCONSIN 53707 (608) 266-7586

September 17, 1984

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Revisor of Statutes Bureau

Gary L. Poulson, Assistant Revisor Revisor of Statutes Bureau Wisconsin Administrative Code 411 West, State Capitol Madison, WI 53702

Dear Gary:

On behalf of the Controlled Substances Board, I am submitting the enclosed ORDER OF THE CONTROLLED SUBSTANCES BOARD CREATING RULES (CSB 2.16) for publication in the next Wisconsin Administrative Register.

It is my understanding from our telephone conversation that there is no statutory provision for an effective date coincident with the publication date of the Register, and that the effective date is the first day of the month following publication in the Register, which in this case will be November 1, 1984.

Thank you for your assistance.

Sincerely,

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David E. Joranson Controlled Substances Policy Specialist Staff, Controlled Substances Board Bureau of Community Programs

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