STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Relating to the Registration of Distributors of Legend Medical Gases and Distributors of Veterinary Drugs and Devices

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. sections 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 rules. The statutory authority for these proposed rules is contained in Minn. Stat. section 151.19, subdivision 3 (1988), which requires the Board to provide for the annual registration of every person or establishment not licensed as a pharmacy or practitioner engaged in the retail sale or distribution of federally restricted medical gases or of veterinary drugs or devices, Minn. Stat. 214.06, which requires the Board to adjust fees so that the total fees collected "....will as closely as possible equal anticipated expenditures during the fiscal biennium" and Minn. Stat. section 151.06, subdivision 1 (9), which authorizes the Board to make and publish uniform rules and regulations to enforce the provisions of the statute.

The rules captioned above are being adopted according to the procedures set forth in Minn. Stat. section 16A.128. A copy of the approval of the Commissioner of Finance relative to the proposed fees is incorporated herein.

The legislature, in the 1988 session, recognized the fact that certain gaseous substances have a recognized use in medical practice and are restricted in their application by the Federal Food and Drug Administration to use only upon the receipt of a prescription from a licensed practitioner. Similarly, the legislature recognized that certain veterinary drugs and devices are also being distributed in this state and are likewise restricted, in the case of veterinary devices, to the order of a licensed veterinarian. In the case of veterinary drugs, the legislature recognized that the unregulated distribution of veterinary drugs poses a potential health risk to the population of the state and recognized that at the federal level veterinary drug distribution is divided into two categories just as the distribution of human use drugs are. Namely, drugs requiring the prescription of a licensed veterinarian and drugs available over the counter without such a prescription. In the case of veterinary drugs, however, evidence has shown that the extra-label use of OTC veterinary drugs poses a potential health risk when used in food producing animals. Studies done by the Food and Drug Administration and other state and federal agencies have shown that inappropriate or extra-label use of OTC veterinary drugs may result in drug residues occurring in the food chain. These drug residues, when consumed by humans, pose significant health risks.

In view of the restrictions on distribution of legend medical gases and veterinary devices and in view of the potential health risks associated with unregulated distribution of veterinary drugs the legislature determined that the state should have a record of who is involved in the

distribution of all of these items and should establish standards for the recordkeeping involved in the distribution of legend gases and veterinary devices.

To that end, the legislature has directed the Board of Pharmacy to license distributors of these products and to establish rules relating to the recordkeeping associated with the distributions.

Because of the similarities involved in the distribution of these products compared to the distribution of drugs for human use the Board has established similar recordkeeping requirements. The registration and recordkeeping requirements associated with the distribution of legend medical gases are virtually identical to those required for the distribution of legend drugs. In both cases, the Food and Drug Administration has determined that these drugs are not safe for use without the supervision of a licensed practitioner and in both cases have required that the products contain a warning from the manufacturer to the effect that "Federal law prohibits dispensing without prescription". Since the restrictions on distribution are identical at the federal level the Board has established a registration and recordkeeping system at the state level that is also similar.

In the case of OTC veterinary drugs the Board did not propose any recordkeeping requirements. Since OTC veterinary drugs are not restricted to the order of a licensed veterinarian at the federal level the Board has not required recordkeeping at the state level. It appears sufficient, at this time, to simply establish a registration of who the individuals are that are distributing veterinary drugs so that inspections of their

facilities can be undertaken, any unauthorized sales of veterinary prescription drugs by OTC distributors can be detected, and issues surrounding extra label use of OTC drugs can be discussed.

Based on the Board's experience with licensing and inspecting pharmacies, drug wholesalers, and drug manufacturers a fee of $50 for the registration of distributors of legend medical gases and veterinary drugs and devices seems appropriate. Once the licensure and inspections begin, additional information can be obtained as to costs of this licensure program and the fee can be adjusted accordingly.

General Board expenses associated with the operation of the Board are paid through appropriations from the legislature. During each biennium, the Board is required to establish its fees in such a manner that the revenues received from licensing fees will, as closely as possible, approximate the appropriations granted the Board by the legislature. Based on an anticipated six hundred new licensees the new fee will ultimately generate additional fees to the Board of $30,000.

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 exiting rule, Minn. Stat. section 14.115 requires the agency to consider whether the rules 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 the statute, could be adopted to reduce the impact of the rule on small businesses. The statute requires

the agency to document in its Statement of Need and Reasonableness how it considers these methods and the feasibility of adopting any of the specific methods.

In addition to the licensure of distributors of medical gases and distributors of veterinary drugs and devices the Board licenses pharmacists, pharmacies, drug manufacturers and drug wholesalers. The Board has reviewed the impact, if any, its rule will have on these existing as well as the potential new licensees. It is anticipated that the new licensees, the distributors of medical gases and veterinary drugs and devices, like virtually all of the other Board licensees, qualify under the statutes as "small business" therefore, virtually everything that the Board does impacts on "small business".

In Statute 14.115, subdivision 2, enumerates the following five methods an agency must consider the reduce the impact of the rules on small business:

(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 business;

(d) the establishment of 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 of the requirements.

The provisions in the proposed rules relating to licensure fees and recordkeeping requirements do impact on small business but the recordkeeping requirements and proposed fees are in line with that established over many years for pharmacies, drug wholesalers and drug manufacturers and have not shown themselves to be problematical in relation to those licensees. Therefore, these requirements will not adversely affect small business.

Since virtually all of the new licensees will qualify as small business it is impossible for the Board to establish less stringent compliance or reporting requirements, less stringent schedules or deadlines or less stringent performance standards for small business. Similarly, it is not possible to exempt small business from these requirements.

In summary, the Board believes it's proposed fee is needed and reasonable in order to meet the statutory requirement of balancing income and expenditures and believes that it's recordkeeping requirements associated with the distribution of legend medical gases and veterinary devices is both needed and reasonable in view of the similarities with recordkeeping requirements already in place for distributors of human use drugs and in view of the restrictions and requirements associated with these distributions at the federal level.

Attached is a copy of the approval of the fee increase from the Department of Finance.

David Kotmeyer

EXECUTIVE DIRECTOR