9/16/91

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the matter of proposed rule amendments relating to the licensing of drug manufacturers and wholesale distributors.

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. sections 14.22 to 14.28 and Minn. rules part 1400.0500, hereby affirmatively presents the needs for and facts establishing the reasonableness of the above captioned proposed amendments and additions 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 (c). The Board is proposing to make these amendments and additions to its rules in order to comply with federal requirements of the Prescription Drug Marketing Act of 1987, the rules of the Food and Drug Administration as published in 21 CFR Part 205, the Wholesale Drug Distribution Licensing Act of 1990 found in Minn. Stat. 151.42 et. seq.

In 1987, the United States Congress, reacting to problems of diversion of prescription drugs from the legitimate channels of distribution, amended the Federal Food, Drug and Cosmetic Act by passing what is known as the Prescription Drug Marketing Act of 1987. Among other things, this Act required each state to establish a system for the licensing of drug manufacturers and wholesale drug distributors doing business in that state. The Prescription Drug Marketing Act (PDMA) also called on the Food and Drug Administration (FDA) to establish regulations outlining the criteria that states must follow in establishing their licensing systems. The PDMA

provided that any state, which does not implement a licensing system in conformity with FDA's guidelines within two years of the publication of FDA's guidelines, will forfeit the right of any drug manufacturing or wholesaling firms in that state to do business in interstate commerce. As a result, all states are in the process of devising or revising a licensure system for drug wholesalers and manufacturers that will comply with the federal mandates.

Toward that end, the Minnesota Wholesale Druggists Association and the Minnesota Board of Pharmacy were successful in modifying the existing licensure system for drug wholesalers and manufacturers during the 1990 legislative session in order to bring the licensing statutes into comformity with the mandates of the PDMA and the FDA's regulations. The rules being proposed, herein, serve to implement the statutory provisions of the "Wholesale Drug Distribution Licensing Act of 1990", as the legislation is called.

Much of the language of these proposed rules comes directly from the FDA regulations, which set forth the criteria that states must consider in their licensing provisions.

The Board is proposing, as an amendment to Minn. Rule 6800.1400, a multi-level categorization of licenses for drug wholesalers and drug manufacturers based on the type of drug involved in their operation. Instead of the flat fee of $100 that had been in effect for drug wholesalers and drug manufacturers for many years, the Board is proposing a fee structure that differentiates between manufacturers and wholesale distributors of different classes of drugs. The differentiation is defendable in that the recordkeeping, security, and technical requirements of Board inspections are different for each of the various classifications.

Manufacturers and wholesalers of prescription drug items require more comprehensive Board inspections in order to assure compliance with state and federal guidelines. Thus, for manufacturers and wholesale distributors of prescription drug products, the fee is proposed at $150.

At the other end of the spectrum, is a pharmacy, which is already licensed by the Board, and which may from time to time engage in wholesale drug distribution on a limited scale. In that inspection visits are already made to pharmacies in order to acertain compliance with other areas of the Board rules, the additional inspection duties, as a result of their wholesale distributions, are comparatively minimal. Thus, a fee of $75 is proposed for those pharmacies engaged in wholesale distribution.

The fee for manufacturers and wholesale distributors of both prescription and non-prescription drugs is set at $150. The fee for the manufacturers and wholesale distributors of veterinary drugs or non-prescription drugs only is set at $125. The fee for manufacturers or wholesale distributors of prescription medical gases is set at $100, which is the same fee as is presently in place for these medical gas distributors.

Subpart 2 of 6800.1400 is included in this proposal to address a potential problem relating to inspections of licensed manufacturers and distributors. In other states, problems have arisen when the Board has licensed a portion of an individual's home as a drug manufacturing outlet or as a drug wholesaler. Since the United States Constitution prohibits searches of an individual's home without a search warrant, cases have arisen where a manufacturer or wholesaler, operating out of the basement of a private residence, refused entry by Board of Pharmacy inspectors on the basis of their 4th Amendment rights. While it is clear, through a long

series of court decisions, that state licensing agencies are not required to obtain search warrants to conduct routine inspection visits of facilities they license, the constitutional safeguards regarding search and seizure in one's home, cloud the issue. In order to avoid legal entanglements of this type, the Board is proposing that no license will be issued to any drug manufacturer or wholesale drug distributor whose intended place of business is a personal residence.

Subpart 3 of 6800.1400 requires separate licensure for each separate location where drugs are stored within the state and requires the licensure of out-of-state wholesale drug distributors who are shipping drugs into Minnesota. Minn. Stat. 151.47, subd. 1 (c), grants the Board the authority to require separate licenses for each separate location. Minn. Stat. 151.48 requires the licensure of out-of-state wholesaler drug distributors. By requiring the separate licensure for each separate location within Minnesota where drugs are stored, the Board can inspect each location to assure compliance with security, sanitation, and recordkeeping standards developed by the Board in conformity with FDA requirements.

Requiring the licensure of wholesale drug distributors from outside of Minnesota, who are shipping drugs into this state, allows the Board to identify those manufacturers and wholesalers who are providing drugs to the legitimate channels of distribution within Minnesota and allows the Board to work cooperatively with the Board of Pharmacy in the state in which the wholesale drug distributor is located, to assure compliance with at least the minimal uniform standards established by FDA and enforced in the other state.

Minnesota Rule 6800.1410 addresses minimum information required for licensure. This language is taken directly from the requirements developed by FDA in 21 CFR section 205.5. This information will be incorporated into the application for licensure developed by the Board.

The minimum information required for licensure is designed to identify accurately the location of, and individuals associated with, each wholesale drug distributor. Receipt of this information will allow the Board to conduct its routine inspection visits and identify those individuals who have an ownership interest in, and bear responsibility for, the operation of the wholesale drug distributor. All of this allows the Board to better control the distribution of drugs within the state and prevent drug diversion which could jeopardize the health and safety of Minnesota residents.

Proposed rule 6800.1420 lists the circumstances under which the Board may act to deny, suspend, revoke, or refuse to renew any license of a wholesale drug distributor. This listing directly reflects the requirements found in 21 CFR 305.6, wherein the Food and Drug Administration states that, "The state's licensing authority shall consider, at a minimum, the following factors in reviewing the qualifications of persons to engage in wholesale distribution of prescription drugs within the state: ...."

Licensing Boards, by their very nature, exercise a good deal of discretion in determining when, and under what circumstances, licenses and registrations issued by the Board may be denied, suspended, or revoked. An example here might be illustrative. While FDA requires that the licensing board consider, "... any felony convictions of the applicant under federal, state, or local laws ...." when reviewing the qualifications for licensure,

there is a substantial body of case law that indicates that the use of felony convictions as grounds for denial of licensure is appropriate only when the felony conviction somehow relates to the license involved. In other words, a conviction of a violation of hunting or fishing laws, for instance, has no relationship to ones ability to properly conduct a drug manufacturing business and, thus, should not stand as a deterrent to licensure. Even a felony conviction, which is in some way related to the license, may not necessarily be of a type which would logically result in denial of licensure. An individual involved in the ownership of a drug manufacturing company might very well have a twenty-year old conviction for the use of marijuana on his record. Assuming the individual's record has been clean since that conviction, the Board should be granted enough discretion to allow licensure inspite of the drug related conviction.

Licensing boards were established as agencies composed, primarily, of representatives of the profession being regulated in order to properly make these judgements.

Proposed rule 6800.1430 addresses qualifications of personnel. In mandating the state licensing authority to require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibilities relating to compliance issues, the FDA is attempting to assure that at least one individual at each wholesale drug distributor becomes familiar with the laws relating to drug distribution and licensure. To meet FDA's requirements in this regard, the Board is proposing that each wholesale drug distributor establish training programs which, when combined with the education and experience of the personnel employed by the wholesale drug distributor, will enable the personnel to assume responsibility for compliance.

In proposed rule 6800.1440, the Board establishes minimum requirements for the storing and handling of drugs and for the establishment and maintanence of drug distribution records. Here again, the Board takes the language directly from the FDA requirements for the establishment of such standards by state licensing authorities. All of the requirements in subparts three through twelve, of this rule, relate to the security, quality control, and recordkeeping requirements for legitimate drug distribution. As was indicated earlier, the Prescription Drug Marketing Act of 1987 was designed, in its entirety, to prohibit drugs from becoming adulterated or misbranded while in interstate commerce and to attempt to put an end to the diversion of drugs from legitimate channels of distribution. Through the establishment of mimimum standards for the various subparts of Minn. rule 6800.1440, the Board is proposing to address these very issues.

Again, the language in these subparts comes directly from the FDA requirements for state licensing agencies.

In summary, these rules are needed to meet, not only the implementation of the Wholesale Drug Distribution Licensing Act of 1990, but also the federal mandates of the Prescription Drug Marketing Act of 1987. The Board's proposals, in this regard, are quite reasonable in that the language generally is taken directly from the federal rules which detail the minimum requirements for state licensing agency regulation of this field.

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 the rule changes will, the agency must consider whether

certain methods, set forth in subdivison 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 feasibility of adopting any of the specific methods.

The Board of Pharmacy currently licenses, and has licensed for over 25 years, pharmacies, drug manufacturers, and drug wholesalers, the business entities affected by the present rule change. The Board has reviewed the impact, if any, its proposed rule changes would have on such businesses.

Minn. Stat. section 14.115, subdivision 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 and 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 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 requirements.

While approximately ten percent of the wholesaler drug distributors licensed by the Board meet the definition of "small business", the Board is unable to establish a less stringent requirement for a small business and is unable to exempt small business from any or all of the requirements of these rules in that the federal government has mandated minimum

requirements that all states must comply with insofar as the licensing of wholesale drug distributors is concerned. In that the proposed rules generally do not exceed the federally mandated minimums, the Board is unable to further accommodate small businesses.

The adoption of these rules will not result in the expenditure of public monies by local public bodies spending in excess of $100,000 in either of the first two years following the rule's adoption, nor affect agriculture land.

The fees associated with this rule have been submitted to and approved by the Department of Finance. Attached is a copy of the approval of the restructuring of the licensing fees for wholesale drug distributors from the Department of Finance.

As required by Minnesota Statutes, section 16A.128, subdivision 2a, a copy of this Notice and the proposed rules have been submitted to the Chairs of the House Appropriations Committee and Senate Finance Committee prior to publication of this Notice.

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Executive Director
Minnesota Board of Pharmacy