STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the matter of a proposed rule amendment relating to controlled substances

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. section 14.22 and 14.23 and Minn. rules part 1400.0500, hereby affirmatively presents the needs for and facts establishing the reasonableness of the above captioned proposed amendment to portions of the Board's rules. The statutory authority for these proposed rule changes is contained in Minn. Stat. section 151.06 subdivision 1 (9) and in Minn. Stat. section 152.02 subdivisions 7 and 8, which authorize the Board to make and publish uniform rules and regulations relating to controlled substances. The Board is proposing to amend these rules in order to bring state controlled substance schedules once again into conformity with the federal schedules. Part of the rescheduling involves the placement of a specific dosage form of THC, the active ingredient in marijuana, in Schedule II. This change is perhaps the most noteworthy of the various reschedulings being proposed by the Board.

Dronabinol, as this marijuana derivative is called, has, in the past few years, been found to be effective in treating nausea associated with cancer chemotherapy in patients who have been unable to control the nausea

with previously available drug entities. Until the past few months this drug was available only for research purposes and was available only through the National Institute on Drug Abuse. Once its usefullness in treating the nausea associated with cancer chemotherapy had been established a major drug company began producing the product and the federal government rescheduled Dronabinol in sesame oil and incapsulated in a soft gelatin capsule from Schedule I to Schedule II at the federal level. The Board is proposing, herein, to do likewise at the state level so that this product can be used in Minnesota by oncology specialists for their cancer patients.

The Board is proposing, in Minn. Rule 6800.4210, to place in Schedule I of the State Controlled Substances Act those "designer drugs" that have been placed in Schedule I at the Federal level by the Drug Enforcement Administration. These drugs are found to have no recognized legitimate medical use in the United States and have been shown to exhibit a high potential for abuse relative to other drug products. Thus these products are being proposed for scheduling in Schedule I.

In Minn. Rule 6800.4220 the Board is proposing the rescheduling of Dronabinol, as previously discussed, in its limited dosage form into Schedule II. Schedule II substances are those which do have the recognized medical use in the United States but which exhibit a high potential for abuse. The Board has found, based on the available literature, that:

1. Dronabinol (synthetic) in sesame oil and incapsulated in soft gelatin capsules in a US Food and Drug Administration approved drug product has a high potential for abuse;

2. Dronabinol (synthetic) in sesame oil and incapsulated in soft gelatin capsules in a US Food and Drug Administration approved drug product has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and

3. Dronabinol (synthetic) in sesame oil and incapsulated in soft gelatin capsules in a US Food and Drug Administration approved drug product may lead to severe psychological or physical dependence.

The above findings are consistant with placement of Dronabinol approved drug products into Schedule II of the Controlled Substances Act.

Minn. Rule 6800.4240 addresses the placement of Midazolam and Quazepam into Schedule IV of the Controlled Substances Act. This too corresponds to changes in the Federal Act. A final rule placing Midazolam and Quazepam into Schedule IV of the Federal Controlled Substances Act was published in the Federal Register on March 25, 1986.

The placement of Quazepam and Midazolam into Schedule IV is based on information now available that each has a low potential for abuse relative to the drugs or other substances listed in Schedule III; each has a currently accepted medical use in treatment in the United States; and abuse of either Quazepam or Midazolam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

The information above is consistant with the placement of Midazolam and Quazepam into Schedule IV of the Controlled Substances Act.

In Minn. Rule 6800.4250 the Board is proposing to add to Schedule V of the State Controlled Substances Act Buprenorphine. Current information

indicates that Buprenorphine does have a recognized medical use in the United States and has a low potential for abuse as compared with the substances listed in Schedule IV of the Controlled Substances Act thus its placement in Schedule V is appropriate.

The Board is also proposing a couple of minor changes in Schedule V that will once again bring state scheduling of controlled substances in this area conformity with the federal act.

It has been determined that Minn. Stat. section 14.11 does not apply to this proposed rule, therefore the Statement of Need and Reasonableness does not address the topic referenced in that statute.

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 change will have an impact on small businesses. If the agency determines that they will, the agency must consider whether certain methods, set forth in subdivision 2 of this 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 feasiability of adopting any of the specific 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. Since virtually all of the Board's licensees qualify under the statutes as "small business" everything the Board does impacts on "small business".

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

A. The establishment of less stringent compliance in 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. Exemption of small businesses from any or all requirements.

Parts B, C, and D of subdivision 2 are not applicable to the Board's Controlled Substance Rule since they relate to reporting requirements or performance standards which are not involved here. The Board is unable to establish a less stringent compliance requirement for a small business and is unable to exempt small businesses from any or all of the requirements in that the Federal government has already completed the rescheduling of the Substances now being proposed for rescheduling at the state level by the Board. All pharmacies, wholesalers and manufacturers in the state are already required to conform to the scheduling of these products under the Federal law therefore exemption under state law would not reduce or eliminate any requirements they might have under this rule.