

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

433 Health

RULES REVIEW CHECKLIST

DATE RULES RECEIVED 6/12/78 Temporary Rule _____

Resubmitted and Received _____

DUE DATE 7/1/78

a. Returned to Agency w/o filing w/Secy of State _____
b. Approved 7/3 Date Sent Back to Agency _____

- -

1. Rules as Adopted ✓
2. Rules as Proposed ✓
3. Certificate of Board's Authorizing Resolution, where applicable ✓
4. Order for Hearing ✓
5. Notice of Hearing ✓
   (i) Sufficiency _____
6. Secretary of State's List ✓
7. Certificate of Acquisition of Secretary of State's List ✓
8. Affidavit of Mailing ✓
   (i) At least 30 days prior to hearing ✓
9. Statement of Need and Evidence ✓
10. Hearing Examiner's Report ✓
11. Agency's Findings of Fact ✓
12. Certificate of Board's Resolution Adopting Rules, where applicable ✓
13. Order Adopting ✓ (Needing to file)
14. Report of Chief Hearing Examiner _____
    (i) Finding of No Substantial Change ✓
    (ii) Permission to Incorporate by Reference, where applicable N.A.
15. Certificate of Compliance with Rulemaking Procedures ✓
16. Copy of Notice of Intent to Solicit Outside Opinion, where applicable N.A.
17. Petition by Public, where applicable N.A.

#433

William G. Miller
Special Assistant
Attorney General

July 10, 1978

Lee

- Board of Pharmacy-Proposed Rule Relating to Controlled Substances Pharm 51

cc: Duane Harves

Pursuant to the provisions of Minn. Stat. § 15.0411 to 15.052, the *State Register* publishes notices of hearing on proposed new or amended rules, including the full text of the new or amended rules, including the full text of the new or amended rule proposed for adoption, at least 30 days before the date set for the hearing.

Pursuant to Minn. Stat. § 15.0412, subd. 4, an agency may, with approval of the chief hearing examiner, incorporate by reference into the text of a rule, provisions of federal law, or rule, or other material which are 3000 words or more in length or would require five or more pages of print in the *State Register* and which are conveniently available to interested persons.

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Board of Pharmacy

Proposed Rule Relating to Controlled Substances

Notice of Hearing

Notice is hereby given that a public hearing in the above-entitled matter will be held pursuant to Minn. Stat. § 15.0412, subd. 4 (1976), in the Room 408, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, on April 5, 1978, commencing at 9:30 a.m.

All interested or affected persons will have an opportunity to participate concerning the adoption of the proposed amendments to Minn. Rules Pharm 51. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted by mail to Peter Erickson, Hearing Examiner, at Room 300, 1745 University Avenue, Saint Paul, Minnesota 55104, telephone (612) 296-8113, either before the hearing or within five (5) days after the close of the hearing. All such statements will be entered into and become part of the record. Testimony or other evidence to be submitted for consideration should be pertinent to the matter at hand. For those wishing to submit written statements or exhibits, it is requested that at least three (3) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The conduct of the hearing shall be governed by the rules of the Office of Hearing Examiners.

A copy of the proposed amendments is attached hereto and made a part hereof.

Copies of the proposed amendments are now available and at least one free copy may be obtained by writing to the Minnesota Board of Pharmacy, 717 Delaware Street Southeast, Minneapolis, Minnesota 55414. Additional copies will be available at the door on the date of the hearing.

A Statement of Need explaining the position of the Board of Pharmacy relative to the necessity for the proposed amendments and a Statement of Evidence outlining the testimony and evidence which will be introduced by the Board in support of the proposed amendments will be filed with the hearing Examiner's Office at least twenty-five (25) days prior to the hearing and will be available there for public inspection. The statutory authority of the Board of Pharmacy to promulgate and adopt these rules is contained in Minn. Stat. ch. 151 (1976).

In addition, please be advised that Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five (5) days after he commences lobbying. Lobbying includes attempting to influence rule making by communicating or urging others to communicate with public officials. A lobbyist is generally any individual who spends more than $250 per year for lobbying or any individual who is engaged for pay or authorized to spend money by another individual or association and who spends more than $250 a year or five (5) hours per month at lobbying. The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, Saint Paul, Minnesota 55155, telephone (612) 296-5615.

Minnesota Board of Pharmacy
David E. Holmstrom
Executive Secretary

Rule as ~~Proposed~~ Adopted

Pharm 51 Controlled Substances.

(Introduction and (a) remain unchanged.)

(b) The following items are listed in Schedule II:

((1) through (3) remain unchanged.)

(4) Depressants. Unless specifically expected or unless

listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(aa) Methaqualone	Sopor, Quaalude, Parest
(bb) Amobarbital	Amytal
(cc) Secobarbital	Seconal
(dd) Pentobarbital	Nembutal Tuinal
(ee) Phencyclidine	Sernyl, Sernylar

(c) The following items are listed in Schedule III:

((1) remains unchanged.)

(2) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(aa) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.	
(bb) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.	
(cc) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules:	Butabarbital, Vinbarbital, Delvinal, Talbutal, Lotusate, Pentothal, Brevital.
(dd) Chlorhexadol	
(ee) Glutethimide	Doriden
(ff) Lysergic acid	
(gg) Lysergic acid amide	
(hh) Methyprylon	Noludar
~~(ii) Phencyclidine~~	~~Sernyl, Sernylar~~
(ii) ~~(jj)~~ Sulfondiethylmethane	
(jj) ~~(kk)~~ Sulfonethylmethane	
(kk) ~~(ll)~~ Sulfonmethane	

((3) Through (5) remain unchanged.)

(d) The following items are listed in Schedule IV:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Barbital	Barbitone
(2) Chloral betaine	Beta-Chlor
(3) Chloral hydrate	Noctec, Somnos
(4) Chlordiazepoxide	Librium, Libritabs
(5) Clonazepam	Clonopin
(6) Clorazepate	Tranxene
(7) Diazepam	Valium
(8) Diethylpropion	Tenuate Tepanil
(9) Ethclorvynol	Placidyl
(10) Ethinamate	Valmid
(11) Fenfluramine	Pondamin ~~(Robins)~~
(12) Flurazepam	Dalmane
(13) Lorazepam	
~~(13)~~ (14) Mebutamate	
~~(14)~~ (15) Meprobamate, except when in combination with the following drugs in the following or lower concentrations: conjugated estrogens 0.4 mg tridihexethyl chloride 25 mg pentaerythritol tetranitrate 20 mg	Equanil, Miltown, Equagesic, Equalysen
~~(15)~~ (16) Methohexital	Brevital
~~(16)~~ (17) Methylphenobarbital	Mebaral, Mephobarbital
~~(17)~~ (18) Oxazepam	Serax
~~(18)~~ (19) Paraldehyde	Paral
~~(19)~~ (20) Pemoline	Cylert
(21) Pentazocine	Talwin
~~(20)~~ (22) Petrichloral	Periclor
~~(21)~~ (23) Phenobarbital	Luminal, Phenobarbitone, Eskabarb
~~(22)~~ (24) Phentermine	Wilpo, Fastin, Ionamin
(25) Prazepam	
(26) Propoxyphene	Darvon

(e) The following items are listed in Schedule V:

KEY: PROPOSED RULES SECTION: Underlining indicates additions to pre-existing rule language. ~~Strike outs~~ indicate deletions from pre-existing rule language. If all proposed rules in a set are totally new (i.e. non-amendatory) the entire set is printed in standard type face. RULES SECTION: Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone,

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Not more than 100 milligrams of dihydrocodeine per 100 milliliters ~~or per 100 milliliters~~ or per 100 grams.	
(2) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.	
(3) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.	Lomotil
(4) Not more than 15 milligrams of anhydrous morphine per 100 milliliters or per 100 grams.	Parapectolin, Donnagel P.G.
(5) Loperamide	Imodium

((f) remains unchanged.)

APPROVED AS TO FORM AND LEGALITY

JUL. 10 1978 19____

WARREN SPANNAUS, ATTORNEY GENERAL

BY Lee E. Shelby

SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
JUL 10 1978
Joan Anderson Growe
Secretary of State
12:15 P.M.

ADMIN 1000 (Rev. 1/78)

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

TO : Lee E. Sheehy
Special Assistant
Attorney General
Administration

DATE: June 9, 1978

FROM : William G. Miller
Special Assistant
Attorney General

PHONE: 5500

SUBJECT: In the Matter of the Proposed Adoption of Revised Rules relating to Controlled Substances

Enclosed for your review are the documents regarding the above-referenced rules.

WGM:klf

Enclosure

cc: David Holmstrom

RECEIVED
JUN 12 1978
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments Relating to Controlled Substances

STATEMENT OF FACTS ESTABLISHING REASONABLENESS OF AMENDMENTS.

The Minnesota Board of Pharmacy (herein after "Board") pursuant to Minn. Stat. 15.0412 Subd. 4, 1976, hereby affirmatively presents facts establishing the reasonableness of and justifying the adoption of the above captioned amendments to the Board's rules. The need and statutory authority for the proposed amendments are set forth in the Statement of Need.

All of the proposed amendments are to sections of Pharm 51. The current setup of Pharm 51 was established in 1971 when the state passed its version of a prohibited drug law. In so doing the state was following the lead of the federal government who in 1970 passed the Federal Controlled Substances Act which, among other things, established five schedules for drugs of abuse based on evidence of their abuse potential. Subsequent to this legislative action and pursuant to its requirements Pharm 51 was established.

While a close reading of MS 152 would seem to indicate legislative intent to require public hearings only when the Board's proposals ran contrary to federal activity in classifying drugs of abuse the Board has continually felt that a public hearing should be held for all proposed rescheduling.

The Board specifically proposes the following items:

1. Pencyclidine, as was indicated in the Statement of Need, finds its legitimate use in the field of veterinary medicine. In recent years it has gained considerable notoriety as a street drug under the name PCP or Angel Dust.

The prevailing patterns of street level abuse are by oral ingestion of tablets or capsules, containing the drug in powder form both alone and in combination with other drugs. Reported experiences under the influence of Phencyclidine are mainly nondescript or unpleasant. In low doses the experience usually proceeds in three successive stages: changes in body image, sometimes accompanied by feelings of depersonalization; perceptual distortions, infrequently evidenced as visual or auditory hallucinations; and feelings of apathy or estrangement. Many users have reacted to its use with an acute psychotic episode.

In rescheduling Phencyclidine on a federal level the Drug Enforcement Administration found that:

a) Phencyclidine has a high potential for abuse
b) Phencyclidine has a currently accepted medical use in veterinary treatment in the United States
c) Abuse of Phencyclidine may lead to severe psychological dependence.

In light of all of the above the proposal of the Board to reschedule Phencyclidine on a state level corresponding to the federal action is indeed reasonable.

2. Lorazepam and Prazepam, as is indicated in the Statement of Need, are chemically related to other benzodiazepin tranquilizers. The Drug Enforcement Administration, while dealing with each chemical has apparently reached the conclusion that all benzodiazepin derivatives are subject to potential abuse and as each new chemical becomes available has called for its inclusion within the Controlled Substances Act. Lorazepam and Prozepam were no exceptions. In each case the Federal Agencies found that:

a) Based on information now available, lorazepam and prazepam have low potential for abuse relative to the drugs in the next higher schedule, Schedule III.
b) Lorazepam and Prazepam have currently accepted medical use in treatment in the United States.
c) Abuse of lorazepam and prozepam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in the next higher schedule, Schedule III.

In light of the above the Board's proposal to likewise schedule these substances in Minnesota is reasonable.

3. Propoxyphene, as is indicated in the Statement of Need, is a non-narcotic analgesic. As with Pentozocine, which will be discussed below, Propoxyphene was first proposed for scheduling federally 4-5 years ago - a proposal which the manufacturer successfully delayed. After further study and preparation the proposal was revived by the federal agencies and with the acquiescence of the primary manufacturer the drug was placed in Schedule IV by federal action taken February 7, 1977.

In taking this action the DEA found that:

a) Propoxyphene has a low potential for abuse relative to the drugs currently listed in the next higher schedule, Schedule III.
b) Propoxyphene has a currently accepted medical use in treatment in the United States.
c) Abuse of propoxyphene may lead to limited physical dependence or psychological dependence relative to the drugs or substances currently listed in the next higher schedule, Schedule III.

In light of the above this Board's proposal to place propoxyphene in Schedule IV is quite reasonable.

4. Loperamide is a new drug developed as an antidiarrheal. After study by the Drug Enforcement Administration it was proposed that this drug be placed in Schedule V. The manufacturer did not object to this classification and the proposed scheduling was effectuated by DEA on May 13, 1977.

In light of this action the Board's proposal to likewise place this drug in Schedule V on the state level is entirely reasonable.

5. Pentazocine, like propoxyphene discussed above, was proposed for placement on the controlled substances list some years ago and like propoxyphene the proposal was withdrawn by DEA under pressure by the manufacturer. The federal agency has spent the interim studying pentazocine and is apparently on the verge of again proposing its inclusion in Schedule IV.

A few other states have considered the scheduling of Talwin and it has been placed under controls in three or four states.

Abuse and potential for abuse have been demonstrated on a state level by studies and police reports.

In that there are five schedules of controlled substances within the act that Petazocine could be placed in and in that the Board has chosen to place it in schedule IV based on its abuse potential relative to other drugs on the controlled substances list the Board's proposal is indeed reasonable and justified.

In conclusion, the Board feels that the proposed scheduling or rescheduling of these various drug products is needed, reasonable, justified, and perhaps even required under the provisions of MS 152.

Dated:

STATE OF MINNESOTA

BOARD OF PHARMACY

_____

DAVID E. HOLMSTROM
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments
Relating to Controlled Substances

STATEMENT OF NEED

The above captioned rules are amendments to an existing rule (Pharm 51) of the Minnesota Board of Pharmacy. Revisions to this rule occur periodically due to changes in the Federal Controlled Substances Act.

The need to adopt these proposed changes to the Board's existing rules arises primarily because of certain legislation adopted during the 1971 legislative session, to-wit, Minn. Laws 1971, ch. 937, and because of changes in the Federal Controlled Substances Act and the regulations thereunder that have taken place within the past two years. The proposed rule changes reflect findings on the state and federal level that certain drug entities are potentially subject to abuse and thus deserve more stringent controls over the recordkeeping and security associated with their use. Each of these changes will be explained below.

1. Phencyclidine, distributed under the trade names of Sernyl and Sernylar, is used as an animal tranquilizer. Its sole legitimate use lies within the field of veterinary medicine. Its illegitimate use as PCP or Angel Dust has been implicated as a contributing or causative factor in psychotic episodes resulting in death to the user or others. Phencyclidine has been categorized as a Schedule III drug based on its abuse potential for some time. On January 23, 1978 the Food and Drug Administration and the Drug Enforcement Administration, acting in response to its increased "street" use, rescheduled Phencyclidine placing it in Schedule II on a federal level. In order to maintain uniformity between state and federal law and in order to bring the drug under stricter controls within legitimate channels of distribution rescheduling into Schedule II on a state level is needed.

2. Lorazepam, marketed as Ativan, is chemically related to several other benzodiazepin tranquilizers and hypnotics such as the well known Valium which have been previously placed in Schedule IV on both the state and federal levels. The federal action placing Lorazepam in Schedule IV took place on October 3, 1977. The need for uniformity between state and federal laws, as well as the drug's potential for abuse place it within the penumbra of MS 152.02 thus demonstrating the need for this addition to Pharm 51.

3. Prazepam, marketed as Verstran, also is chemically related to several other benzodiazepin tranquilizers and hypnotics such as the well know Valium which have been previously placed in Schedule IV on both the state and federal levels. The federal action placing Prazepam in Schedule IV took place on December 8, 1976. The need for uniformity between state and federal laws, as well as the drug's potential for abuse, again place this drug within the penumbra of MS 152.02 thus demonstrating the need for this addition to Pharm 51.

4. Propoxyphene, marketed as Darvon and other trade names, is a non-narcotic analgesic that was found to be subject to abuse. This drug was placed into Schedule IV on the federal level on February 11, 1977. Again, as with Lorazepam and Prazepam, the need for uniformity between state and federal law and the abuse of this drug on a state level call for the scheduling of this drug on a state level also.

5. Loperamide, marketed under the trade name of Imodium, was found by the Food and Drug Administration and the Drug Enforcement Administration to have abuse potential and as a result was placed in Schedule V of the CSA and the rules thereunder through action taken on May 13, 1977. Once again there is a need for the state to follow suit.

6. Pentazocine, marketed as Talwin, was proposed for placement under the Controlled Substances Act at the federal level some years ago but through the efforts of the manufacturer of this product the proposal was dropped pending further study. Studies have been conducted at the state level in Minnesota and in various other states with some states taking action to control this substance. While it seems that most of the abuse of this substance arises from among health professionals, the fact that Talwin is often stolen along with narcotics and barbiturates during the course of drug store robberies would indicate that there is a demand for the drug among those that are involved in illicit drug traffic and use. It is the position of the board that there is sufficient evidence of abuse <u>potential</u> and it is only potential that need be demonstrated here as it is at the federal level, to call for the scheduling of Pentazocine.

The Board of Pharmacy proposes these changes to Pharm 51 in response to needs demonstrated by the abuse potential of these drugs, the difficulty in prosecuting by law enforcement agencies under the federal statutes only, and under the requirements and guidelines of MS 152.02 subd. 8.

Dated:

STATE OF MINNESOTA

BOARD OF PHARMACY

_____

DAVID E. HOLMSTROM
Executive Secretary

STATEMENT OF COMPLIANCE WITH

MANUAL OF RULE MAKING PROCEDURES

I, Special Assistant Attorney General William G. Miller, do hereby declare that I have examined the proposed rules relating to Controlled Substances and all related documents and that, based on such examinations and my personal familiarity with the applicable procedures, the Manual of Rule Making Procedures has been followed.

Dated: 6-9, 19 78

William G. Miller
Special Assistant
Attorney General

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments
Relating to Controlled Substances

STATEMENT OF NUMBER OF
PERSONS EXPECTED TO ATTEND
AND LENGTH OF HEARING

The number of persons expected to attend the hearing in the above-captioned matter is 50.

It is estimated that the length of the hearing will be four hours.

Dated: March 10, 1978.

STATE OF MINNESOTA
BOARD OF PHARMACY

DAVID E. HOLMSTROM
Executive Secretary

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
BOARD OF PHARMACY

In the Matter of Proposed Amendments
Relating to Controlled Substances

STATEMENT OF EVIDENCE

The Minnesota Board of Pharmacy (hereinafter "Board") will introduce the following evidence at the hearing in the above-entitled matter scheduled for April 5, 1978, commencing at 9:30 a.m. in the Board Room, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota.

1. Documents attached hereto and made a part hereof evidencing the Board's compliance with procedural requirements for rule making:

(a) Order for Hearing;

(b) Notice of Hearing as mailed;

(c) Affidavit of Receipt of the Secretary of State's list;

(d) Certificate of the Secretary of State;

(e) Affidavit of Mailing of the Notice of Hearing; and

(f) Certificate of Board's Authorizing Resolution.

2. Documents attached hereto and made a part hereof constituting the Board's affirmative presentation of facts establishing the need for and reasonableness of the proposed rule and evidencing the Board's compliance with substantive requirements for rule making;

(a) Statement of Need; and

(b) Statement of Facts Establishing Reasonableness of Rule.

3. The following witness will represent the Board at the hearing:

David Holmstrom, Executive Secretary of the Board.

Said witness will be available to answer questions as they might relate to the Board's affirmative presentation of facts as set forth through the previously listed and attached documents.

4. The Statement of Need attached hereto contains the citations to the Board's statutory authority to promulgate the proposed amendments to the Board's rules.

Dated: March 10, 1978.

STATE OF MINNESOTA
BOARD OF PHARMACY

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Secretary

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Board of Pharmacy

Proposed Rule Relating to Controlled Substances

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Minnesota Board of Pharmacy
David E. Holmstrom
Executive Secretary

Rule as Proposed

Pharm 51 Controlled Substances.

(Introduction and (a) remain unchanged.)

(b) The following items are listed in Schedule II:

((1) through (3) remain unchanged.)

(4) Depressants. Unless specifically expected or unless

listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

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(bb) Amobarbital	Amytal
(cc) Secobarbital	Seconal
(dd) Pentobarbital	Nembutal Tuinal
(ee) Phencyclidine	Sernyl, Sernylar

(c) The following items are listed in Schedule III:

((1) remains unchanged.)

(2) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(aa) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.	
(bb) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.	
(cc) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules:	Butabarbital, Vinbarbital, Delvinal, Talbutal, Lotusate, Pentothal, Brevital.
(dd) Chlorhexadol	
(ee) Glutethimide	Doriden
(ff) Lysergic acid	
(gg) Lysergic acid amide	
(hh) Methyprylon	Noludar
~~(ii) Phencyclidine~~	~~Sernyl, Sernylar~~
(ii) ~~(jj)~~ Sulfondiethylmethane	
(jj) ~~(kk)~~ Sulfonethylmethane	
(kk) ~~(ll)~~ Sulfonmethane	

((3) Through (5) remain unchanged.)

(d) The following items are listed in Schedule IV:

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Barbital	Barbitone
(2) Chloral betaine	Beta-Chlor
(3) Chloral hydrate	Noctec, Somnos
(4) Chlordiazepoxide	Librium, Libritabs
(5) Clonazepam	Clonopin
(6) Clorazepate	Tranxene
(7) Diazepam	Valium
(8) Diethylpropion	Tenuate Tepanil
(9) Ethclorvynol	Placidyl
(10) Ethinamate	Valmid
(11) Fenfluramine	Pondamin ~~(Robins)~~
(12) Flurazepam	Dalmane
(13) Lorazepam	
~~(13)~~ (14) Mebutamate	
~~(14)~~ (15) Meprobamate, except when in combination with the following drugs in the following or lower concentrations: conjugated estrogens 0.4 mg tridihexethyl chloride 25 mg pentaerythritol tetranitrate 20 mg	Equanil, Miltown, Equagesic, Equalysen
~~(15)~~ (16) Methohexital	Brevital
~~(16)~~ (17) Methylphenobarbital	Mebaral, Mephobarbital
~~(17)~~ (18) Oxazepam	Serax
~~(18)~~ (19) Paraldehyde	Paral
~~(19)~~ (20) Pemoline	Cylert
(21) Pentazocine	Talwin
~~(20)~~ (22) Petrichloral	Periclor
~~(21)~~ (23) Phenobarbital	Luminal, Phenobarbitone, Eskabarb
~~(22)~~ (24) Phentermine	Wilpo, Fastin, Ionamin
(25) Prazepam	
(26) Propoxyphene	Darvon

(e) The following items are listed in Schedule V:

KEY: PROPOSED RULES SECTION: Underlining indicates additions to pre-existing rule language. ~~Strike outs~~ indicate deletions from pre-existing rule language. If all proposed rules in a set are totally new (i.e. non-amendatory) the entire set is printed in standard type face. RULES SECTION: Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone,

Statutory Name	Some examples of common names, trade names, or names of products which contain a controlled substance.
(1) Not more than 100 milligrams of dihydrocodeine per 100 milliliters ~~or per 100 milliliters~~ or per 100 grams.	
(2) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.	
(3) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.	Lomotil
(4) Not more than 15 milligrams of anhydrous morphine per 100 milliliters or per 100 grams.	Parapectolin, Donnagel P.G.
(5) Loperamide	Imodium

((f) remains unchanged.)

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments
Relating to Controlled Substances

NOTICE OF HEARING

NOTICE IS HEREBY GIVEN that a public hearing in the above-entitled matter will be held pursuant to Minn. Stat. § 15.0412 subd. 4 (1976), in Room 408, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, on April 5, 1978, commencing at 9:30 a.m.

All interested or affected persons will have an opportunity to participate concerning the adoption of the proposed amendments to Minn. Rules Pharm 51. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted by mail to Peter Erickson, Hearing Examiner, at Room 300, 1745 University Avenue, Saint Paul, Minnesota 55104, telephone (612) 296-8113, either before the hearing or within five (5) days after the close of the hearing. All such statements will be entered into and become part of the record. Testimony or other evidence to be submitted for consideration should be pertinent to the matter at hand. For those wishing to submit written statements or exhibits, it is requested that at least three (3) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The conduct of the hearing shall be governed by the rules of the Office of Hearing Examiners.

The proposed amendments, if adopted, would place on the list of controlled substances the drugs Loperamide (also known as Imodium), Propoxyphene (Darvon), Lorazepam, Pentazocine (Talwin) and Prazepam, all on Schedule IV of that list. The proposed amendments would also remove Phencyclidine (Sernyl, Sernylar) from Schedule III of that list and place it in Schedule II.

Copies of the proposed amendments are now available and at least one free copy may be obtained by writing to the Minnesota State Board of Pharmacy, 717 Delaware Street Southeast, Minneapolis, Minnesota 55414. Additional copies will be available at the door on the date of the hearing.

A Statement of Need explaining the Board of Pharmacy position relative to the necessity for the proposed amendments and a Statement of Evidence outlining the testimony and evidence which will be introduced by the Board in support of the proposed amendments will be filed with the Hearing Examiner's Office at least twenty-five (25) days prior to the hearing and will be available there for public inspection. The statutory authority of the Board of Pharmacy to promulgate and adopt these rules is contained in Minn. Stat. ch. 151 (1976).

In addition, please be advised that Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five (5) days after he commences lobbying. Lobbying includes attempting to influence rule making by communicating or urging others to communicate with public officials. A lobbyist is generally any individual who spends more than $250 per year for lobbying or any individual who is engaged for pay or authorized to spend money by another individual or association and who spends more than $250 a year or five (5) hours per month at lobbying. The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, Saint Paul, Minnesota 55155, telephone (612) 296-5615.

Dated: February 27, 1978.

STATE OF MINNESOTA

BOARD OF PHARMACY

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

In the Matter of the Proposed
~~Rules~~ (Amendments) Relating
to Controlled Substances.

AFFIDAVIT
OF MAILING

Alice D. Hummer, Pharmacy Board, being first duly sworn, deposes and says:

That on the 24th day of February, 1978, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Hearing by depositing in the United States mail at said City of Minneapolis, a true and correct copy thereof, properly enveloped, with postage prepaid, to all persons and associations at the addresses listed on the Certificate of the Secretary of State attached and made a part hereof as Exhibit A, to all persons and associations at the addresses listed on Exhibit B, attached and made a part hereof, as well as to all members of the Minnesota Legislature as of the date of mailing.

Alice D. Hummer

Subscribed and sworn to before
me this 24th day of February, 1978.

Marie B. Tromiczak

MARIE B. TROMICZAK
NOTARY PUBLIC - MINNESOTA
HENNEPIN COUNTY
My Commission Expires Oct. 9, 1980

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments
Relating to Controlled Substances

AFFIDAVIT OF RECEIPT OF THE
SECRETARY OF STATE'S LIST

David E. Holmstrom, being duly sworn upon oath, deposes and says:

1. That he is Executive Secretary of the Minnesota Board of Pharmacy.

2. That on the 14th day of Feb, 1978, he called the Minnesota Secretary of State's office and requested a current list of all representatives of associations or other interested groups or persons who had registered their names with the Secretary of State for the purpose of obtaining notices of public hearings relating to the promulgation of rules or amendments thereto pursuant to Minn. Stat. § 15.0412 subd. 4 (1976).

3. That on the 21st day of Feb, 1978, in response to the above request, the Secretary of State provided him with such a list, a photocopy of which is attached hereto and incorporated by reference.

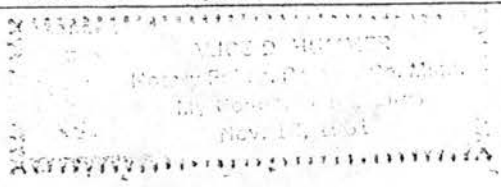
Further affiant sayeth not.

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Secretary

Subscribed and sworn to before me
this 10th day of March, 1978.

Alice D. Hummer



STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Proposed Amendments
Relating to Controlled Substances

ORDER FOR HEARING

To effectively implement the powers and duties of the Minnesota Board of Pharmacy, the Board deems it necessary to consider adoption of proposed Revisions to the rules, a copy of which is attached hereto, marked Exhibit "A" and made a part hereof, pursuant to the authority vested in the said Board by Minnesota Statute 151.06 Subd. 1 (10).

NOW THEREFORE, IT IS ORDERED this 10th day of January 1978, that a public hearing on the proposed rules set forth in said Exhibit "A" be held in Room 408 of the Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota on April 5, 1978, commencing at 9:30 o'clock a.m. and continuing thereafter until all representatives of associations or other interested groups or persons have had an opportunity to be heard.

IT IS FURTHER ORDERED that notice of said hearing be given to all of the current members of the Legislature of the State of Minnesota and to all representatives of associations or other interested groups or persons who have registered their names with the Secretary of State for that purpose.

MINNESOTA BOARD OF PHARMACY

By 

David E. Holmstrom
Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Amendments
Relating to Controlled Substances

CERTIFICATE OF RESOLUTION

I, DAVID E. HOLMSTROM, do hereby certify that I am the Secretary of the Board of Pharmacy, a Board duly authorized under the laws of the State of Minnesota, and that the following is a true, complete and correct copy of a Resolution adopted at a meeting of the Board of Pharmacy duly and properly called and held on the 9th day of January 1978, that a quorum of said Board was present at this meeting, that said Resolution, set forth below, was passed by a majority vote of the members of the Board, and that said Resolution, set forth below, is also set forth in the Minute Book of the Minnesota Board of Pharmacy and has not been rescinded or modified:

January 9, 1978

Among its deliberations the Board discussed the proposed rescheduling of Darvon and Talwin and several other drugs. After this discussion the Board passed the following resolution:

"Resolve, that David E. Holmstrom, Secretary of the Minnesota Board of Pharmacy, be and hereby is granted the authority and is directed to call a hearing for the purpose of promulgating rules of the Board of Pharmacy relating to the rescheduling of several drugs as Controlled Substances as well as perform any and all acts incidental thereto, including, without being limited to, that of signing an order for hearing and notice of hearing as well as completing the documents necessary for securing the appointment of a hearing examiner for the hearing."

David E. Holmstrom

Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Controlled Substances.

FINDINGS OF FACT

The above-entitled matter came on for hearing before the Minnesota State Board of Pharmacy on the 5th day of April, 1978, at 9:30 a.m. in the Minnesota Department of Health Building after proper notice required by M.S. in 1976, Sec. 15.0412 was served upon all persons, associations and other interested groups registered with the Secretary of State for that purpose.

After affording interested persons an opportunity to present written and oral data, statements and arguments, having heard all of the testimony, having considered all of the evidence adduced and upon the records, files and proceedings herein, and upon the report of the Hearing Examiner, the Board does adopt as their own the Findings of Fact Prepared and Presented to the Board by the Hearing Examiner.

MINNESOTA BOARD OF PHARMACY

David C. Holmstrom

Executive Secretary

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed
Adoption of Revised Rules
Relating to Controlled Substances.

CERTIFICATE OF BOARD ADOPTION
OF RULES RESOLUTION.

I, David E. Holmstrom, do hereby certify that I am secretary of the Board of Pharmacy, a board duly authorized under the laws of the state of Minnesota, and that the following is true, complete, and correct copy of a resolution adopted at a meeting of the Board of Pharmacy duly and properly called and held on the 24th day of May, 1978. That a quorum was present at said meeting; that a majority of those present voted for the resolution; that said resolution is set forth in the minutes of said meeting and not been rescinded or modified.

The first item to come before the Board for discussion was the Hearing Examiner's report on the proposed changes in Pharm 51 for which a public hearing had been held on April 5, 1978. After discussing the Hearing Examiner's report Mr. Marc Frederickson moved and Mr. Tom Jones seconded the following resolution:

> "Resolved, that the rules relating to controlled substances identified as Pharm 51 which were considered at a public hearing held on the 5th day of April, 1978, are found to be reasonable, necessary, and supported by the evidence contained in the record, and are hereby approved and adopted pursuant to authority vested in the Board of Pharmacy by MN Stat. 151 and 152 and that David E. Holmstrom, Executive Secretary of the Board, be and hereby is authorized to sign an order adopting those rules.
>
> Be it further resolved that the report of the Hearing Examiner relating to this matter be and hereby is expressly adopted by the Board as its own."

The motion passed unanimously.

David E. Holmstrom
Executive Secretary

Subscribed and sworn to before me
this 9th day of June, 1978.

Alice D. Hummer
Notary Public

Ramsey County, Minnesota
My Commission expires 11-18-81.

ALICE D. HUMMER
Notary Public, Ramsey Co. Minn.
My Commission Expires
Nov. 18, 1981

STATE OF MINNESOTA

COUNTY OF HENNEPIN

MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Adoption of Revised Rules Relating to Controlled Substances.

ORDER ADOPTING RULES

The above-entitled matter came on for hearing before the Minnesota Board of Pharmacy on the 5th day of April, 1978, at 9:30 a.m. in the Minnesota Department of Health Building, Minneapolis, Minnesota, after proper notice required by M.S. 1976, Section 15.0412 was served upon all persons, associations and other interested groups registered with the Secretary of State for that purpose.

After affording interested persons an opportunity to present written and oral data, statements and arguments, having heard all of the testimony, having considered all of the evidence adduced and upon the records, files and proceedings herein, and applicable statutory standards or criteria, and having confirmed the need for the above captioned rules;

NOW, THEREFORE, IT IS ORDERED that these rules identified as Rules of the Minnesota Board of Pharmacy are adopted this 1st day of June, 1978, pursuant to authority vested in me by the Board.

MINNESOTA BOARD OF PHARMACY

David E. Holmes

Executive Secretary

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE MINNESOTA BOARD OF PHARMACY

IN THE MATTER OF THE PROPOSED ADOPTION)
OF REVISED RULES RELATING TO CONTROLLED)
SUBSTANCES.)

REPORT OF THE
CHIEF HEARING EXAMINER

WHEREAS, a hearing was held on April 5, 1978, before Peter Erickson a Hearing Examiner of the State Office of Hearing Examiners, on the above-entitled matter in compliance with Minn. Stat. § 15.0412, Subd. 4; and

WHEREAS, the Report of Hearing Examiner made pursuant to Minn. Stat. § 15.052, Subd. 3, was issued to the Minnesota Board of Pharmacy on April 24, 1978; and

WHEREAS, the Board of Pharmacy has now determined to adopt rules pursuant to Minn. Stat. § 15.0412, Subd. 4; and

WHEREAS, the Board of Pharmacy has submitted said rules to the Chief Hearing Examiner for review pursuant to Minn. Stat. § 15.052, Subd. 4, and Rule HE 107; and

WHEREAS, the Chief Hearing Examiner finds that the final proposed rules are not substantially different from those proposed at the public hearing and that the Board has met all requirements of Minn. Stat. § 15.0412, Subd. 4.

NOW, THEREFORE, upon receipt of this Report, the Minnesota Board of Pharmacy has the responsibility of submitting the complete hearing record and the rules as adopted by the Board to the Attorney General and to publish in the State Register, all pursuant to Minn. Stat. § 15.0412, Subd. 4.

Dated this 12th day of June, 1978.

Duane R. Harves

DUANE R. HARVES
Chief Hearing Examiner

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE MINNESOTA BOARD OF PHARMACY

In the Matter of Proposed
Amendments Relating to
Controlled Substances

REPORT OF HEARING EXAMINER

The above-entitled matter came on for hearing before Hearing Examiner Peter C. Erickson of the State Office of Hearing Examiners at 9:30 a.m. on Wednesday, April 5, 1978 in the Department of Health Building, Minneapolis, Minnesota.

William G. Miller, SAAG, appeared as counsel on behalf of the Board of Pharmacy. David E. Holmstrom, Executive Secretary of the Board, testified in support of the rules on behalf of the Board. The hearing continued until all interested groups or persons had an opportunity to be heard concerning the adoption of the proposed rules.

Pursuant to Minn. Stat. § 15.0412, subd. 4 (1976), this Report shall be available for review to all affected individuals upon request for at least ten days.

The Board of Pharmacy shall, if it proposes to adopt the rules as originally proposed or amended, submit the complete hearing record, including its Findings and Order, to the Chief Hearing Examiner no earlier than ten days subsequent to the receipt of this Report. This submission shall also clearly indicate any changes made to the rules as originally proposed, preferably in the format that will be submitted to the State Register for publication. The Chief Hearing Examiner shall complete his review and submit his report to the Board on the issues of substantial changes in the rule and compliance with Minn. Stat. § 15.0412 within ten calendar days. Thereafter, the Board shall be responsible for filing the rules with the Attorney General.

Based upon all the records and proceedings herein, the Examiner makes the following:

FINDINGS OF FACT

1. On March 10, 1978, the Board filed the following documents with the Chief Hearing Examiner:

(a) A copy of the proposed rules;
(b) A proposed Order for Hearing;
(c) A proposed Notice of Hearing; and
(d) A Statement of the estimated length and number of people attending the hearing.

2. On February 27, 1978, a Notice of Hearing and a copy of the proposed rules were published at 2 State Register 1594.

3. On February 24, 1978, the Board mailed the Notice of Hearing to all persons and associations who had registered their names with the Secretary of State for the purpose of receiving such notice.

4. On March 10, 1978, the Board filed the following documents:

(a) The Order for Hearing;
(b) The Notice of Hearing as mailed;
(c) The Affidavit of Receipt of the Secretary of State's list;
(d) The Affidavit of Mailing;
(e) The Secretary of State's Certificate and list;
(f) The Statement of Need; and
(g) The Statement of Evidence, including the names of witnesses to be called;
(h) The names of Board personnel who will represent the agency.

The documents were available for inspection at the Office of Hearing Examiners from the date of filing to the date of the hearing.

5. The record remained open through April 12, 1978 for the receipt of written comments and statements.

6. Statutory authority to promulgate the proposed rules is contained in Minn. Stat. § 152.02 (1976).

7. The Examiner finds that the need for and reasonableness of the proposed amendments to Pharm 51 was sufficiently demonstrated by the Statement of Need, attached hereto.

8. Hoffman-La Roche, Inc. requested that librax and menrium be given exempted status as was done on the federal level. See 21 C.F.R. 1308.32.

Because Minnesota currently has no exempt status schedule, and no such schedule was proposed by the Board at this time, to initiate an exempt drug schedule as a result of the hearing herein would constitute a substantial change. See Minn. Rule HE 108.

9. Winthrop Laboratories suggested that the effective date for the scheduling of Pentazocine should not be until 30 days following publication of federal action pursuant to Minn. Stat. § 152.02, Subd. 12.

The Examiner points out that the action proposed herein is taken pursuant to Minn. Stat. § 152.02, Subd. 8. No "30 day" requirement is mandated.

Based upon the foregoing Findings of Fact, the Hearing Examiner makes the following:

CONCLUSIONS

1. Due, timely and adequate legal notice of the hearing was properly served and filed by the Board of Pharmacy. All other substantive and procedural requirements of statute or rule have been complied with.

2. Pursuant to Minn. Stat. § 15.052, subd. 3 (1976), it is the duty of the Hearing Examiner to: "...(4) make a report on each proposed agency action...taking notice of the degree to which the agency has (i) documented its statutory authority to take the proposed action, (ii) fulfilled all relevant, substantive and procedural requirements of law or rule, and (iii) demonstrated the need for and reasonableness of its proposed action with an affirmative presentation of facts."

3. The Examiner concludes that the Board has documented its statutory authority to take the proposed action.

4. The Examiner concludes that the Board has demonstrated the need for an reasonableness of the proposed rule amendments with an affirmative presentation of facts.

Based upon the foregoing Conclusions the Hearing Examiner makes the following:

RECOMMENDATION

That the Board of Pharmacy adopt the proposed amendments to Pharm 51.

Dated: April 24, 1978.

Peter C. Erickson

PETER C. ERICKSON
Hearing Examiner