STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Amendment of Rules Concerning Licensure Fees and Controlled Substances

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. section 14.14, subd. 2, and 14.23 and Minn. Rules part 1400.0500 hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendment of Board rules. The statutory authority for these proposed rule changes is contained in Minn. Stat. section 151.06, subd. 1 (9), which authorizes the Board to make and publish uniform rules and regulations to enforce the provisions of the statute, Minn. Stat. section 152.02 subd. 7, 8 and 9, which authorize the Board to schedule and reschedule controlled substances, and laws of Minnesota 1984, Chapter 628, article 2 which authorizes the Board to adjust its fees without a public hearing. Minnesota Rules part 6800.4200 through part 6800.4500 are the Board's current rules on controlled substances. The Board is proposing to amend all of those subparts to provide easier understanding and reading and amend various parts by scheduling, rescheduling, or deleting various substances from the schedules. Most of the proposed changes involving controlled substances are for clarification only and do not change the substance of existing rules.

FEE CHANGES.

The need to adopt these proposed fee change amendments to the Board's existing rules arises out of the necessity that licensure fees be set at a level which, over the biennium, will as nearly as possible, match the appropriation which has been granted the Board by the legislature. This requirement is found in Minn. Stat. section 214.06.

MINN. RULE PART 6800.0400 AND 6800.1000.

The intent of the proposed changes in Minn. Rules 6800.0400 and 6800.1000 is to allow the Board to meet its statutory requirement of adjusting its fees to meet the legislatively authorized expenditures over each biennium. Minn. Stat. section 16A.128 allows agencies to use the non-controversial rules promulgation process and eliminates the public hearing process as long as the amount of fee requested approximates the sum of all direct appropriations, statewide indirect costs, general support costs, transfers in, and salary supplements for each biennium. Attached hereto as Exhibit 1 is the approval of the Commissioner of Finance of the proposed fee increases.

It should be noted that both individual pharmacist license fees, which have been increased only once since 1978, and pharmacy license fees, which have been increased only once since 1977, are being proposed for increase at this time. Even with these increases the fees proposed are in line with those of neighboring states and are, in fact, lower than the corresponding fees found in some neighboring states.

MINN. RULE PART 6800.1100.

While it would appear that two changes are being made to this section the change regarding the examination fee was made in 1982 pursuant to the procedures provided for at that time in Minn. Stat. section 16A.128 and Minn. Stat. section 214.06 subd. 1. The $90 examination fee thus established, however, does not appear in the printed editions of the Board's rules. The examination fee amount is included herein solely for the purpose of providing for its inclusion in the printed versions of the Board's rules.

The other change proposed in this section involves the time for submission of applications to participate in the Board's licensure examination. The Board has found that the 30 day lead time currently included in the Board's rule does not provide sufficient time for Board staff to adequately review the submitted applications and other documents. The additional lead time provided by this change should not involve any substantial inconvenience to the potential applicants in that students at the College of Pharmacy at the University of Minnesota and students from other schools who are completing their required internship in Minnesota receive their applications to sit for the Board exam from the Board office several months, and in some cases up to two or three years, in advance of the examination date.

CONTROLLED SUBSTANCES.

The need to adopt these proposed changes to the Board's existing rules relating to controlled substances arises primarily because of the

difficulty in reading the existing rule the way it is set up and because of changes in the Federal Controlled Substances Act and the regulations thereunder that have taken place over the past few years. The proposed scheduling 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. In one instance a drug which had no previously legitimate known medical use was found to have legitimate uses in the practice of medicine and is being rescheduled accordingly. In one other instance a drug previously thought to show abuse potential was found not to have the abuse potential originally thought and is thus being removed from control.

MINN. RULE PART 6800.4210 SCHEDULE I CONTROLLED SUBSTANCES.

Schedule I controlled substances are those substances found to have a very high potential for abuse and which, at the same time, have no legitimate use in medical practice.

Items listed as A (2) and (7) are new additions to the list of Schedule I substances which will bring state law into conformity with federal law in this area. In placing Alfentanil and Alpha-methylfentanyl in Schedule I the Federal Drug Enforcement Administration found that they had a high potential for abuse, they did not currently have accepted medical use in treatment in the United States and that there is a lack of accepted safety in their use even under medical supervision.

In the cases of items A (16) and A (20) the change is simply one of correcting a previous misspelling.

The final change in section A of part 6800.4210 is the transferring of the drug Sufentanil from Schedule I into Schedule II. As previously indicated, Schedule I substances are those substances that do not have a recognized medical use in the United States. Until recently this was the case for Sufentanil. A medical usefulness of the drug has now been established and the drug has been reclassified into Schedule II on the Federal level. The drug is being marketed under the trade name Sufenta by Janssen Pharmaceutica for use in managing patients under anesthesia. The drug is said to provide a more comfortable recovery following surgery for patients who have had this drug administered to them.

The Board has been contacted both by hospitals in the Twin Cities metropolitan area and by hospitals associated with the Mayo Clinic in Rochester urging rapid rescheduling of this product so that hospital use could begin.

In section B, item 10 involves a new substance being added to the list of Schedule I substances on the state level. Again this simply brings the State Controlled Substances Act into conformity with the Federal Act. The changes in items B (11) and B (15) are included simply for clarification purposes.

In section C, item 7 is a new item being added to the controlled substances list at the state level. In discussing this item at the federal level it was indicated that the World Health Organization is recommending control of this substance on a world wide level in that the substance is a hallucinatory substance that produces behavior effects similar to those

produced by LSD although some affects appear to be amphetamine like. The substance has a very high potential for abuse and does not have an accepted medical use in treatment in the United States.

Item C (16) is also a change designed to bring state law into conformity with the federal law. Parahexyl has a high potential for abuse and does not have a recognized medical use in treatment in the United States.

The remaining changes in section C represent restructuring of the layout of the entire rule rather than new items being added to the schedules or items being deleted from the schedules.

The change in section E, the placing of Methaqualone in Schedule I brings state statutes into conformity with federal. On June 29, 1984, President Reagan signed PL 98.329 which placed Methaqualone into Schedule I of the Federal Controlled Substances Act effective September 26, 1984. This law follow the November 14, 1983 announcement by Lemmon Company, the nations sole manufacturer of Methaqualone, that it is discontinuing production of the drug.

MINN. RULE PART 6800.4220 SCHEDULE II CONTROLLED SUBSTANCES.

Most of the changes in this part represent a rewriting and restructuring of the various sections and subparts to make them easier to read and to better provide uniformity with the Federal Act.

Items B (1) (g) and E (e), which was discused previously, is being deleted in conformity with deletions in the Federal Act. Items B (1) (i) and C (24) are being added in conformity with Federal changes. Item B(1)

(i) has been a Schedule II controlled substance on the federal level for some time and it was simply through oversight that it was not included previously in the state schedules. Item C (24), Sufentanil, has been discussed previously. All of the remaining changes in part 6800.4220 are simply rewrites and clarification making the sections easier to read and placing them in closer conformity to the layout of the Federal Act.

The importance of laying out the State Controlled Substances Act in a manner identical to or nearly identical to that of the Federal Act comes into play during rescheduling activities at the Federal level. It is much easier to accomodate similar scheduling changes at the state level if the item being changed at the federal level can be "plugged in" to the same spot at the state level.

MINN. RULE PART 6800.4230 SCHEDULE III CONTROLLED SUBSTANCES.

All of the changes in this part are of a clarification and categorization nature only. No new substances are being added to Schedule III and no existing substances are being deleted from Schedule III.

MINN. RULE PART 6800.4240 SCHEUDLE IV CONTROLLED SUBSTANCES.

In this section the changes represent not only clarification and categorization of the substances listed but also the addition of a number of substances in conformity with changes being made at the federal level.

In the Federal Register of Wednesday, August 1, 1984 the Drug Enforcement Administration announced its intention to place twenty-one different Benzodiazapine substances in Schedule IV of the Controlled Substances Act. This action is required in order for the United States to

discharge its obligations under the Convention on Psychotropic Substances, 1971. On March 29, 1984 the Secretary General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs has decided that thirty-three Benzodiazapines be added to Schedule IV of the 1971 Convention on Psychotropic Substances. Of the thirty-three Benzodiazapines twelve have already been controlled in Schedule IV.

By a letter dated May 1, 1984 the Assistant Secretary for Health, on behalf of the Secretary of the Department of Health and Human Services, recommended to the Administrator of DEA that the remaining twenty-one Benzodiazapines also be controlled in the Controlled Substances Act Schedule IV. The changes being proposed here in section C accomplish the rescheduling of these same substances at the state level. All of the other changes in 6800.4240 are of a clarification and categorization nature.

MINN. RULE PART 6800.4250 SCHEDULE V CONTROLLED SUBSTANCES.

The only substantive change proposed by the Board in this part involves the drug Loperamide.

When the drug Loperamide, commonly known as Imodium, first came on the market the Federal Drug Enforcement Administration and the Food and Drug Administration placed the drug in the category of Schedule V controlled substance at the federal level. Likewise, the Board placed Loperamide in Schedule V at the state level.

Subsequent to its marketing, additional studies were completed which demonstrated that the drug does not have the abuse potential that was

originally ascribed to it. As a result of that finding the Drug Enforcement Administration deleted Loperamide from its list of controlled substances. The Board is now proposing to do likewise.

SMALL BUSINESS IMPACT.

Whenever an agency proposes a new rule or seeks to amend an existing rule, Minn. Stat. section 14.115 requires the agency to consider whether the rule changes will have an impact on small businesses. If the agency determines that they will, the agency must consider whether certain methods, set forth in subd. 2 of the statute, could be adopted to reduce the impact of the rule changes on small businesses. The statute requires the agency to document in its Statement of Need and Reasonableness how it considered these methods and the feasibility of adopting any of the specified methods.

In addition to the licensure of pharmacists, the Board licenses pharmacies, drug manufacturers, and drug wholesalers. The Board has reviewed the impact, if any, its proposed rule changes would have on such businesses. The increase in license fees does not, at this time, affect drug wholesalers or drug manufacturers at all and the effect on licensed pharmacies is insignificant.

The effect of the rescheduling of the various controlled substances at the state level is also negligible. All pharmacies, drug wholesalers and drug manufacturers licensed by the Board are already required to comply with whatever standards are adopted at the federal level. Changing state law to conform with the federal law will not have any additional impact on the Board's licensees.

Minn. Stat. section 14.115, subd. 2 enumerates the following five methods an agency must consider to reduce the impact of the rules on small businesses:

(a) The establishment of less stringent compliance or reporting requirements for small businesses;

(b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

(c) The consolidation or simplification of compliance or reporting requirements for small businesses;

(d) The establishment or performance standards for small businesses to replace design or operational standards required in the rule; and

(e) The exemption of small businesses from any or all requirements of the rule.

The Board's proposed rule changes do not contain any reporting requirements, deadlines for compliance or performance standards. Therefore parts (a) to (d) are not applicable to the Board's proposed rules. The Board finds it impossible to exempt small businesses from either the fee increase or from the changes in the controlled substance rules. To exempt small businesses from the fee increase would amount to not being able to implement the fee increase at all. To exempt small businesses from the effect of the Controlled Substances Act would serve no logical purpose in that small businesses are already subject to the Act from the federal level.