

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

mjm

RULE REVIEW CHECKLIST

File No. 1889
DATE RECEIVED 1-9-92
REVIEW DATE 1-17-92
DUE DATE 1-23-92
~~DISAPPROVED~~ APPROVED 1-23-92
WITHDRAWN

Docket No. 05 0009 0484
ADOPTED W/O HEARING
EMERGENCY RULE
TO REVISOR ON 1-15-92
REVISOR (DISAPPROVED) 1-16-92
FILED W/SEC. OF STATE 1-24-92
RETURNED TO AGENCY 1-24-92

✓ Rule as adopted (4 copies)

Notice to Solicit Outside Information/Opinion (if applicable)
- Date published in State Register
- Comments

Petition for Adoption of a Rule

✓ Board's Authorizing Resolution
January 24, 1991 Date adopted - affadavit Dec. 1991

✓ Proposed Rule
- ✓ Revisor's Certificate

✓ Notice of Intent to Adopt Rule
- 214.06 subd 1A Statutory Authority
- Small Business Statement
- Expenditure of public money statement
- August 15, 1989 Signature - notice was signed prior to resolution

✓ Statement of Need and Reasonableness (if applicable)
- Small Business Statement
- Fees - § 16A.128

✓ Affidavit of Mailing Notice of Intent to Adopt Rule
- September 11, 1991 Dated (30)/25 days before adoption
- Notice attached / indicates it is attached
- Copy of rule or summary attached

✓ Publication in State Register
Sept 16, 1991 Date (30)/25 days before adoption

✓ 180-day deadline from:
- ✓ Effective date of law requiring rule (14.12) (both rules) amendments don't apply
- ✓ end of ~~comment period (§ 14.26)~~ (rules without hearing)
- effective date of statutory authority (§ 14.29) (emergency rules)

✓ Resolution Adopting
Dec. 10, 1991 Date adopted

✓ Findings of Fact, Conclusions & Order Adopting
December 10, 1991 Date

✓ Written Requests, Submissions or Comments

✓ Declaration of Attorney
Bob Holly Name of SAAG representing agency

Notice of Submission to Attorney General (if applicable)

Affidavit of Mailing Notice to Attorney General (if applicable)

DEPARTMENT: Office of the Attorney General **STATE OF MINNESOTA**

OFFICE MEMORANDUM

DATE: January 24, 1992

TO: DAVID E. HOLMSTROM
Executive Director
Minnesota Board of Pharmacy
Room 197, Colonial Office Building
2700 University Avenue West
St. Paul

FROM: MARY JO MURRAY
Special Assistant Attorney General
525 Park Street, Suite 500 (55103)

PHONE: 296-3258

SUBJECT: In the Matter of the Adopted Rule Relating to Drug Manufacturers and Wholesalers Licensing

The above-referenced rule has been approved as to its legality by the Attorney General on January 23, 1992.

Enclosed is your copy of the approved rule. This office has already filed two copies with the Secretary of State, who will forward one copy to the Revisor of Statutes. The fourth is being retained by this division of the Attorney General's Office for its records.

Also enclosed are any petitions, requests, submissions or comments along with any extra copies of documents which you submitted to the Attorney General.

Your next step is to arrange for publication of the Notice of Adoption in the State Register. In a day or two, you should receive from the Revisor's Office three copies of the notice of adoption of your rule. You should submit two copies of the Notice of Adoption to the State Register for publication. A permanent rule without a hearing does not become effective until five days after a notice of adoption is published in the State Register in accordance with Minn. Stat. § 14.27. An emergency rule becomes effective five working days after approval by the Attorney General; however, the agency must publish a notice in the State Register in accordance with Minn. Stat. § 14.34.

If you have any questions in this regard, please contact me.

MJM:jj
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cc: Robert T. Holley
William Brown, Chief Judge
MaryAnn Hruby

Goes With Cert of Mailing

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Board of Pharmacy

Adopted Permanent Rules Relating to Drug Manufacturers and Wholesalers Licensing

Rules as Adopted

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE.

Subpart 1. **Licensing; fees.** Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public or patient shall annually be licensed by the board. Upon the filing of an application, and upon payment of a fee of $150 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; $150 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; $125 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; $100 for manufacturing or wholesale distribution of prescription medical gases only; and $75 for licensed pharmacies engaged in wholesale distribution, the board may issue or renew a license in such form as it may prescribe to the manufacturer or wholesale distributor. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire at midnight on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with the applicable fee. Renewal applications received after June 1 shall be subject to a late filing fee of one-half of the renewal fee in addition to the amount of the renewal fee.

Subp. 2. **Prohibition.** No license may be issued to any manufacturer or wholesale distributor whose intended place of business is a personal residence.

Subp. 3. **Separate licenses required.** A separate license is required for each separate location where drugs are stored

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within this state. Out-of-state wholesale drug distributors shipping drugs into Minnesota who do not maintain or operate a physical facility within Minnesota are not required to license each separate location from which drugs are shipped to Minnesota, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.

6800.1410 MINIMUM INFORMATION REQUIRED FOR LICENSURE.

The following information is required from each wholesale drug distributor applying for licensure or renewal:

A. the name, full business address, and telephone number of the licensee;

B. all trade or business names used by the licensee;

C. addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of drugs;

D. whether the ownership or operation is a partnership, corporation, or sole proprietorship; and

E. the name of the owner and operator of the licensee, including:

(1) if an individual, the name of the individual;

(2) if a partnership, the name of each partner, and the name of the partnership;

(3) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(4) if a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.

Changes in any information in items A to E shall be submitted to the board within 30 days of the change.

6800.1420 MINIMUM QUALIFICATIONS.

The board may deny, suspend, revoke, or refuse to renew any license for a wholesale drug distributor based on the board's finding of any of the following factors:

A. any convictions of the applicant under any

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federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. any felony convictions of the applicant under federal, state, or local laws;

C. the lack of previous experience on the part of the applicant in the manufacture or distribution of drugs, including controlled substances;

D. the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

E. the suspension or revocation by federal, state, or local government bodies of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. the lack of compliance by the applicant with licensing requirements under previously granted licenses, if any;

G. the lack of compliance by the applicant with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials those records required under this part; and

H. the lack of compliance by the applicant with requirements for the storage and handling of drugs as specified in part 6800.1440.

6800.1430 PERSONNEL.

Each wholesale drug distributor shall ~~establish training programs which, when combined with the~~ require each person employed in any prescription drug wholesale activity to have enough education, training, and experience ~~of the personnel, will enable the personnel to~~, in any combination, sufficient for that person: (1) to do assigned work in a manner that maintains the quality, safety, and security of the drug products in accordance with parts 6800.1400 to 6800.1440; and (2) to assume responsibility for ~~positions related to~~ compliance with ~~state~~

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and federal the licensing requirements of parts 6800.1400 to 6800.1440.

6800.1440 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS AND FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS.

Subpart 1. **Application.** The minimum requirements in this part apply to all wholesale drug distributors located in this state and to their officers, agents, representatives, and employees.

Subp. 2. **Incorporation by reference.** "United States Pharmacopeia/National Formulary" means the United States Pharmacopeia/National Formulary published by the United States Pharmacopeial Convention Inc. (Rockville, Maryland, 1990), which is incorporated by reference. The United States Pharmacopeia/National Formulary is subject to frequent change. The book is available for inspection and copying at the Biomedical Library, University of Minnesota, Diehl Hall, 505 Essex Street S.E., Minneapolis, Minnesota 55455, or through the Minitex interlibrary loan system.

Subp. 3. **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

A. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

B. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

C. have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

D. be maintained in a clean and orderly condition; and

E. be free from infestation by insects, rodents, birds, or vermin of any kind.

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Subp. 4. **Security.** The requirements in items A to C govern security.

A. All facilities used for wholesale drug distribution shall be secure from unauthorized entry as follows:

(1) access from outside the premises shall be kept to a minimum and be well-controlled;

(2) the outside perimeter of the premises shall be well-lighted; and

(3) entry into areas where prescription drugs are held shall be limited to authorized personnel.

B. All facilities shall be equipped with an alarm system to detect entry after hours.

C. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Subp. 5. **Storage.** Items A to D govern storage of drugs.

A. All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary.

B. If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.

D. The record keeping requirements in subpart 8 shall be followed for all stored drugs.

Subp. 6. **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This

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examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

The record keeping requirements in subpart 8 shall be followed for all incoming and outgoing drugs.

Subp. 7. **Returned, damaged, and outdated drugs.** Items A to D govern returned, damaged, outdated, deteriorated, misbranded, and adulterated drugs.

A. Drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier.

B. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be physically separated from other drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

D. The record keeping requirements in subpart 8 shall be followed for all damaged, outdated, deteriorated, misbranded,

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or adulterated drugs.

Subp. 8. **Record keeping.** Items A to C govern record keeping.

A. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

(1) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) the identity and quantity of the drugs received and distributed or disposed of; and

(3) the dates of receipt and distribution or other disposition of the drugs.

B. Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

C. Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Subp. 9. **Written policies and procedures.** Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs. They must include policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include the written policies and procedures described in items A to D.

A. A procedure where the oldest approved stock of a

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drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

B. A procedure to be followed for handling recalls and withdrawals of drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;

(2) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

C. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

Subp. 10. **Responsible persons.** Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Subp. 11. **Compliance with federal, state, and local law.** Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

Approved
by Revisor _____

Wholesale drug distributors shall permit the board of pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect both their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

Wholesale drug distributors who deal in controlled substances shall register with the board of pharmacy and with the Drug Enforcement Administration, and shall comply with all applicable state, local, and Drug Enforcement Administration regulations.

Subp. 12. **Salvaging and reprocessing.** Wholesale drug distributors are subject to any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing, including Code of Federal Regulations, title 21, parts 207, 210, and 211, and Minnesota Statutes, section 151.39.

Approved
by Revisor _____

APPROVED AS TO FORM AND LEGALITY

Jan 23 19 92

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

BY _____
SPECIAL ASSISTANT ATTORNEY GENERAL

10:45 AM PRB

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

JAN 24 1992

Joan Anderson Growe
Secretary of State

Stat Authority 214.06 subd 1. A

Notwithstanding any law to the contrary, the commissioner of health as authorized by section 214.13, all health-related licensing boards and all non-health-related licensing boards shall by rule, with the approval of the commissioner of finance, adjust any fee which the commissioner of health . . .

strange + sloppy but n/worth rejecting there it all there

SOLAR Weak Generally refers to CFR

dates are strange - Resolution - Jan 24, 1991 signed Dec 1991
Letters to ~~Senate~~ Finance & House appropriators - dated 8-29-91
~~notice of intent dated~~ notice of intent dated August 15, 1989

Rules 6800.1420 - to much discretion for all those factors if there are some that can be overlooked under certain circumstances they should state that are all A-H discretionary?

SOLAR - talks about A and B but what about C-H.

6800.1440 just because they come directly from the FDA requirements does that make them reasonable

did they need a resolution to do N/I?

No: intro is for minimum; explanation of discretion in SNR is reasonable (felony conviction for poaching n/related to drugs + won't affect

B/d needs discretion

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 205.6, 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.

David Katherman

Executive Director
Minnesota Board of Pharmacy

Department: of Finance

STATE OF MINNESOTA

Office Memorandum

Date: August 1, 1991

To: David E. Holmstrom, Executive Director
Minnesota Board of Pharmacy



From: Bruce J. Reddemann, Director B.J.R.
Budget Operations

Phone: 296-5188

Subject: Fee Approval

Approval is hereby granted at the following fee amounts, from your memo of June 5, 1991:

Wholesale Renewal Fees (Prescription or Prescription/Non-Prescription)	$150.00
Manufacturer Renewal Fees (Prescription or Prescription/Non-Prescription)	$150.00

It is understood that an additional fee review will be submitted to Finance covering remaining fees from the original submission on June 5, 1991. If you have any questions, please check with your assigned Executive Budget Officer.

cc: Pam Wheelock
Charlie Bieleck
Glenn Olson

Department of Finance
FEE REVIEW

Date Prepared: June 18, 1991

Department/Agency: Board of Pharmacy

Budget Activity: Board Operations

Fee Name: Various

Legal Citation: M.S. 151, 152 and 214

Fee Set By: ☐ Law ☒ Agency

Purpose of Fee:
To ensure that all pharmacists in Minnesota are properly identified and that all facilities engaged in the distribution of prescription drugs are registered.

☐ Dedicated ☒ Non-Dedicated

Revenue Code:

APID: 21516:00 | Fund: 17 | Accumulated Difference Thru 1988: 219 | Dollars in Thousands (137.522=138)

Fiscal Year	Actual F.Y. 89	Actual F.Y. 90	Estimated F.Y. 91	Requested F.Y. 92	Requested F.Y. 93
Actual/Anticipated Receipts	505	528	514	~~594~~	~~601~~
Less Actual/Anticipated Costs	414	480	503	568	625
Current Difference	91	48	11	26	(24)
Accumulated Difference	91	139	150	176	152
Number Paying Fee			See Below		
Present Fee			See Below		
Date Fee Last Changed			9/89		

Remarks:

# Paying Fee	Fee Explanation	Proposed FY 92 Fee Amount
4,537	Pharmacist Renewal Fees	$65.00
Varies	Pharmacist Fees in Arrears	Varies
108	Pharmacist Late Fees	$25.00
1,143	Pharmacy Renewal Fees	$100.00
Varies	Pharmacy Renewals in Arrears	Varies
21	Pharmacy late Fees	$50.00
129	Wholesaler Renewal Fees (Prescription or Prescription/Non-Prescription)	$150.00
109	Wholesaler Renewal Fees (Non-Prescription/Veterinary or Gases)	$100.00
75	Wholesaler Renewal Fees (Pharmacy)	$75.00
98	Manufacturer Renewal Fees (Prescription or Prescription/Non-Prescription)	$150.00

Department Authorized Signature: David Holmestrom

Finance Department Recommendation:
Recommend approval of the requested increase in wholesaler & manufacturer renewal fees (prescription or prescription/non-prescription) with the understanding that the other fee increases noted in the October fee renewal will follow - along with an accurate fee renewal.

Executive Budget Officer Signature: L D Kulock

FI-00194-07 (3/90)

DEPARTMENT : MINNESOTA BOARD OF PHARMACY

STATE OF MINNESOTA

Office Memorandum

DATE : June 17, 1991

TO : Bruce J. Reddemann, Director
Budget Operations
Dept. of Finance

FROM : David E. Holmstrom
Executive Director

PHONE : 642-0541

SUBJECT : Fee Approval Request of June 5, 1991

As you requested in your memo of June 10, 1991, I am providing the following information:

1. Legal citation from 1990 Laws that require conformity with federal mandates;

2. Date of the proposed fee increases, and;

3. Completed fee review forms.

The laws of Minnesota for 1990, Chapter 568, Article 2, Section 18 through 29 relate to the rewriting of the previously existing requirement for the licensure/registration of drug wholesalers and manufacturers. Specifically, section 25, subdivision 2, references the requirement for conformity with federal law. Further, section 28 mandates that the Board adopt rules to carry out the purposes of the licensure/registration provisions and further mandates that the Board's rules be in conformity with federal guidelines as well.

The date of the proposed fee increase is dependent upon the effective date of the Board's rules implementing the statutory requirement. The proposed fee changes are part of the general rules package called for in section 28 of Chapter 568, Article 2, Laws of 1990. Since license renewal dates for drug wholesalers and manufacturers has previously and will continue to be June 1, any fee changes associated with the wholesaler rules revisions would not be imposed on existing licensees until June of next year. Once implemented, the new fee structure would be applicable to any previously unlicensed drug wholesalers or manufacturers that may seek licensure from the Board. It is presently anticipated that the rules will be promulgated through the non-controversial rule making process and thus will become effective in September or October of this year. If a specific effective date for the fee changes is required, we can certainly build that into the draft rules. Please let me know if that is, indeed, the case.

Finally, a completed fee review document is attached along with a copy of the fee review from our budget request.

DEH:pe

Enc.

Department of Finance

FEE REVIEW

Date Prepared: June 18, 1991

Department/Agency: Board of Pharmacy

Budget Activity: Board Operations

Fee Name: Various

Legal Citation: M.S. 151, 152 and 214

Fee Set By: ☐ Law ☒ Agency

Purpose of Fee: To ensure that all pharmacists in Minnesota are properly identified and that all facilities engaged in the distribution of prescription drugs are registered.

☐ Dedicated ☒ Non-Dedicated

Revenue Code:

APID: 21516:00

Fund: 17

Accumulated Difference Thru 1988: 219

Dollars in Thousands (137.522=138)

Fiscal Year	Actual F.Y. 89	Actual F.Y. 90	Estimated F.Y. 91	Requested F.Y. 92	Requested F.Y. 93
Actual/Anticipated Receipts	505	528	514	594	601
Less Actual/Anticipated Costs	414	480	503	568	625
Current Difference	91	48	11	26	(24)
Accumulated Difference	91	139	150	176	152
Number Paying Fee			See Below		
Present Fee			See Below		
Date Fee Last Changed			9/89		

Remarks:

# Paying Fee	Fee Explanation	Proposed FY 92 Fee Amount
4,537	Pharmacist Renewal Fees	$65.00
Varies	Pharmacist Fees in Arrears	Varies
108	Pharmacist Late Fees	$25.00
1,143	Pharmacy Renewal Fees	$100.00
Varies	Pharmacy Renewals in Arrears	Varies
21	Pharmacy late Fees	$50.00
129	Wholesaler Renewal Fees (Prescription or Prescription/Non-Prescription)	$150.00
109	Wholesaler Renewal Fees (Non-Prescription/Veterinary or Gases)	$100.00
75	Wholesaler Renewal Fees (Pharmacy)	$75.00
98	Manufacturer Renewal Fees (Prescription or Prescription/Non-Prescription)	$150.00

Department Authorized Signature: David Holmestrom

Finance Department Recommendation:

Executive Budget Officer Signature:

FI-00194-07 (3/90)

DATE PREPARED:
June 17, 1991

DEPARTMENT/AGENCY:
Board of Pharmacy

BUDGET ACTIVITY:
Board Operations

FEE NAME:
Varies

REMARKS:

# Paying Fees	Fee Explanation	Proposed FY 92 Fee Amount
101	Manufacturer Renewal Fees (Non-Prescription/Veterinary or Gases)	$100.00
7	Manufacturer Renewal Fees (Pharmacy)	$75.00
58	Certificate of Ratings	$10.00
5	Duplicate Certificate	$20.00
134	Examination Fees	$200.00
0	Partial Examination Fee	$150.00
5	Partial Examination Fee	$125.00
2	Partial Examination Fee	$100.00
5	Partial Examination Fee	$75.00
118	Original Licensure Fee	$65.00
72	Reciprocity Fee	$165.00
191	Intern Registration Fees	$20.00
Varies	Readmittance Fee	Varies
1	Corporation Fee	$100.00
0	Corporation Renewals	$25.00
64	Drug Researcher Fee	$25.00
20	Medical Gas Distributor Fee	$50.00
0	Medical Gas Late Fee	$25.00
5	Proceedings Cost	Varies
7	Service Charge	Varies
Varies	Reimbursement of Expenses	Varies

FEE REVIEW - Details of Cost

Date Prepared: June 18, 1991

Department/Agency: Board of Pharmacy

Budget Activity: Board Operations

Fee Name: Various

Detailed Listing of Items Included as Costs on Fee Review Form FI-00194-07 Dollars in Thousands (137,522 = 138)

Fiscal Year	Actual F.Y. 89	Actual F.Y. 90	Estimated F.Y. 91	Requested F.Y. 92	Requested F.Y. 93
Agency Direct Expenditures	400	465	484	554	609
Salary Increases	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX		
Attorney General	17	14	18	20	20
Statewide Indirect	10	10	10	10	10
Agency Indirect	4	5	4	4	5
Totals: must agree with cost on Fee Review Form	414	480	503	568	625

Remarks:

1. Please note that the Attorney General costs are an "off budget" item for the licensing boards. The costs must still be covered by fees, however.

2. FY 91 had a $5000 additional appropriation for the development of the rules which are involved in this request. It is non-recurring.

3. The other fee changes anticipated in our budget request will be forthcoming shortly through a separate rule change.

FEE REVIEW

Date Prepared: October 1, 1990

Department/Agency: Board of Pharmacy

Budget Activity: Board Operations

Fee Name: Various

Legal Citation: M.S. 151, 152 and 214

Fee Set By: ☐ Law ☒ Agency

Purpose of Fee: To ensure that all pharmacists in Minnesota are properly identified and that all facilities engaged in the distribution of prescription drugs are registered.

☐ Dedicated ☒ Non-Dedicated

Revenue Code:

APID: 21516:00

Fund: 17

Accumulated Difference Thru 1988: 219

Dollars in Thousands (137,522=138)

Fiscal Year	Actual F.Y. 89	Actual F.Y. 90	Estimated F.Y. 91	Requested F.Y. 92	Requested F.Y. 93
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Current Difference	91	48	11	26	(24)
Accumulated Difference	91	139	150	176	152
Number Paying Fee			See Below		
Present Fee			See Below		
Date Fee Last Changed			9/89		

Remarks:

# Paying Fee	Fee Explanation	FY 91 Fee Amount	Anticipated FY 92
4,537	Pharmacist Renewal Fees	$65.00	$75.00
Varies	Pharmacist Fees in Arrears	Varies	
108	Pharmacist Late Fees	$25.00	
1,143	Pharmacy Renewal Fees	$100.00	
Varies	Pharmacy Renewals in Arrears	Varies	
21	Pharmacy Late Fees	$50.00	
279	Wholesaler Renewal Fees	$100.00	$150.00
0	Wholesaler Renewals in Arrears	Varies	
12	Wholesaler Late Fees	$25.00	
156	Manufacturer Renewal Fees	$100.00	$150.00
0	Manufacturer Renewals in Arrears	Varies	
9	Manufacturer Late Fees	$25.00	

Continued on next page

Department Authorized Signature: David G. Kuhlmann

Finance Department Recommendation:

The Department of Finance recommends the adoption of fees at the levels identified by the Board.

Executive Budget Officer Signature: Arnold Kludt

Date Prepared:
October 1, 1990

Department/Agency:
Board of Pharmacy

Budget Activity:
Board Operations

Fee Name:
Varies

Remarks:

# Paying Fees	Fee Explanation	FY 91 Fee Amount	Anticipated FY 92
58	Certificate of Rating	$10.00	
5	Duplicate Certificate	$20.00	
134	Examination Fee	$200.00	$225
0	Partial Examination Fee	$150.00	
5	Partial Examination Fee	$125.00	$150
2	Partial Examination Fee	$100.00	
5	Partial Examination Fee	$75.00	$100
118	Original Licensure Fee	$65.00	$75.00
72	Reciprocity Fee	$165.00	$175.00
191	Intern Registration Fee	$20.00	
Varies	Readmittance Fee	Varies	
1	Corporation Fee	$100.00	
0	Corporation Renewal Fee	$25.00	
64	Drug Researcher Fee	$25.00	
20	Medical Gas Distributor Fee	$50.00	
0	Medical Gas Distributor Late Fee	$25.00	
5	Proceedings Cost	Varies	
7	Service Charge	Varies	
Varies	Reimbursement of Expenses	Varies	

Agency recommends that certain fee amounts be increased in FY 92.

Department: of Finance

STATE OF MINNESOTA

Office Memorandum

Date: June 10, 1991

To: David Holmstrom, Executive Director
Minnesota Board of Pharmacy

From: Bruce J. Reddemann, Director BJR
Budget Operations



Phone: 296-5188

Subject: Your fee approval request of June 5, 1991

The purpose of this of this memo is to get additional information related to your requested fee increases.

Please provide the following information:

- o legal citation from 1990 Laws that require conformity with federal mandates;
- o date of the proposed fee increases, and
- o complete the attached fee review forms (FI-00194-07 and FI-00195-02) as mandated by our department's accounting policy and procedures manual, operating policy and procedure # 06:03:17.

A prompt reply will be appreciated.

cc: Pam Wheelock
Charlie Bieleck
Glenn Olson

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : MINNESOTA BOARD OF PHARMACY

DATE : June 5, 1991

TO : Bruce T. Reddemann, Director
Budget Operations and Support
Department of Finance

FROM : David E. Holmstrom
Executive Director

PHONE : 642-0541

SUBJECT : Approval of Fee Changes

A request is hereby made for approval of a fee change for drug wholesalers and manufacturers. Presently, all drug wholesalers and drug manufacturers licensed by the Board are subject to the same fee. The fee for both drug wholesalers and drug manufacturers is $100. The Board is proposing, in its new rules relating to wholesale drug distributors, to differentiate between different types of drug wholesalers and drug manufacturers based on the types of drug products they are handling, which also impacts on the scope and depth of Board inspections conducted at these types of facilities.

In the 1990 legislative session, the legislature passed a new wholesale drug distributor licensing requirement in conformity with federal mandates. Based on this new legislation relating to drug wholesalers and drug manufacturers the Board has developed a new set of rules that will serve to implement the new legislation and bring Minnesota into conformity with federally mandated guidelines. As part of the new rule package relating to drug wholesalers and drug manufacturers, the Board is proposing, as indicated above, to differentiate between types of wholesalers and manufacturers.

The following is a description of the Board's proposals for restructuring the fees associated with drug wholesalers and drug manufacturers.

LICENSE TYPE	PRESENT FEE	PROPOSED FEE
All Drug Wholesalers	$100.00	
All Drug Manufacturers	$100.00	
Drug Wholesalers or Manufacturers distributing prescription drugs only, not including medical gases		$150.00
Manufacturers or Wholesalers distributing prescription and non-prescription drugs, no including medical gases		$150.00

Manufacturers or wholesalers distributing non-prescription drugs or veterinary drugs only	$125.00
Manufacturers or Wholesalers distributing prescription medical gases only	$100.00
Licensed Pharmacies engaged in wholesale distribution	$75.00

In addition, the Board is proposing to change the late filing fee for drug wholesalers and drug manufacturers from a flat fee of $25.00 to a fee that is equal to 1/2 of the licensure fee.

All of these changes will affect only about 250 licensed wholesalers and manufacturers on file with the Board.

Since approval of this request must be included as part of the Statement of Need and Reasonableness required for adoption of the new rules relating to drug wholesalers and manufacturers, your prompt attention to this request for approval would be greatly appreciated.

DEH:pe

federal register

Friday
September 14, 1990

APPENDIX A

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 205

Guidelines for State Licensing of Wholesale Prescription Drug Distributors; Final Rule

21 CFR Part 205

Applicability to Blood and Blood Components Intended for Transfusion; Guidelines for State Licensing of Wholesale Prescription Drug Distributors

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 205

[Docket No. 88N-0258]

RIN 0905-AC81

Guidelines for State Licensing of Wholesale Prescripton Drug Distributors

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to implement those sections of the Prescription Drug Marketing Act of 1987 (PDMA) that require FDA to issue regulations setting forth guidelines for State licensing of wholesale drug distributors. The guidelines prescribe minimum standards, terms, and conditions for the storage and handling of prescription drugs for human use (hereinafter prescription drugs) and for the establishment and maintenance of records of their distribution. PDMA prohibits wholesale distribution of prescription drugs in interstate commerce unless the wholesale distributor is licensed by a State in accordance with these guidelines. In this rule, FDA has tentatively determined that PDMA does not apply to the distribution of blood and blood components intended for transfusion. In a separate notice elsewhere in this issue of the Federal Register, FDA invites further comment on this matter.

EFFECTIVE DATE: September 14, 1990.

FOR FURTHER INFORMATION CONTACT: Diane P. Goyette, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 1988 (53 FR 35325), FDA published a proposed rule to issue guidelines for State licensing of wholesale drug distributors as required by the Prescription Drug Marketing Act of 1987 (Pub. L. 100-293, 102 Stat. 95). PDMA amends the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) to provide, among other things, that no person may engage in the wholesale distribution in interstate commerce of drugs subject to section 503(b) of the act (21 U.S.C. 353(b)) (prescription drugs for human use), unless such person is licensed by the State in accordance with federally prescribed minimum standards. PDMA requires that these minimum standards be established in "guidelines" issued by FDA regulation. The guidelines must prescribe minimum standards, terms, and conditions for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution (21 U.S.C. 353(e)(2)).

The State licensing guidelines established by this regulation should not be confused with FDA guidelines issued under the agency's rules governing administrative practices and procedures (21 CFR 10.90). Guidelines issued under § 10.90 suggest procedures or present standards of general applicability that are not legal requirements, but that one can rely on as acceptable to FDA. Such guidelines allow persons to choose alternate courses of conduct that comply with the general standards or suggested procedures. In contrast, PDMA directs that the guidelines issued by this regulation "* * * shall *prescribe requirements* for the storage and handling of (prescription) drugs and for the establishment and maintenance of records of (their) distribution * * *" (emphasis added). Moreover, PDMA requires that wholesale drug distributors who distribute human prescription drugs in interstate commerce be licensed in accordance with the minimum requirements set forth in these guidelines (21 U.S.C. 353(e)(2)). Thus, the guidelines prescribed by this regulation are binding substantive rules that have the force and effect of law.

Unless express reference is made to guidelines issued under § 10.90 (as in paragraph 25, below), all references to guidelines in this document are made to these "Guidelines for State Licensing of Wholesale Prescription Drug Distributors" established under the requirements of PDMA.

The PDMA prohibition against interstate distribution of prescription drugs by persons who are not licensed by the State in accordance with these Federal guidelines takes effect 2 years after the date of publication of this final rule. Any person who distributes prescription drugs in violation of this prohibition is subject to imprisonment for not more than 10 years or a fine of not more than $250,000, or both (21 U.S.C. 333(b)(1)).

In developing the guidelines, FDA followed the recommendation of the House of Representatives' Committee on Energy and Commerce that it consider the "Model Regulations for Wholesale Drug Distribution" issued by the National Association of Boards of Pharmacy (NABP). FDA also considered the "Proposed Uniform Standards of Practice for Wholesale Drug Distribution," which have been adopted by the National Wholesale Druggists' Association (NWDA).

Additionally, FDA has carefully considered the approximately 50 comments received on the proposed rule. The comments came from members of Congress, trade associations, professional groups, individual pharmaceutical manufacturing firms, wholesale drug distributors, chain drug store companies, State boards of pharmacy, individual hospital and retail pharmacies, and pharmacists. Highlights of this final rule and the agency's economic analysis are followed by a summary and discussion of the comments in section VII below.

II. Highlights of the Final Rule

This final rule establishes guidelines for State licensing of wholesale prescription drug distributors as required under PDMA. The guidelines provide minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution. The guidelines ensure that all prescription drug wholesalers who distribute drugs in interstate commerce will operate according to these minimum standards while leaving States discretion to impose stricter licensing requirements. In response to comments and further internal deliberations, the final rule modifies certain provisions of the proposal to meet these objectives better. The major provisions of the final rule are summarized as follows:

1. *Scope.* The final rule applies to all wholesale distributors of human prescription drugs in interstate commerce.

2. *Definitions.* Section 205.3 sets forth definitions as they apply to this final rule. The distribution of drug samples by manufacturers' representatives, distributors' representatives, and the distribution of blood and blood components intended for transfusion by registered blood establishments are excluded from the definition of wholesale distribution in the final rule. These activities are, therefore, not subject to the licensing requirements under the guidelines.

3. *Wholesale drug distributor licensing requirement.* Section 205.4 of the final rule sets forth the requirement that a wholesale distributor conducting interstate transactions in a State be licensed by the State. This requirement is mandated by section 503(e)(2)(A) of the act.

4. *Minimum required information for licensure.* Section 205.5 of the final rule sets forth minimum information to be required from each licensing applicant.

5. *Minimum qualifications.* The final rule sets forth certain minimum qualifications for licensing under § 205.6. The agency believes that careful screening of applicants is necessary and prudent in reducing the opportunities for diversion of prescription drugs. State authorities must consider an applicant's history, which may reflect upon the applicant's ability to prevent drug diversion. Where granting a license would not be in the public interest, State authorities may deny a license to an applicant.

6. *Personnel.* The final rule establishes minimum personnel standards for licensees under § 205.7. Employees must be qualified by education and/or experience to perform their duties.

7. *Violations and penalties.* Section 205.8 of the final rule provides for suspension or revocation of licenses, and permits fines, imprisonment, or civil penalties upon conviction of violations of Federal, State, or local drug laws.

8. *Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.* The final rule sets forth the minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distributions. The final rule includes sections describing physical requirements of facilities where prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed. Such facilities must have certain characteristics, outlined in § 205.50(a) of the final rule, that make them suitable places for the storage of prescription drugs. Facilities must also have adequate security systems and be capable of ensuring a proper environment for the storage of prescription drugs.

a. *Wholesaler examination of incoming shipments of prescription drugs.* The final rule requires examinations of incoming and outgoing shipments to prevent acceptance of prescription drugs that are contaminated or otherwise unfit for distribution. The proposed section has been clarified in the final rule to limit the required inspection of incoming shipments of prescription drugs by wholesale distributors to a visual examination, adequate to reveal shipping container damage that would suggest damage to the contents. The final rule also deletes the requirement that the inspection of incoming shipments extend to an examination of the delivery vehicle.

b. *Handling of prescription drug products returned to the wholesale distributor.* Section 205.50(e) includes detailed instructions for the handling of returned, damaged, and outdated prescription drugs. The final rule permits the wholesaler to send back to the original supplier prescription drug products that have been returned to the wholesaler under circumstances that cast doubt on the product's integrity. This change is consistent with stated agency policy with regard to returned prescription drug products under PDMA.

c. *Recordkeeping requirements.* Section 205.50(f) sets forth recordkeeping requirements to ensure a high degree of accountability for all prescription drug transactions. Proposed § 205.50(f)(1) has been revised so that wholesale distributors are not required to include the expiration dates of prescription drugs in the records of their transactions under the final rule. Records must be retained for a period of 2 years following disposition of the prescription drug product under § 205.50(f)(2) of the final rule. Section 205.50(f)(3) of the final rule provides that records kept at the inspection site or immediately retrievable by computer or other means must be readily available for authorized inspection during the retention period. Those that are kept at another location must be made available within 48 hours of an authorized request.

d. *Written policies and procedures.* Section 205.50(g) sets forth minimum standards for the establishment and maintenance of written policies and procedures related to the receipt, security, storage, inventory, and distribution of prescription drugs. By following such pre-established procedures, a firm can better assure proper storage and distribution of prescription drugs on a consistent basis.

e. *Responsible persons.* Section 205.50(h) of the final rule requires the maintenance of lists of persons in responsible company positions. Such lists provide a deterrent to drug diversion.

f. *Compliance with Federal, State, and local law.* Section 205.50(i) of the final rule emphasizes that wholesale drug distributors must operate in compliance with all applicable laws and regulations.

g. *Salvaging and reprocessing.* Section 205.50(j) of the final rule states that wholesale drug distributors are subject to any applicable Federal, State, or local laws relating to salvaging or reprocessing. Salvaging and reprocessing operations can be very complex and are outside the scope of traditional wholesaler activities. Additional controls are therefore necessary to ensure that these operations are carried out in the appropriate fashion. Accordingly, § 205.50(j) of the final rule makes clear that FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals in 21 CFR parts 210 and 211 apply to wholesalers' salvaging and reprocessing operations.

III. Economic Analysis

FDA has examined the economic consequences of the changes implemented by the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354).

As recommended by Congress, FDA consulted the NABP Model Regulations for Wholesale Drug Distribution in the development of the standards set by these guidelines. (See H. Rept. 100-76, p. 17.) The agency believes that the standards in these guidelines represent the norm of current practices and procedures among drug wholesalers and expects minimal incremental costs to occur when these standards become effective 2 years after the publication of this final rule. Any substantial costs that may arise will be attributable to the statute itself. Thus, this rule is not expected to produce economic consequences beyond those contemplated by the act. Accordingly, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291. For similar reasons, the agency certifies, in accordance with the Regulatory Flexibility Act, that this final rule will not have a significant impact on a substantial number of small entities.

IV. Executive Order 12612: Federalism

Executive Order 12612 requires Federal agencies to carefully examine regulatory actions to determine if they would have significant impact on federalism. Using the criteria and principles set forth in the Order, the agency has considered the impact of this final rule on the States, on their relationship with the national government, and on the distribution of power and responsibilities among the various levels of government.

FDA is required by statute to issue this regulation to establish guidelines setting forth minimum standards for State licensing of wholesale prescription drug distributors. The regulation is to include minimum requirements for recordkeeping, storage, and handling of prescription drugs. States are affected to the extent that their wholesale distributors are not permitted to

distribute prescription drugs in interstate commerce unless they are licensed by the State in accordance with these guidelines. Under these guidelines, however, States are free to adopt standards that exceed the minimum requirements. They also maintain maximum administrative discretion, and can develop their own policies to achieve program objectives. States have had the opportunity to participate in the development of these guidelines through the notice and comment rulemaking process.

FDA certifies that it has examined this final rule, and while it may have some effect on federalism issues, for the reasons stated above, these effects are not significant and do not require an assessment under Executive Order 12812. Moreover, the agency's action is mandated by law; the agency has no discretion in carrying out its legal mandate by regulation.

V. Paperwork Reduction Act of 1980

This final rule contains information collections which have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 and assigned OMB control number 0910–0251. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Prescription Drug Marketing Act of 1987; Guidelines for State Licensing of Wholesale Prescription Drug Distributors.

Description: The reporting requirement includes the submission of certain descriptive information concerning each wholesale drug distributor (e.g., corporate address, contact person address) (§ 205.5). The recordkeeping requirements include establishing and maintaining inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs (§ 205.50(f) and (h)).

Description of respondents: State or local governments; businesses or other for-profit organizations; small businesses or organizations.

Estimated annual reporting and recordkeeping burden:

Section	Annual number of respondents	Annual frequency	Average burden per response (minutes)	Annual burden hours
202.5(a)	7,300	1	15	1,825
205.50(f) and (h)	7,300	1	20	2,434
Total				4,259

FDA, as a result of the comments received on the proposal, has deleted the provision in § 205.50(f)(1)(iii) requiring distributors to maintain records of expiration dates of prescription drugs. As reflected in the table above, this change will reduce the estimated burden from 30 minutes per response to 20 minutes, and from 3,650 annual burden hours to 2,434. There were no comments received on the Paperwork Reduction Act clearance submission or on the burden estimates.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a) (7), (8), and (10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Comments on the Proposed Rule

A. General Comments

1. Several comments addressed general issues raised by the proposed rule. Some comments questioned whether FDA should be regulating wholesale drug distributors, saying that regulations for State licensure of drug wholesalers should be left to the individual States. Other comments argued that the proposed rule is unnecessary and duplicative because State regulatory and private quality control systems already in place adequately address the goals of PDMA, and that the pharmacists' role in drug distribution precludes the need for wholesaler licensing by State or Federal authorities.

Section 503 of the act, as amended by PDMA, requires FDA to publish these State guidelines. It is not left to the agency's discretion (21 U.S.C. 353(e)(2)(B)). Moreover, the legislative history of PDMA reveals that Congress examined existing drug distribution systems, State licensing schemes, private quality control systems, and the role of pharmacists in meeting the goals of PDMA, and concluded that, although such programs might be individually effective, a national strategy was necessary to protect the public health.

These Federal guidelines set minimum standards for States to follow in designing their licensing systems. The guidelines assure that all wholesale drug distributors conducting business in interstate commerce will comply with the same minimum requirements. The agency believes that the guidelines leave States sufficient discretion to determine appropriate structures for the regulation of wholesale distributors conducting business in their States.

2. Some comments argued that the proposed guidelines should be modified or abandoned because they duplicate, and at times contradict, provisions of FDA's CGMP regulations (21 CFR parts 210 and 211).

The agency's CGMP regulations include provisions that are similar to some requirements in these guidelines. However, the CGMP regulations do not apply to the traditional activities of wholesale drug distributors (see 43 FR 45027), whereas these guidelines are expressly applicable to the traditional activities of wholesale drug distributors. FDA is unaware of any inconsistencies within its regulatory scheme that would dictate changes in these guidelines.

The provisions of this rule and other FDA regulations may have common elements, but the agency finds that this is appropriate. FDA finds that the guidelines are not only consistent with other Federal regulations, but complement the Federal scheme to enable FDA to have better control over the distribution of prescription drugs. The agency's views on the relationship between these guidelines and the current good manufacturing practice provisions of the act are discussed in paragraph 25 below.

3. Some comments discussed the economic impact of the proposed rule on wholesale distributors. Generally, these

comments contended that the proposed rule would impose substantial additional costs on wholesalers, without a corresponding benefit. Some comments estimated that new paperwork and personnel expenses would impose a burden. Other comments expressed concern that additional costs will force smaller, marginally profitable wholesale distributors out of business. The comments asserted that the proposed rule would impose many new procedural burdens on wholesale distributors that go beyond current practice and would be expensive to implement.

As noted earlier, the agency considered both the NABP "Model Regulations for Wholesale Drug Distribution" and the NWDA "Proposed Uniform Standards of Practice for Wholesale Drug Distribution" in developing these guidelines. Therefore, the agency believes that the guidelines represent the norm of current practice and procedure among drug wholesalers. The comments offered no examples of significant deviation from current procedures to bolster the general claim that implementation of these minimum requirements would have substantial economic consequences. Moreover, the comments suggested no specific changes in the proposed requirements to lessen the asserted economic impact.

When Congress passed PDMA, it determined that some changes should be made in the wholesale distribution system to protect the public from prescription drugs of questionable integrity. While some additional expenses are anticipated as these changes are implemented, the agency does not expect these minimum requirements to impose costs that are overly burdensome. The agency has reviewed this rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act and finds it satisfactory.

4. One comment asserted that compliance with the minimum standards set forth in the rule will greatly increase paperwork burdens. The comment also stated that the proposed guidelines governing the handling of prescription drugs, particularly those provisions dealing with destruction of returned or damaged prescription drugs, could have a significant effect on the human environment.

The agency has concluded that the standards described in these guidelines represent current procedure among responsible wholesale distributors. It is not expected that unreasonable, new paperwork burdens or significant effects on the human environment will be created.

5. One comment asked that FDA clarify its authority to enforce these guidelines.

These guidelines are minimum standards for State licensing of wholesale drug distributors. State licensing authorities are the primary agencies responsible for establishing and enforcing wholesaler licensing schemes in the States in accordance with the guidelines. FDA, however, will enforce section 503(e)(2)(A) of the act (21 U.S.C. 353(e)(2)(A)), which prohibits wholesale distribution of prescription drugs in interstate commerce in a State, except by persons licensed by the State in accordance with these minimum guidelines.

This specific authority under PDMA does not replace or dimish the agency's authority over wholesalers under other statutory provisions, including the adulteration, misbranding, and new drug provisions of the act.

B. Scope

6. Two comments requested that manufacturers' distribution centers be specifically excluded from the scope of the licensing requirements because they are adequately governed by FDA's CGMP regulations.

FDA does not find it necessary to make the change requested. Congress intended that all wholesale distributors of human prescription drugs, with certain specific exceptions, be licensed according to these gudielines. Manufacturers' warehouses that are conducting wholesale distributions are wholesale distributors and are subject to the licensing requirements unless their activities fall under one of the specific exclusions defined under § 205.3(f) of the final rule.

7. Three comments addressed issues raised by application of these guidelines to the distribution and sale of blood and blood components by blood establishments and hospitals. Two of these comments requested clarification of PDMA's scope and urged FDA to "exempt" blood establishments from all of PDMA's provisions. The comments contended that application of PDMA to blood distributors would seriously disrupt the nation's blood services. The third comment suggested that the agency could, by notice and comment rulemaking, exempt blood and blood components from PDMA by declaring that they are not prescription drugs for PDMA purposes.

After considering these comments and reviewing PDMA's purpose and legislative history, FDA has tentatively determined that PDMA does not apply to blood and blood components intended for transfusion. However, in a notice published elsewhere in this issue of the **Federal Register**, FDA is inviting further comments on this matter.

PDMA, by its literal terms, applies to all drugs that are subject to section 503(b) of the act; that is, to all human prescription drugs. There is no doubt that blood and blood components intended for transfusion are prescription drugs. See, e.g., 21 CFR 606.121(c)(8)(i); 21 CFR 610.61(f). See also May 25, 1982, 47 FR 22518; August 1, 1981, 46 FR 40121. However, if PDMA, and particularly PDMA's restrictions on the resale of prescription drugs, were considered applicable to the distribution of such blood and blood components, the result would be to seriously impede the present blood distribution system, thereby substantially interfering with, and reducing, our nation's blood supply. Because application of PDMA to blood and blood components intended for transfusion would produce this untenable result, FDA believes that Congress did not intend to subject such blood and blood components to PDMA's provisions.

Moreover, the legislative history lacks any discussion of PDMA's application to blood and blood components intended for transfusion and also clearly shows that Congress intended that PDMA remedy problems associated with the distribution of those drugs that are popularly referred to as "medicines" or "pharmaceuticals." See, *e.g.*, Public Law 100-293, section 2 (1988) (Congressional Findings). As is discussed in further detail in the companion notice to this final rule that is published elsewhere in this issue of the Federal Register, blood and blood components intended for transfusion are unique drug products that are distributed in an entirely different way than other prescription drugs. For example, such blood and blood components are not promoted through samples and coupons. FDA believes that the fact that such blood and blood components are not part of the system of distribution and marketing that Congress intended to regulate under the terms of PDMA further signals that Congress did not intend to include blood and blood components intended for transfusion within the scope of PDMA.

Accordingly, FDA's tentative determination is to limit the scope of these guidelines so that they do not apply to blood and blood components intended for transfusion. This limitation is accomplished by amending the definitions in § 205.3 to add new paragraph (f)(8), which specifically excludes from the definition of "wholesale distribution" the sale, purchase, or trade of blood and blood

components intended for transfusion. FDA is also adding definitions of "blood" and "blood component" in § 205.3 of the final rule.

If further comments on this issue in response to the companion notice persuade FDA to include distribution of blood and blood components intended for transfusion in these guidelines, FDA will amend the guidelines to cover such blood and blood components.

C. Definitions

8. On its own initiative, the agency has changed the definition of "prescription drug" in proposed § 205.3(c) (now § 205.3(e)) by removing the reference to State law. The applicability of these guidelines is limited to wholesale distributions in interstate commerce of drugs that are "prescription drugs" under section 503(b) of the act.

9. Several comments addressed proposed § 205.3, which sets forth definitions of terms to be used in the wholesaler licensing regulations. One comment requested clarification of the meaning of "under common control" as used in proposed § 205.3(d)(4) (now § 205.3(f)(4)).

Neither PDMA nor its legislative history defines the term "under common control" which is used in section 503(c)(3)(B)(iii) of the act (21 U.S.C. 353(c)(3)(B)(iii)). The term, however, has been used in other Federal regulatory schemes which were in use at the time PDMA was enacted into law. Both the Security Exchange Commission and the Environmental Protection Agency define "common control" to mean the power to direct or cause the direction of the management and policies of a person or an organization, whether by the ownership of stock, voting rights, by contract, or otherwise. See 17 CFR 230.405, 40 CFR 66.3(f). FDA has included this definition in this final rule.

10. A number of comments perceived a conflict between the definitions of "wholesale distribution" (proposed § 205.3(d)) and "wholesale distributor" (proposed § 205.3(e)). The comments noted that chain drug warehouses are specifically included in the definition's list of "wholesale distributors" while intracompany sales are specifically excluded from the scope of the definition of "wholesale distribution." The comments contended that the business of chain drug warehouses is generally limited to intracompany distribution of products, namely, to retail stores that are under common ownership or within a corporate structure. The comments stated that these activities should be considered "intracompany sales," and thus should be excluded from "wholesale distribution" and the licensing requirements of the regulations.

The agency does not find the definitions of "wholesale distribution" and "wholesale distributor" to be inconsistent. A "wholesale distributor" is any person who "engages in wholesale distribution of prescription drugs." The legislative history includes a discussion of the scope of the definition of "wholesale distribution" for the purposes of these guidelines. It was clearly the intent of Congress to require licensing of the wholesale distributions of human prescription drugs by chain drug warehouses (see H. Rept. 100-76, p. 17).

Some chain drug warehouses may limit distribution of prescription drug products to subdivisions within a corporate structure, and those distributions would fall under the "intracompany sales" exception and not be considered wholesale distributions under § 205.3(f). A chain drug warehouse that sells prescription drugs to a franchised store or to establishments outside the corporate umbrella, however, would be engaging in wholesale distribution, as defined in § 205.3(f) of this final rule, and its distributions in interstate commerce would be subject to the licensing requirements.

11. Several comments suggested that the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives be specifically excluded from the definition of "wholesale distribution" and thus from the licensing requirement. The comments argued that licensing persons who distribute prescription drug samples is inconsistent with the intent of PDMA and would make the current practice of sample distribution by representatives virtually impossible.

Other comments argued that manufacturers' and distributors' representatives should be licensed and be required to store and handle samples in accordance with the guidelines or the guidelines will fail to assure that prescription drugs are stored properly in all cases.

After considering the comments and reviewing PDMA's purpose and legislative history, FDA has determined that the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives, done in accordance with other applicable provisions of the act, is not "wholesale distribution" within the meaning of § 205.3(f) of these guidelines and will not be subject to licensing under this final rule. FDA believes that this result is consistent with a congressional intent to establish a separate, comprehensive regulatory scheme designed specifically for prescription drug samples.

The licensing of manufacturers' representatives and distributors' representatives as wholesalers would go beyond the intent of PDMA. PDMA was enacted to address certain problems in the human drug distribution system that Congress believed threatened the integrity of the nation's prescription drug supply. Wholesale distribution of drugs and sample distribution by manufacturers' representatives and distributors' representatives were two of the areas where Congress believed more controls were necessary. However, PDMA addressed these two areas in somewhat different ways.

In the case of wholesale distribution, Congress sought to improve storage and handling practices and accountability by requiring that wholesale distributors of human prescription drugs be licensed under State licensing requirements that meet prescribed minimum Federal standards. The legislative history suggests that Congress expected these licensing standards to be based on the NABP "Model Regulations for Wholesale Drug Distribution," a model inapplicable to the control of sample distribution. (H. Rept. 100-76, p. 17.) Moreover, the House Report also indicates that Congress intended the licensing requirement to be confined to "* * * distribution by chain drug warehouses, wholesale drug warehouses, and all sellers of prescription drugs in wholesale quantities to persons or firms other than the consumer or patient." (H. Rept. 100-76, p. 17.) The reference in the House Report supports a conclusion that PDMA's licensing provisions are not intended to cover the distribution of prescription drug samples, which, by statutory definition, are never sold (section 503(c)(1) of the act; 21 U.S.C. 353(c)(1)).

Congress chose a different method of regulation with regard to the distribution of prescription drug samples. These requirements are set forth in section 503(d) of the act, and establish express and comprehensive provisions governing the storage, handling, distribution, and disposition of prescription drug samples by manufacturers, their distributors, and representatives. The scope and specificity of these provisions indicate that Congress determined that sample distributions be conducted under this separate regulatory scheme. Section 503(d) and the legislative history of

PDMA contain no suggestion that any additional regulatory scheme, such as licensing prescription drug sample distribution as wholesale activity, was either necessary or contemplated by Congress.

Accordingly, the agency is adding § 205.3(f)(7) to the final rule, excluding the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives from the "wholesale distribution" definition and the licensing requirements.

Because sample distribution by manufacturers' representatives and distributors' representatives will not be subject to State licensing in accordance with these guidelines, the agency does not intend that such sample distribution be subject to the storage and handling requirements of these guidelines. The agency disagrees with the contention of some comments that excluding such sample distribution from these storage and handling requirements will prevent prescription drugs from being properly stored in all cases. Under section 503(d)(3)(B) of the act, manufacturers and distributors must store prescription drug samples under conditions that will maintain their stability, integrity, and effectiveness, and take measures to assure that their prescription drug samples are kept free of contamination, deterioration, and adulteration. Manufacturers and distributors are thus responsible for the proper handling of prescription drug samples throughout their distribution.

12. One comment asked if those entities excluded from the "wholesale distribution" definition in proposed § 205.3(d) (1) through (8) would also be excluded from the storage, handling, and recordkeeping requirements of § 205.50.

The guidelines require only those persons engaged in the wholesale distribution in interstate commerce of prescription drugs to be subject to the guidelines' minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of the distribution of such drugs. By definition, therefore, the entities involved in the transactions listed in § 205.3(f) (1) through (8) of the final rule are not wholesale distributors under PDMA and are not subject to other provisions of the guidelines. Of course any person engaged in manufacturing, processing, packing, or holding of a drug is subject to all pertinent provisions of the act, including the current good manufacturing practice provisions of section 501(a)(2)(B) of the act (21 U.S.C. 352(a)(2)(B)).

13. A number of comments suggested that the definition of "wholesale distributor" be expanded to include manufacturers' representatives, sales agents, doctors, various kinds of clinics, and others. The comments asserted that addition of these categories to the definition would make the regulations more specific and all-inclusive and would assure compliance with storage and labeling requirements wherever prescription drugs are handled.

Section 205.3(g) of the final rule defines "wholesale distributor" to include anyone engaged in wholesale distribution of prescription drugs. The list of wholesale distributors enumerated in the guidelines is not exhaustive, but, as it clearly states, only illustrates the type of persons or firms who could, depending on the nature of their activity, be considered wholesale distributors under these provisions. The determinative consideration is the nature of the activity, not whether the entity is listed among the examples. If an activity is wholesale distribution and is not excluded under § 205.3(f) of the final rule, then the person engaged in the distribution is a wholesale distributor and his or her activity in interstate commerce must be licensed. FDA concludes that no purpose would be served by adding to the examples given in § 205.3(g).

14. One comment suggested that the phrase in proposed § 205.3(e) (now 205.3(g)), which included "retail pharmacies that conduct wholesale distributions" in the definition of wholesale distributors, be clarified. The comment asked that more guidance be given to determine when a retail pharmacy would be conducting wholesale distributions requiring licensure.

The nature of the operations of a retail pharmacy determines when it is a wholesale distributor. If its activities fit the definition of wholesale distribution and do not fall under any of the exclusions, the guidelines provide that the retail pharmacy is a wholesale distributor and must be licensed as such.

15. Another comment pointed out that the definition of "wholesale distributor" lists both "manufacturers" and "manufacturers' warehouses" as examples. The comment asked if both could be required to obtain licensure under the guidelines. The comment added that requiring a manufacturer to obtain licensure in a State if its warehouse is already licensed would be redundant, costly, and wasteful.

Both a manufacturer and its warehouse could be required to obtain a license as wholesale distributors under these guidelines if both are engaged in wholesale distributions as defined in § 205.3(f) of the final rule, and if the licensing State has no single license provision as permitted by § 205.5(b). Under § 205.5(b), States can set up a system permitting a single license for a business entity operating more than one facility in a State. Under such a system, one license would suffice for the regulation of a manufacturer and its warehouse, but both facilities would be subject to all of the licensing requirements.

D. Wholesale Drug Distributor Licensing Requirement

16. Several comments addressed the wholesale drug distributor licensing requirement described in proposed § 205.4. One comment asserted that the concept of interstate shipment is essential to the licensing requirement, but was not included in the section of the proposed guideline.

FDA does not agree that interstate shipment is a key element of the wholesaler licensing requirement under PDMA. The statute says that "[n]o person may engage in the wholesale distribution in interstate commerce [of prescription drugs] * * * in a State unless such person is licensed by the State in accordance with * * *" these guidelines (21 U.S.C. 353(e)(2)(A)). A product may be in interstate commerce before it has been shipped from one State to another. For example, a product manufactured in one State from components made in other States is in interstate commerce even if the finished product is shipped only within the State of manufacture. While FDA does not find interstate shipment to be an essential part of the licensing requirement, the agency does not find it necessary to otherwise clarify the licensing requirement by revising § 205.4 of the final rule to more closely reflect the statutory language. As revised, the final rule requires all wholesale distributors of prescription drugs who engage in interstate commerce in a State to be licensed by the State.

17. Numerous comments addressed the second sentence of proposed § 205.4. As proposed, that section said that the "mere shipment of prescription drugs into the State does not necessarily require licensing." Several comments argued that the word "necessarily" should be deleted from the sentence because it changes the meaning of the licensing requirement from that intended by Congress, as revealed in the legislative history of PDMA. Many other comments argued that the entire second

sentence of proposed § 205.4 should be removed from the final rule. These comments contend that the sentence could undermine the efforts of several States that currently license all wholesale drug distributors who ship prescription drugs into the State.

Proposed § 205.4 was derived from the discussion of the wholesale drug distributor licensing requirement in the legislative history accompanying PDMA. That discussion states, in pertinent part, that—

> Subparagraph 503(e)(2)(A) is intended to ensure that any person or firm engaging in the wholesale distribution of pharmaceuticals to any person or firm for resale shall be licensed in the state in which it does business and that the state licensing requirements meet certain minimum standards. The mere shipment of pharmaceuticals into a state would not trigger the requirement that the distributor be licensed in that state. However, the operation of a facility from which a wholesaler makes shipments outside the state would trigger the licensing requirement with respect to the state in which the facility is located.
>
> (H. Rept. 100-76, p. 17)

The legislative history indicates that when the Congress used the words "in the State" in section 503(e)(2)(A) of the act, it was referring to the physical location of the facility from which a wholesaler makes shipments. Thus, PDMA only requires that wholesalers who have a facility in a State be licensed by that State, and that wholesalers who have their facility outside the State, but who ship into the State, need not be licensed by that State pursuant to PDMA. However, States are free to require the licensing of any wholesaler who ships into the State, even if the wholesaler does not have a facility in the State, subject to all pertinent constitutional constraints. But the failure of such out-of-State wholesalers to have such a State license would not be a violation of section 503(e)(2)(A) of the act. The agency has concluded that the changes made to § 205.4 indicate the proper scope of PDMA, and that the second sentence of the proposed § 205.4 was unclear and is unnecessary.

E. Minimum Required Information for Licensure

18. Several comments discussed the provisions pertaining to minimum information required for licensure in proposed § 205.5. Some comments asserted that certain information required by § 205.5(a) is burdensome and unnecessary, because it is already a matter of public record. The comments contended that the State licensing authority is not entitled to have this information and that it is of no value to the State for the purpose of licensing. A few comments recommended that § 205.5(a) be revised to indicate that only information relating directly to activities conducted in the licensing State be required.

The agency has reviewed the information requirements and finds that the information does not go beyond the minimum necessary for a State licensing authority to enforce its licensing system. Furthermore, because the information is readily available in corporate records, it will not be overly burdensome for a wholesale distributor seeking licensure to supply it to the State.

The information required for licensure, described in § 205.5(a) of the final rule, goes no further than information that is pertinent to activities within the licensing State. In designing its licensing scheme, however, each state is free to require such additional information as it finds appropriate.

19. Several comments recommended against the single licensing provision in proposed § 205.5(b) that would allow a State to issue a single license to a business entity operating more than one wholesale distribution facility within the State. This section also allows a State to issue a single license to a parent entity that has divisions or affiliate companies conducting wholesale distributions at more than one location within the State. The comments argued that separate licenses would provide better accountability and more effective application of sanctions.

The agency disagrees. In cases where a State chooses to include a single licensing provision in its wholesaler licensing scheme, other sections of these guidelines will assure that all of the wholesale distribution facilities subject to the license are adequately regulated. Section 205.5(a) (1) through (4) requires that comprehensive information about the identity, nature, and location of a business be submitted to obtain a license. This information must include names and addresses of contact persons for all facilities used by the licensee. The agency believes that this information will provide a sufficient guarantee of accountability and effective application of sanctions under a single licensing provision. States are, of course, free to design single licensing schemes with other guarantees or to choose not to provide for single licensing at all.

20. Two comments recommended that proposed § 205.5(b) be amended to allow for license reciprocity. Under this plan, a State could grant wholesale distributor licenses based on reciprocal agreements with other States having comparable licensing requirements. The comments are concerned that States may refuse to license by reciprocity if the issue is not addressed in these guidelines.

Reciprocal licensing arrangements between State licensing authorities have traditionally been a matter within the exclusive discretion of the States. This final rule does not prohibit States from allowing license reciprocity with other States, and FDA would not discourage such cooperative arrangements, but the agency declines to include a reciprocal licensing provision in these minimum guidelines.

21. Two comments objected to proposed § 205.5(c), which states that the State licensing authority shall be notified of any changes in the information required under § 205.5(a) within 5 days of the change. Both comments found the 5-day time period to be unreasonably short. One comment suggested a 30-day reporting period, while the other argued that an annual report of such changes would be sufficient.

The agency is removing the 5-day notice requirement in § 205.5(c) and leaving the determination of the time period up to the State licensing authority. The State licensing authority receives and maintains the information required under § 205.5(a) and is thus in the best position to determine appropriate time frames for notification of changes in this information.

F. Qualifications of Personnel

22. One comment asserted that proposed § 205.6(b), which describes the right of a State licensing authority to deny a license that would not be "in the public interest," is too vague and should be removed.

FDA has provided a general—"in the public interest"—standard for the State licensing authority to deny a license. A State may choose to further define what it believes to be "in the public interest." The agency, however, declines to do so in these minimum guidelines.

23. Some comments objected to proposed § 205.7, which sets forth minimum personnel standards for licenses. The comments found the proposed minimum personnel standards to be an "unwarranted intrusion" into the right of wholesalers to choose their own employees. They recommended that § 205.7 be removed, saying that the requirement that personnel employed in wholesale distribution meet certain minimum education and experience standards goes beyond the intent of PDMA.

The agency disagrees with the contention that requiring a minimum education and training level for personnel employed in wholesale distribution is overly intrusive, inappropriate for these guidelines, or beyond the intent of Congress. The guidelines do not specify the kinds of education and experience required for personnel. Rather, the impact of the guidelines is to assure that personnel have an acceptable level of proficiency to carry out the licensing requirements. The agency believes that it is reasonable and appropriate to require that personnel involved in the handling, recordkeeping, and distribution of prescription drugs be competent to perform these important tasks.

G. Violations and Penalties

24. One comment suggested that removing the words "or any felony" from proposed § 205.8(a) would make the section on violations and penalties "more fair." The comment believed that the language in this section of the proposed rule could allow suspension or revocation of a wholesaler license for the criminal act of a single employee or for a felony involving a business that is completely separate and distinct from the corporation's wholesale distribution operation.

The agency believes that the determination of grounds for suspension or revocation of wholesaler licenses is a matter more appropriately left to the discretion of the State licensing authority. The agency is removing the words "or any felony" from § 205.8(a) of the final rule.

On its own initiative, FDA is revising proposed § 205.8(b), which sets forth the requirement that State licensing laws provide for suspension and revocation of licenses for violations of the licensing provisions. As proposed, § 205.8(b) implied that even insignificant or minor technical violations of wholesaler licensing laws could be the basis for suspension and revocation of licenses. As a minimum licensing requirement, FDA intended that significant or consistent infractions of State licensing provisions would be necessary to justify suspension and revocation of licenses. States are free to impose stricter requirements, but FDA should not do so. FDA is removing the word "any" from this section in the final rule to convey more accurately the agency's intended meaning, and is stating that State licensing laws shall provide for suspension or revocation of licenses "where appropriate," considering the facts of the violation in question.

H. Minimum Requirements for the Storage and Handling of Prescription Drugs

1. General Comments

25. Several comments objected to the reference to "current good manufacturing practices" in the introductory paragraph to proposed § 205.50. The comments asserted that the agency lacks the authority to impose such requirements on wholesale drug distributors. One comment contended that current good manufacturing practices are "not applicable to the proposed guidelines," and added that making them applicable would be beyond FDA's statutory authority. Another comment stated that the reference to current good manufacturing practices reflected the agency's "confusion." The comment argued that the agency is only entitled to regulate wholesaler operations in "housekeeping and stockkeeping" matters. The comment added that wholesalers deal only with drugs in containers sealed by the manufacturer, so wholesale distributors could not be subject to manufacturing standards.

FDA agrees that it may be confusing to refer, in § 205.50, to "current good manufacturing practices." The provision has been revised accordingly. FDA disagrees, however, that it lacks authority to apply current good manufacturing practice requirements to wholesalers, or that its authority over wholesalers extends only to "housekeeping and stockkeeping matters." Section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)) provides that a drug shall be deemed to be adulterated if "* * * the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to * * * current good manufacturing practice * * *." This section, through the operation of section 301(k) of the act (21 U.S.C. 331(k)), applies to drug wholesalers, retailers, pharmacies, and hospitals, as well as to manufacturers.

While the statutory current good manufacturing practice provisions of the act apply to wholesalers, FDA has not yet issued specific CGMP regulations covering traditional wholesaler activities. (FDA has previously stated that the CGMP regulations set forth in 21 CFR part 211 do not apply to wholesalers engaging in activities that are traditional to those establishments (see 43 FR 45027)). In the absence of specific CGMP regulations governing wholesaler activities, FDA advises that the minimum requirements in § 205.50 of these guidelines may be relied upon by wholesalers to meet applicable obligations under section 501(a)(2)(B) of the act. FDA intends, in the near future, to issue a guideline under § 10.90 of its procedural regulations (21 CFR 10.90), describing acceptable current good manufacturing practices for wholesalers that reflect the approach taken in this final rule.

26. Two comments made the general claim that the storage and handling provisions in proposed § 205.50 are too specific and restrictive. The comments argued that wholesale distributors should be free to choose systems and facility designs that will achieve the goals of PDMA.

The agency disagrees. Congress directed FDA to establish guidelines to "assure uniform standards covering the proper storage and handling of pharmaceuticals by wholesale distributors without regulatory duplication at the State and Federal level," and recommended consideration of the NABP model guidelines for licensing wholesalers in developing this guideline. (H. Rept. 100-76, p. 17). The storage and handling provisions of § 205.50 are responsive to this Congressional direction.

2. Facilities

27. Some comments asserted that proposed § 205.50(a)(3), which says that wholesale distribution facilities must have a designated area for the quarantine of outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs, is burdensome and would result in inefficient use of space by wholesale distributors. One comment stated that this problem could be minimized by specifying that one quarantine area for all substandard goods would be sufficient to comply with the minimum standards. Another comment suggested that deficient products could be identified and isolated by means of computerized inventory control, which would prevent inadvertent shipment without requiring separate quarantine space.

The agency has removed the word "separate" from § 205.50(a)(3), to clarify that a single quarantine area for outdated, damaged, deteriorated, misbranded, and adulterated prescription drugs is permissible. States can, of course, impose quarantine requirements that are stricter than this minimum guideline.

The agency does not believe that a computer-controlled quarantine system, which does not provide for physical separation of the drugs, is appropriate. A contaminated or adulterated prescription drug product is quarantined not only to ensure that it will not be

distributed to the consumer, but also to prevent it from coming into contact with other drugs it might contaminate. The agency has no knowledge of computer or other systems that would be as effective as physical separation in achieving these goals. In addition, the comments have not shown that providing a physical space for the separation of damaged goods would be burdensome.

28. One comment asked for clarification of the phrase "opened or used outside the care, custody, or control" as used in the description of quarantine procedures required under proposed § 205.50(a)(3). The comment is concerned that the phrase could be interpreted to require quarantine of prescription drugs in circumstances where there has been no compromise of the physical integrity of the drug.

The agency is removing this phrase from the final rule. Section 205.50(a)(3) of the final rule requires that prescription drugs whose immediate containers have been opened or apparently damaged must be quarantined. It is not necessary that there be actual injury to a drug product for quarantine to be required. A suggestion of product damage—such as a dirty or broken immediate product container—would trigger the quarantine requirement.

29. Another comment stated that repackaging facilities should be listed under § 205.50(a) to ensure that storage and labeling standards envisioned by PDMA will be complied with at all facilities where prescription drugs are handled.

The agency does not agree that it is necessary to add repackaging or other facilities under § 205.50(a). These provisions apply to all "wholesale distributors," specifically to any facility that stores, handles, warehouses, or holds prescription drugs for wholesale sale. The provisions thus have a broad application that clearly includes repackaging facilities.

3. Security

30. Two comments argued that the security provisions described at proposed § 205.50(b) are too restrictive and suggested more general alternatives. One of the comments particularly objected to the requirement of an "internal alarm system," noting that other types of systems could be as effective for a given wholesale distribution business. The comment said that wholesale distributors should be free to choose the best alarm system for their facility.

The agency agrees that the requirement that the alarm system be "internal" is too specific and goes beyond the minimum standards to be set by these guidelines. The agency is thus removing this word from § 205.50(b) (2) and (3). Wholesale distributors can choose any alarm system design, consistent with State law and regulations, that is adequate to detect unauthorized entry into the facility and to protect the prescription drug inventory from theft and diversion. The type of alarm system that will satisfy this requirement will depend upon the characteristics of the facility, the wholesale operation, and the State's licensing law.

4. Storage

31. One comment asserted that the storage provisions at § 205.50(c) were too specific and suggested that they be removed. The comment argued that it should be "satisfactory" for FDA to require only that prescription drugs be stored at appropriate temperatures and under proper conditions.

The agency's obligation to impose reasonable storage requirements for prescription drugs goes beyond the general standard suggested by this comment. Congress has mandated that FDA set standards for the storage and handling of prescription drugs by wholesale distributors. These are meant to be minimum standards, but they must be adequate to serve as direction to States in setting up their licensing systems. General statements about "appropriateness" and "adequacy" do not offer sufficient direction to the States. The requirements of § 205.50(c) conform to the storage provisions of the NABP model guideline and, as discussed in paragraph 28, are in line with congressional intent.

32. One comment stated that the storage requirements in proposed § 205.50(c) should specifically exclude wholesale distributors from responsibility for the condition of prescription drugs during transport.

While FDA recognizes practical difficulties involved in maintaining proper storage and handling conditions for prescription drugs in transit, it believes that prescription drugs must be properly handled at all points in the distribution process. Drugs that are improperly handled at any point in the distribution process are subject to enforcement action under the adulteration and misbranding provisions of the act.

It should be noted, however, that the proposed rule does not place the responsibility for assuring proper storage conditions for prescription drugs in transit on the wholesale distributor. The guidelines require that incoming shipping containers be visually inspected by the wholesale distributor for obvious defects or problems caused by improper storage conditions in transit or at any other point in their distribution. Based on this inspection, the wholesale distributor can elect to accept or to refuse acceptance of prescription drugs that appear to be adulterated or misbranded. Responsibility for the condition of shipped drugs does not fall upon the wholesale distributor until acceptance is made.

33. A number of comments asked for clarification of the meaning of "room temperature" as used in the storage requirements in § 205.50(c)(1). The comment asked if FDA meant "controlled room temperature," as the term is used in the United States Pharmacopeia (USP), or "ambient" room temperature. The comments noted that maintaining a "controlled" room temperature would require more sophisticated equipment and higher utility outlays than "ambient" room temperature.

Properly stored prescription drugs must be protected from temperature extremes at all times. To ensure that this minimum standard is met, the agency is requiring that storage facilities be maintained at "controlled room temperature," which is defined in the USP as a temperature that is maintained between 15 and 30 °C (USP XXII (1990), p. 7). This requirement can be met using standard building thermostats and conventional heating ventilating, and air conditioning systems. The agency does not expect this minimum requirement to be burdensome or necessitate the purchase of sophisticated, expensive equipment.

34. A number of comments objected to the proposed requirement in § 205.50(c)(2) that temperature and humidity be recorded on manual, mechanical, electromechanical, or electronic equipment or logs. The comments asserted that this requirement was too costly and argued that current distribution systems include safeguards to ensure proper storage of the few prescription drug products requiring special treatment.

The agency disagrees with the claim that requiring records of storage conditions will impose unnecessary burdens on wholesale distributors. Section 205.50(c)(2), which describes the requirement, does so in very broad terms. The provision allows for operators of facilities to choose from a wide range of possible recording and documentation methods, as long as the choice is appropriate for their facility.

One of the listed choices is a "manual" procedure by which temperature and humidity information could be written in a log by an employee who reads a thermometer and hydrometer. This option is neither expensive nor burdensome. Other options are similarly reasonable in cost and operation.

5. Examination of Goods and Vehicles

35. Several comments concerned the proposed requirement in § 205.50(d)(1) that wholesalers inspect incoming prescription drugs and delivery vehicles. All of the comments recommended that the scope of any inspection be limited to obvious, apparent defects that can be discovered through a visual inspection. The comments cited the difficulty of determining transit conditions, and questioned the ability and expertise of personnel employed by the wholesale distributor to discover latent defects in vehicles or prescription drugs. The comments argued that requiring more in-depth inspections would be burdensome, costly, and could interfere with commercial relationships.

Some comments noted that a drug may be shipped in more than one vehicle and that only the last one would be available for inspection by the wholesaler. Inspection of this last vehicle would not assure that all transit vehicles were sound and protective of product integrity.

The agency generally agrees with these assertions and has modified the proposed inspection provisions in the final rule so that inspection of the delivery vehicle is no longer required, and inspection of incoming prescription drugs is limited to a visual examination of shipping containers. This inspection should be aimed at detecting damage that would suggest possible contamination of the container's contents. Some level of inspection must be conducted by wholesale distributors to identify the prescription drug and to remove obviously damaged drugs from the distribution system. Wholesale distributors must employ personnel who can perform such inspections.

Moreover, it is in the wholesale distributor's interest to employ personnel who have the ability and expertise to conduct inspections of incoming prescription drug shipments adequate to detect drugs that are not suitable for acceptance. One of the stated purposes of requiring inspection of incoming shipments is to provide an opportunity for wholesale distributors to refuse acceptance of prescription drugs that are unfit for distribution. Once the wholesale distributor has inspected the shipped drugs and elected to accept them, the distributor is responsible for the condition of the drugs. Until that time, the shipper or manufacturer remains responsible for delivering a prescription drug product in acceptable condition.

6. Returned, Damaged, and Outdated Prescription Drugs

36. Several comments addressed proposed § 205.50(e), which describes the obligations of wholesalers with respect to returned, damaged, and outdated prescription drugs. The comments found the entire section to be redundant because its subject matter is covered in other FDA regulations. The comments cited 21 CFR 211.204 and 211.208 as examples of regulations that make proposed § 205.50(e) unnecessary. These are the sections of FDA's CGMP regulations that pertain, respectively, to returned drugs and salvaged drug products.

As discussed previously in this document, the CGMP regulations set forth in 21 CFR part 211 apply to wholesale distributors only when they are engaged in activities that fall outside the scope of a traditional wholesale distribution practice (see 43 FR at 45027). A wholesaler who chooses to handle returned, damaged, or outdated drugs within the scope of traditional wholesale distribution practice is not subject to the CGMP requirements in 21 CFR part 211. Thus, the provisions of § 205.50(e) are not redundant with respect to these procedures. Of course, as stated in § 205.50(j) of this final rule, a wholesaler who engages in repackaging, salvaging, reprocessing, or other manufacturing activities is subject to the CGMP requirements in 21 CFR part 211.

37. Another comment suggested that § 205.50(e) be removed, saying the role that pharmacists play in the distribution of prescription drugs to consumers makes the provision unnecessary.

The requirements of this section are intended to prevent distribution of potentially adulterated or misbranded prescription drugs to consumers. FDA agrees that pharmacists play an important role in achieving this goal, but this does not replace the need for wholesale distributors to take measures, such as those described in proposed § 205.50(e), to remove prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated from wholesale distribution.

38. One comment recommended that proposed § 205.50(e)(2), which requires that prescription drugs in damaged containers be quarantined and physically separated from other drugs, be removed. The comment stated that the requirements of this section are adequately covered by proposed § 205.50(e)(1), which deals with quarantine of adulterated drugs.

The agency disagrees that proposed § 205.50(e)(2) is unnecessary and should be removed. Section 205.50(e)(1) states the requirement that adulterated drug products be quarantined, but does not specifically address the situation, described in § 205.50(e)(2), where damage to prescription drug product containers suggests that the quality of their contents has been compromised. The agency expects that this is the most common circumstance where quarantine is necessary and believes that it must be specifically addressed in the guidelines.

39. Another comment requested that "palletized bulk shipments" be specifically excluded from the container inspection requirement in proposed § 205.50(e)(2), because the language could be interpreted to mean that a prescription drug product would have been quarantined, destroyed, or returned the moment the outer seal of the bulk shipment is opened.

The agency has clarified § 205.50(e)(2) in the final rule to require quarantine when the prescription drug product is damaged or the condition of the sealed immediate or sealed secondary drug container suggests that the contents have been damaged. The guideline does not require quarantine when only the outer seal of a bulk shipment of prescription drug products is opened and this seal is not the immediate or secondary container of the product.

40. Several comments objected to the proposed requirements in § 205.50(e) for handling returned prescription drugs, finding them confusing and inconsistent within the proposal. The comments contend that unlike proposed § 205.50(e)(1) and (e)(2), proposed § 205.50(e)(3) does not allow for return of substandard prescription drugs to the manufacturer as an option for wholesale distributors. Other comments asserted that the requirements of proposed § 205.50(e)(3) were inconsistent with guidance given in FDA's August 1, 1988, letter on PDMA to regulate industry and other interested persons with regard to the handling of returned prescription drugs. That letter provided that hospitals, health care entities, or charitable institutions could destroy unwanted prescription drugs or return them to the manufacturer. The August 1, 1988, letter was supplemented by November 3, 1988, and January 25, 1990, letters that permitted these entities to return prescription drugs under certain specified circumstances.

The agency agrees and has added language to permit the return of

prescription drugs to the manufacturer or supplier under § 205.50(e)(3) of the final rule.

41. Several comments objected to the requirement in proposed § 205.50(e)(3) that wholesale distributors perform "examination, testing, or other investigation" to determine that a prescription drug meets standards of safety, identity, quality, strength, and purity before returning the product to their shelves. Other comments contended that reshelving of returned drugs products after examination and testing is inconsistent with PDMA because it allows such products to be redistributed. Some of the comments questioned the analytic capability of distributors to comply with the requirement, saying that most wholesale distributors do not now conduct such testing. One comment argued that the requirement could fairly be imposed on manufacturers, but not on wholesalers, and another recommended that only a visual examination be required, with further investigations performed by the manufacturer if the distributor's visual inspection suggested a problem.

PDMA was enacted to decrease the risk that counterfeit, adulterated, misbranded, subpotent, or expired prescription drugs will reach the American consumer. It would violate the purpose of PDMA to allow returned prescription drugs to be distributed to the public without certain assurances. It is not inconsistent with PDMA, however, to permit reshelving of returned drugs that have been shown, through adequate testing measures, to meet acceptable standards.

Section 205.50(e)(3) of the final rule offers several options for the disposition of returned prescription drugs. Under the provision, the wholesaler is allowed to send the returned drug back to the manufacturer, destroy the returned drug, or reshelve it if it meets the testing standards outlined. The wholesaler is not required to choose the testing alternative. If the testing alternative is chosen, the wholesale distributor may elect to have a qualified outside laboratory conduct the analysis if it does not have the appropriate in-house capability. If the wholesale distributor chooses to conduct the testing procedures, pertinent CGMP requirements must be followed, and analyses should be adequate to detect problems with the drug's safety, identity, strength, quality, and purity. The agency does not want to limit testing to a visual examination that could fail to detect potential problems.

7. Recordkeeping

42. Several comments objected to the requirement in proposed § 205.50(f)(1)(iii) that expiration dates be included in disposition records, saying that the requirement would be costly, burdensome, and unnecessary. The comment added that current procedures, such as pharmacists checking dates before dispensing prescription drugs, are adequate to keep expired drugs out of the distribution system as intended by PDMA.

The comments provide adequate evidence that maintaining records of expiration dates is not current standard business practice in the industry, and that incorporating the requirement into current practice may impose some unnecessary burdens on wholesale distributors. The agency is removing proposed § 205.50(f)(1)(iii) and will not require that wholesale drug distributors maintain records of expiration dates of prescription drugs at this time. FDA may impose the requirement in the future if experience with these guidelines suggests it is necessary.

Although not required at this time, the agency encourages keeping records of drug expiration dates. In the agency's view, drug disposition records that include expiration dates are more complete, better facilitate recalls, and help to ensure that outdated drug products are not distributed to American consumers.

43. Several comments questioned the requirement in proposed § 205.50(f)(2), which states that records of the disposition of prescription drugs by wholesale distributors must be available for inspection by authorized officials for a period of 2 years following the expiration dates of such drugs. The comments suggested several alternatives to associating the retention period to the expiration date of the drug.

As previously mentioned, FDA has removed proposed § 205.50(f)(1)(iii), which set forth the requirement that wholesale distributors maintain records of expiration dates of prescription drugs. FDA will therefore not require a record retention time period linked to the expiration date of the drug. Instead, the agency is changing the pertinent provision to establish a record retention period of 2 years following the date of disposition of the prescription drug product. FDA has concluded that this retention period is sufficient to enable the agency to respond to public health emergencies related to the distribution of prescription drugs. The agency anticipates that a vast majority of prescription drugs would be consumed, expired, or destroyed within this time.

44. Several comments objected to proposed § 205.50(f)(3), which established the 24-hour time period allowed for making records available to an authorized official. Calling the time period "unreasonable," the comments suggested it be changed to 72 hours. The comments claimed this would make the requirement consistent with other, unspecified FDA record production requirements.

The provision has been changed in the final rule to allow 2 working days for the production of records that are not kept at the inspection site and are not immediately retrievable by computer or other means. The agency finds this to be a reasonable and appropriate time frame, and is consistent with analogous record production requirements of other government agencies (see, for example, 21 CFR 1304.04).

8. Written Policies and Procedures

45. Some comments addressed the written policies and procedures requirements for licensed wholesale drug distributors in proposed § 205.50(g). The comments agreed that it is appropriate to require a procedure for distributing oldest stock first, but objected to the requirement that deviation from this procedure be justified and documented, arguing that this provision would add to recordkeeping burdens and operating costs.

The agency believes that consistent stock rotation practices, as contemplated in proposed § 205.50(g)(1), are an effective means of ensuring that outdated stock will not be distributed to the consumer. The agency agrees that documentation of deviations from proper stock rotation practices goes beyond minimum standards and has removed the documentation requirement from the final rule. The guidelines now permit deviations from proper stock rotation practices if the deviation is temporary and appropriate.

46. Several comments addressed the proposed provisions in § 205.50(g) (2) and (3) on recall procedures. One comment suggested removal of § 205.50(g)(3)(iii), which requires that there be a procedure for recall of a prescription drug that is to be replaced by a superior product or package design. The comment noted that such a product withdrawal has little to do with health and safety and should be handled at the discretion of the manufacturer and distributor.

The agency agrees that product withdrawals undertaken to enable a manufacturer to replace one packaging design with another for reasons other

than the promotion of public health and safety goes beyond the scope of this rulemaking. The final rule reflects this change.

47. Several other comments asserted that procedures currently followed by drug manufacturers, wholesale and retail drug distributors, and pharmacists have been quite effective in dealing with recalls. The comments contended that the recall procedures proposed in § 205.50(g) (2) and (3) would impose substantial economic burdens on wholesale distributors without offering any significant improvement in recall accuracy and should therefore be removed from the final rule.

The agency disagrees. The agency believes it necessary that all entities involved in the distribution of prescription drugs have procedures in place for the efficient handling of drug recalls. In this way, each party will be aware of its role in removing potentially dangerous products from the drug distribution system. While prescription drug manufacturers have a primary role in implementing a drug recall, other entities in the drug distribution system must share responsibility for ensuring that all drugs subject to recall are prevented from reaching the American consumer.

48. One comment asserted that the requirement in § 205.50(g)(3) that a wholesale distributor have procedures sufficient to handle "any crisis" is too vague. The comment suggested that the section describe specific procedures to follow in case of strike, fire, flood, and natural disaster or emergency.

Specific procedures for crisis situations, such as a strike, fire, flood, or other natural disaster, are best left to the individual States. It would not be appropriate for the agency to attempt to describe plans for handling specific kinds of crises.

49. Two comments questioned the expertise of the wholesale distibutor for making the determination, required in proposed § 205.50(g)(5)(i), that prescription drug stock in wholesale distribution has an expiration date that is sufficient for a drug to get to the consumer. Both suggested that it would be more appropriate for a pharmacist or physician to make such a judgment.

The agency agrees that making the determination required under proposed § 205.50(g)(5)(i) may require a degree of judgment that is beyond the expertise of wholesale distribution personnel. The agency has therefore removed this requirement from the final rule.

51. One comment objected to the 2-year retention requirement, under proposed § 205.50(g)(5)(ii), for documents relating to the disposition of outdated stock. The comment recommended that requiring retention for 1 year from the expiration of the prescription drug would be consistent with FDA's CGMP regulations in 21 CFR part 211.

A 2-year record retention requirement is consistent with the other record retention provisions in these guidelines, and the agency is not persuaded that the change recommended by this comment is appropriate.

9. Responsibility

52. One comment suggested that § 205.50(h) be amended to clarify whether manufactures could be "held liable" for using unlicensed wholesale distributors. This comment was not specific as to what kind of liability was of concern.

The liability of manufacturers for actions in tort is governed by State law and is beyond the scope of this rulemaking.

53. Another comment asserted that the requirement in proposed § 205.50(h) that a list of qualifications of management, directors, and others in charge be maintained is an "unnecessary police state intrusion and subject to a difference of opinion." The comment said that such a list is irrelevant to achieving the goals of PDMA and would be difficult and costly for State boards to administer.

The agency disagrees with the contention that the list of responsible persons required by this section is unnecessary or excessively burdensome. The agency expects that a majority of wholesale distribution businesses would have this information readily available. The information required in this list is minimum information necessary for administration of these guidelines by the State licensing authorities.

10. Compliance With Other Laws

54. Proposed § 205.50(i) required wholesale drug distributors to operate in compliance with all applicable laws and regulations, including local laws. Proposed section 205.50(j) required wholesale drug distributors to comply with only applicable Federal and State laws relating to salvaging and reprocessing, but did not require wholesale drug distributors to comply with local laws relating to salvaging and reprocessing. On its own initiative, FDA is amending § 205.50 to make paragraphs (i) and (j) consistent, and to make it clear that wholesale drug distributors must comply with local laws relating to salvaging and reprocessing.

This substantive rule is being made effective immediately upon publication. The agency has found that there is good cause for this immediate effective date (see 5 U.S.C. 553(d)(3)). PDMA provides that the licensing requirements for wholesale distributors mandated by section 503(e)(2)(A) of the act (21 U.S.C. 353(e)(2)(A)) will not go into effect until the expiration of 2 years after the date this regulation is promulgated and takes effect (see section 8(b)(2) of PDMA). States and wholesalers will have 2 years in which to conform their activities to this rule before any enforcement action could be taken by FDA. Thus, the normal 30-day delay in effectiveness is subsumed in the 2-year delay mandated by PDMA. There is no need to have the rule take effect 2 years and 30 days after publication, because the 2-year period provides ample time for the States and wholesalers to conform their activities to the requirements of this rule. In addition, Congress has indicated its interest in having this rule promulgated expeditiously (see section 8(a)(2) of PDMA). The waiver of the 30-day delay is consistent with the congressional desire that FDA promulgate this rule in a short time.

List of Subjects in 21 CFR Part 205

Drugs, Labeling, Manufacturing, Warehouses, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, chapter I, subchapter C of title 21 of the Code of Federal Regulations is amended by adding new part 205 to read as follows:

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Sec.

205.1 Scope.
205.2 Purpose.
205.3 Definitions.
205.4 Wholesale drug distributor licensing requirement.
205.5 Minimum required information for licensure.
205.6 Minimum qualifications.
205.7 Personnel.
205.8 Violations and penalties.
205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

Authority: Secs. 501, 502, 503, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 371, 374).

§ 205.1 Scope.

This part applies to any person, partnership, corporation, or business firm in a State engaging in the wholesale

distribution of human prescription drugs in interstate commerce.

§ 205.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.

§ 205.3 Definitions.

(a) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(b) *Blood component* means that part of blood separated by physical or mechanical means.

(c) *Drug sample* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(d) *Manufacturer* means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(e) *Prescription drug* means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(f) *Wholesale distribution* and *wholesale distribution* means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

(g) "Wholesale distributor" means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

§ 205.4 Wholesale drug distributor licensing requirement.

Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.

§ 205.5 Minimum required information for licensure.

(a) The State licensing authority shall require the following minimum information from each wholesale drug distributor as part of the license described in § 205.4 and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) The State licensing authority may provide for a single license for a business entity operating more than one facility within that State, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within that State when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) Changes in any information in paragraph (a) of this section shall be submitted to the State licensing authority as required by such authority.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0251)

§ 205.6 Minimum qualifications.

(a) The State licensing authority shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:

(1) Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under Federal, State, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State licensing authority or to Federal, State, or local law enforcement officials those records required under this section; and

(8) Any other factors or qualifications the State licensing authority considers relevant to and consistent with the public health and safety.

(b) The State licensing authority shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

§ 205.7 Personnel.

The State licensing authority shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

§ 205.8 Violations and penalties.

(a) State licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties.

(b) State licensing laws shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

§ 205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

The State licensing law shall include the following minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(a) *Facilities.* All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) *Security.* (1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) *Storage.* All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all stored drugs.

(d) *Examination of materials.* (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) *Returned, damaged, and outdated prescription drugs.* (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) *Recordkeeping.* (1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 2 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not

electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

(g) *Written policies and procedures.* Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) *Responsible persons.* Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) *Compliance with Federal, State, and local law.* Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0251)

Dated: June 9, 1990.

James S. Benson

Acting Commissioner of Food and Drugs.

[FR Doc. 90-21618 Filed 9-13-90; 8:45 am]

BILLING CODE 4160-01-M

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

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December 31, 1991

Recd 1-9-92 mjf

Patricia S. Nolte
Legal Assistant
Office of the Attorney General
Public Finance Division
525 Park St. Suite 500
St. Paul, MN 55103

Attention: Patricia S. Nolte

RE: In the Matter of the Proposed Adoption of Rules of the Minnesota Board of Pharmacy Relating to the Licensing of Drug Manufacturers and Wholesale Distributors.

Dear Ms. Nolte:

Herewith submitted for your review under Minn. Stat. Subd. 14.26 and Minn. Rules pt. 2010.0300 are the following noncontroversial rulemaking documents of the Minnesota Board of Pharmacy in the above subject matter:

1. certificate of Board's authorizing resolution;

2. proposed rules with a certificate of approval as to form by the revisor of statutes;

3. notice of proposed adoption of rules without a public hearing;

4. statement of need and reasonableness in support of the proposed rules;

5. affidavit of mailing the notice of proposed adoption of rules without a public hearing along with the certificate of mailing list;

6. photocopy of the notice of proposed adoption of the rules without a public hearing as published in the State Register;

7. four copies of the rules as adopted;

8. certificate of Board's resolution adopting the rules;

9. findings of fact, conclusions, and order adopting the rules;

10. copy of written comments received (two were received); and

11. statement of compliance with rulemaking procedures (Declaration of Counsel).

In connection with the foregoing, please note that Minn. Rules pts. 2010.0300 A, B, N and O are not applicable to this proceeding. Also, enclosed herewith, and attached to the Statement of Need and Reasonableness, is the approval from the Commissioner of Finance regarding the fee involved.

Please note that, in the letter of approval by the Department of Finance, reference is made to other fee changes. Those other fee changes are the subject of a second rulemaking action by the Board. It was, in fact, this proposed fee changes that was recently withdrawn from review by your office due to a discovered defect in notifying the Chairs of the Senate Finance and House Appropriations Committees.

The withdrawn proposal is being republished after proper notice was given and will be refiled with your office at the appropriate time.

If there are any questions about this submission please notify me as soon as possible.

Very truly yours,

David E. Holmstrom
Executive Director

DEH:ekp

Enc. (11)

RECEIVED

JAN 09 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg. - Suite 500
525 Park Street
St. Paul, MN 55103

CERTIFICATE OF BOARD OF PHARMACY

AUTHORIZING RESOLUTION

I, David E. Holmstrom, do hereby certify that I am the Executive Director of the Minnesota 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 duly and properly called and held on the 24th day of January, 1991, that a quorum was present at the meeting, that a majority of those present voted for the resolution and that the resolution is set forth in the minutes of the meeting and has not been rescinded or modified:

> "RESOLVED, that David E. Holmstrom, Executive Director of the Minnesota Board of Pharmacy, be and hereby is granted the authority and is directed to sign and publish a notice of intent to adopt rules without a public hearing for the purpose of amending existing Board rules by adding new sections relating to the registration of wholesale drug distributors. If the statutorily required number of persons request a hearing in response to the notice, Mr. Holmstrom is also granted the authority and is directed to call such a hearing and to perform any and all acts incidental thereto, including the requesting of the appointment of an Administrative Law Judge, and complying with all the applicable provisions of the Minnesota Administrative Procedures Act and the rules of the Office of Administrative Hearings."

IN WITNESS WHEREOF, I have hereunto subscribed my name this 24th day of Jan., 1991.

STATE OF MINNESOTA

BOARD OF PHARMACY

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Director

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

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

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Minnesota Board of Pharmacy (hereinafter "Board") proposes to adopt Minn. Rules pts. 6800.1400, through 6800.1440 relating to the licensing of drug manufacturers and wholesale drug distributors. A copy of the proposed amendments is attached to this Notice. One additional free copy is available from the Board upon request. Procedures for the adoption of noncontroversial rules found in Minn. Stat. 14.22 to 14.28 (1986) will be used.

THE PUBLIC IS HEREBY ADVISED that:

1. They have 30 days in which to submit comment in support of or in opposition to the proposed amendments, and comment is encouraged.

2. Each comment should identify the portion of the proposed rules addressed, the reason for the comments, and any change proposed.

3. In addition to submitting comments, interested persons may request in writing during the 30 day comment period that a hearing be held on the proposed rule amendment.

4. All comments, including requests for a public hearing, shall be submitted to David E. Holmstrom, Executive Director, Minnesota Board of Pharmacy, Room 107, Colonial Office Building, 2700 University Avenue West, St. Paul, Minnesota 55114-1079.

5. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any change proposed.

6. The proposed amendments may be modified if the modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language.

7. A public hearing will be held only if 25 or more persons submit in writing requests for a hearing on the proposed rules or a portion thereof within 30 days of this notice. If a hearing is required, it will be held in accordance with the provisions of Minn. Stat. 14.131 to 14.20 (1986).

8. Under the procedure for adopting noncontroversial rules, the Board must submit any action on its rules to the Attorney General for review of the form and legality of the rule change. Notice of the date of submission of the proposed amendments to the Attorney General for review will be mailed to any person requesting to receive the notice. Requests to receive notice must be submitted to Mr. Holmstrom at the above address.

9. Authority to adopt Minn. Rules pts. 6800.1400 through 6800.1440 is contained in Minn. Stat. sections 151.06 sub. 1 (c) and 151.42, et seq. Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

10. The approval of the Commissioner of Finance for adoption of rules relating to fees is required by Minn. Stat. section 214.06, subd. 1. A document entitled "Commissioner of Finance Approval" in which the Commissioner has approved the proposed Rules pt. 6800.1400 is available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

11. Promulgation of the proposed fee changes will not result in the expenditure of public monies by local public bodies and will not affect agricultural land in the state. Likewise, it is not believed that the changes will have a quantitative or qualitative impact on any small business. Persons representing small businesses are nevertheless invited to participate in the rulemaking process.

12. Any rules adopted pursuant to this proceeding shall be effective five working days after publication in the State Register of a notice of the adoption of the rules.

August 15, 1989

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Director

Board of Pharmacy

Proposed Permanent Rules Relating to Drug Manufacturers and Wholesalers Licensing

Rules as Proposed

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE.

Subpart 1. **Licensing; fees.** Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public or patient shall annually be licensed by the board. Upon the filing of an application ~~therefor~~, and upon payment of a fee of ~~$100~~ $150 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; $150 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; $125 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; $100 for manufacturing or wholesale distribution of prescription medical gases only; and $75 for licensed pharmacies engaged in wholesale distribution, the board may issue or renew a license in such form as it may prescribe to the manufacturer or ~~wholesaler~~ wholesale distributor. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire at midnight on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with ~~a fee of $100~~ the applicable fee. Renewal applications received after June 1 shall be subject to a late filing fee of ~~$25~~ one-half of the renewal fee in addition to the amount of the renewal fee.

Subp. 2. **Prohibition.** No license may be issued to any manufacturer or wholesale distributor whose intended place of business is a personal residence.

Subp. 3. **Separate licenses required.** A separate license

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is required for each separate location where drugs are stored within this state. Out-of-state wholesale drug distributors shipping drugs into Minnesota who do not maintain or operate a physical facility within Minnesota are not required to license each separate location from which drugs are shipped to Minnesota, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.

6800.1410 MINIMUM INFORMATION REQUIRED FOR LICENSURE.

The following information is required from each wholesale drug distributor applying for licensure or renewal:

A. the name, full business address, and telephone number of the licensee;

B. all trade or business names used by the licensee;

C. addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of drugs;

D. whether the ownership or operation is a partnership, corporation, or sole proprietorship; and

E. the name of the owner and operator of the licensee, including:

(1) if an individual, the name of the individual;

(2) if a partnership, the name of each partner, and the name of the partnership;

(3) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(4) if a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.

Changes in any information in items A to E shall be submitted to the board within 30 days of the change.

6800.1420 MINIMUM QUALIFICATIONS.

The board may deny, suspend, revoke, or refuse to renew any license for a wholesale drug distributor based on the board's finding of any of the following factors:

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by Revisor _____

A. any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. any felony convictions of the applicant under federal, state, or local laws;

C. the lack of previous experience on the part of the applicant in the manufacture or distribution of drugs, including controlled substances;

D. the furnishing by the applicant of false or fradulent material in any application made in connection with drug manufacturing or distribution;

E. the suspension or revocation by federal, state, or local government bodies of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. the lack of compliance by the applicant with licensing requirements under previously granted licenses, if any;

G. the lack of compliance by the applicant with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials those records required under this part; and

H. the lack of compliance by the applicant with requirements for the storage and handling of drugs as specified in part 6800.1440.

6800.1430 PERSONNEL.

Each wholesale drug distributor shall establish training programs which, when combined with the education and experience of the personnel, will enable the personnel to assume responsibility for positions related to compliance with state and federal licensing requirements.

6800.1440 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS AND FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS.

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by Revisor _____

Subpart 1. **Application.** The minimum requirements in this part apply to all wholesale drug distributors located in this state and to their officers, agents, representatives, and employees.

Subp. 2. **Incorporation by reference.** "United States Pharmacopeia/National Formulary" means the United States Pharmacopeia/National Formulary published by the United States Pharmacopeial Convention Inc. (Rockville, Maryland, 1990), which is incorporated by reference. The United States Pharmacopeia/National Formulary is subject to frequent change. The book is available for inspection and copying at the Biomedical Library, University of Minnesota, Diehl Hall, 505 Essex Street S.E., Minneapolis, Minnesota 55455, or through the Minitex interlibrary loan system.

Subp. 3. **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

A. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

B. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

C. have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

D. be maintained in a clean and orderly condition; and

E. be free from infestation by insects, rodents, birds, or vermin of any kind.

Subp. 4. **Security.** The requirements in items A to C govern security.

A. All facilities used for wholesale drug distribution shall be secure from unauthorized entry as follows:

(1) access from outside the premises shall be kept to a minimum and be well-controlled;

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by Revisor _____

(2) the outside perimeter of the premises shall be well-lighted; and

(3) entry into areas where prescription drugs are held shall be limited to authorized personnel.

B. All facilities shall be equipped with an alarm system to detect entry after hours.

C. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Subp. 5. **Storage.** Items A to D govern storage of drugs.

A. All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary.

B. If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.

D. The record keeping requirements in subpart 8 shall be followed for all stored drugs.

Subp. 6. **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of drugs that have been damaged in storage

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or held under improper conditions.

The record keeping requirements in subpart 8 shall be followed for all incoming and outgoing drugs.

Subp. 7. **Returned, damaged, and outdated drugs.** Items A to D govern returned, damaged, outdated, deteriorated, misbranded, and adulterated drugs.

A. Drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier.

B. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be physically separated from other drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

D. The record keeping requirements in subpart 8 shall be followed for all damaged, outdated, deteriorated, misbranded, or adulterated drugs.

Subp. 8. **Record keeping.** Items A to C govern record keeping.

A. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

Approved
by Revisor _____

These records shall include the following information:

(1) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) the identity and quantity of the drugs received and distributed or disposed of; and

(3) the dates of receipt and distribution or other disposition of the drugs.

B. Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

C. Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Subp. 9. **Written policies and procedures.** Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs. They must include policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include the written policies and procedures described in items A to D.

A. A procedure where the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

B. A procedure to be followed for handling recalls and withdrawals of drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

Approved
by Revisor _____

(1) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;

(2) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

C. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

Subp. 10. **Responsible persons.** Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Subp. 11. **Compliance with federal, state, and local law.** Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

Wholesale drug distributors shall permit the board of pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect both their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

Approved
by Revisor _____

Wholesale drug distributors who deal in controlled substances shall register with the board of pharmacy and with the Drug Enforcement Administration, and shall comply with all applicable state, local, and Drug Enforcement Administration regulations.

Subp. 12. **Salvaging and reprocessing.** Wholesale drug distributors are subject to any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing, including Code of Federal Regulations, title 21, parts 207, 210, and 211, and Minnesota Statutes, section 151.39.

Approved
by Revisor _____

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Drug Manufacturers and Wholesalers Licensing

AGENCY: Board of Pharmacy

MINNESOTA RULES: Chapter 6800

INCORPORATION BY REFERENCE:

Part 6800.1440, subpart 2: United States Pharmacopeia/National Formulary, published by United States Pharmacopeial Convention Inc. (Rockville, Maryland, 1990). Available through Minitex interlibrary loan system and Biomedical Library, University of Minnesota.

The attached rules are approved for publication in the State Register

by Carla M. Riehle

Carla M. Riehle
Assistant Revisor

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : MINNESOTA BOARD OF PHARMACY

DATE : August 29, 1991

TO : Representative Wayne A. Simoneau
Room 365 State Office Building
St. Paul, Minnesota 55155

FROM : David E. Holmstrom
Executive Director

PHONE : 642-0541

SUBJECT : Proposed Rule Changes Involving Fees

In accordance with the requirements of Minnesota Statutes 16A.128, subdivision 2a, a copy of Board of Pharmacy rules relating to the licensure of drug wholesalers and manufacturers, which includes sections relating to licensure fees, is being sent to you. Also enclosed is a copy of the Notice of Intent to Adopt Rules Without a Public Hearing.

These rules were required under statutes passed during the 1990 Legislative Session and also by federal legislation on this subject.

DEH:ekp

Enc.

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : MINNESOTA BOARD OF PHARMACY

DATE : August 29, 1991

TO : Senator Eugene R. Merriam
122 State Capitol
St. Paul, Minnesota 55155

FROM : David E. Holmstrom
Executive Director

PHONE : 642-0541

SUBJECT : Proposed Rule Changes Involving Fees

In accordance with the requirements of Minnesota Statutes 16A.128, subdivision 2a, a copy of Board of Pharmacy rules relating to the licensure of drug wholesalers and manufacturers, which includes sections relating to licensure fees, is being sent to you. Also enclosed is a copy of the Notice of Intent to Adopt Rules Without a Public Hearing.

These rules were required under statutes passed during the 1990 Legislative Session and also by federal legislation on this subject.

DEH:ekp

Enc.

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Amendments Relating to the Licensing of Drug Manufacturers and Wholesale Distributors

AFFIDAVIT OF MAILING THE NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING AND CERTIFICATION OF MAILING LIST

Patricia Eggers, being sworn says:

I hereby certify that the list of persons and associations who have requested, pursuant to Minnesota Statutes, sections 14.14, subdivision 1a and 14.22 or 14.30, that their names be placed on the Board of Pharmacy rulemaking mailing list is accurate, complete, and current as of this 11th day of September, 1991.

That on the 11th day of September 1991, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Intent to Adopt A Rule Without a Public Hearing by depositing in the United States mail, a copy thereof, with postage prepaid, to all persons and associations on the aforementioned mailing list.

Patricia Eggers

Subscribed and sworn to before me
this 11th day of Sept., 1991.

BETTY L. MESSERVEY
NOTARY PUBLIC-MINNESOTA
DAKOTA COUNTY
MY COMMISSION EXPIRES AUGUST 23, 1995

Betty L. Messervey

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Amendments Relating to the Licensing of Drug Manufacturers and Drug Wholesalers.

CERTIFICATE OF MAILING LIST

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minnesota Statutes, section 14.14, subdivision 12, and 14.22, that their names be placed on file with and be maintained by the Board of Pharmacy for the purpose of receiving notice of the proposed adoption of rules by this agency is accurate and complete as of 9:00 A.M., this 11th day of September, 1991.

I hereby further certify that the list attached hereto and made a part hereof constitutes the complete list of such persons who have so registered with the Minnesota Board of Pharmacy.

Patricia Eggers

Proposed Rules

Pursuant to Minn. Stat. §§ 14.22, an agency may propose to adopt, amend, suspend or repeal rules without first holding a public hearing, as long as the agency determines that the rules will be noncontroversial in nature. The agency must first publish a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register*. The notice must advise the public:

1. that they have 30 days in which to submit comment on the proposed rules;
2. that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;
3. of the manner in which persons shall request a hearing on the proposed rules; and
4. that the rule may be modified if the modifications are supported by the data and views submitted.

If, during the 30-day comment period, 25 or more persons submit to the agency a written request for a hearing of the proposed rules, the agency must proceed under the provisions of §§ 14.14-14.20, which state that if an agency decides to hold a public hearing, it must publish a notice of intent in the *State Register*.

Pursuant to Minn. Stat. §§ 14.29 and 14.30, agencies may propose emergency rules under certain circumstances. Proposed emergency rules are published in the *State Register* and, for at least 25 days thereafter, interested persons may submit data and views in writing to the proposing agency.

Board of Pharmacy

Proposed Permanent Rules Relating to Drug Manufacturers and Wholesalers Licensing

Notice of Intent to Adopt Rules Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Board of Pharmacy (hereinafter "Board") proposes to adopt *Minnesota Rules* pts. 6800.1400, through 6800.1440 relating to the licensing of drug manufacturers and wholesale drug distributors. A copy of the proposed amendments is attached to this Notice. One additional free copy is available from the Board upon request. Procedures for the adoption of noncontroversial rules found in *Minnesota Statutes* 14.22 to 14.28 (1986) will be used.

THE PUBLIC IS HEREBY ADVISED that:

1. They have 30 days in which to submit comment in support of or in opposition to the proposed amendments, and comment is encouraged.

2. Each comment should identify the portion of the proposed rules addressed, the reason for the comments, and any change proposed.

3. In addition to submitting comments, interested persons may request in writing during the 30 day comment period that a hearing be held on the proposed rule amendment.

4. All comments, including requests for a public hearing, shall be submitted to:

David E. Holmstrom
Executive Director
Minnesota Board of Pharmacy
Room 107, Colonial Office Building
2700 University Avenue West
St. Paul, Minnesota 55114-1079

5. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any change proposed.

6. The proposed amendments may be modified if the modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language.

7. A public hearing will be held only if 25 or more persons submit in writing requests for a hearing on the proposed rules or a portion thereof within 30 days of this notice. If a hearing is required, it will be held in accordance with the provisions of *Minnesota Statutes* 14.131 to 14.20 (1986).

8. Under the procedure for adopting noncontroversial rules, the Board must submit any action on its rules to the Attorney General for review of the form and legality of the rule change. Notice of the date of submission of the proposed amendments to the Attorney General for review will be mailed to any person requesting to receive the notice. Requests to receive notice must be submitted to Mr. Holmstrom at the above address.

9. Authority to adopt *Minnesota Rules* pts. 6800.1400 through 6800.1440 is contained in *Minnesota Statutes* sections 151.06 sub. 1 (c) and 151.42, et seq. Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

10. The approval of the Commissioner of Finance for adoption of rules relating to fees is required by *Minnesota Statutes* section 214.06, subd. 1. A document entitled "Commissioner of Finance Approval" in which the Commissioner has approved the proposed Rules pt. 6800.1400 is available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

11. Promulgation of the proposed fee changes will not result in the expenditure of public monies by local public bodies and will not affect agricultural land in the state. Likewise, it is not believed that the changes will have a quantitative or qualitative impact on any small business. Persons representing small businesses are nevertheless invited to participate in the rulemaking process.

12. Any rules adopted pursuant to this proceeding shall be effective five working days after publication in the *State Register* of a notice of the adoption of the rules.

David E. Holmstrom
Executive Director

Rules as Proposed

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE.

Subpart 1. **Licensing; fees.** Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public or patient shall annually be licensed by the board. Upon the filing of an application ~~therefor~~, and upon payment of a fee of ~~$100~~ $150 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; $150 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; $125 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; $100 for manufacturing or wholesale distribution of prescription medical gases only; and $75 for licensed pharmacies engaged in wholesale distribution, the board may issue or renew a license in such form as it may prescribe to the manufacturer or ~~wholesaler~~ wholesale distributor. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire at midnight on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with ~~a fee of $100~~ the applicable fee. Renewal applications received after June 1 shall be subject to a late filing fee of ~~$25~~ one-half of the renewal fee in addition to the amount of the renewal fee.

Subp. 2. **Prohibition.** No license may be issued to any manufacturer or wholesale distributor whose intended place of business is a personal residence.

Subp. 3. **Separate licenses required.** A separate license is required for each separate location where drugs are stored within this state. Out-of-state wholesale drug distributors shipping drugs into Minnesota who do not maintain or operate a physical facility within Minnesota are not required to license each separate location from which drugs are shipped to Minnesota, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.

6800.1410 MINIMUM INFORMATION REQUIRED FOR LICENSURE.

The following information is required from each wholesale drug distributor applying for licensure or renewal:

A. the name, full business address, and telephone number of the licensee;

B. all trade or business names used by the licensee;

C. addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of drugs;

D. whether the ownership or operation is a partnership, corporation, or sole proprietorship; and

E. the name of the owner and operator of the licensee, including:

(1) if an individual, the name of the individual;

(2) if a partnership, the name of each partner, and the name of the partnership;

(3) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(4) if a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.

Changes in any information in items A to E shall be submitted to the board within 30 days of the change.

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." **ADOPTED RULES SECTION** — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

6800.1420 MINIMUM QUALIFICATIONS.

The board may deny, suspend, revoke, or refuse to renew any license for a wholesale drug distributor based on the board's finding of any of the following factors:

A. any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. any felony convictions of the applicant under federal, state, or local laws;

C. the lack of previous experience on the part of the applicant in the manufacture or distribution of drugs, including controlled substances;

D. the furnishing by the applicant of false or fradulent material in any application made in connection with drug manufacturing or distribution;

E. the suspension or revocation by federal, state, or local government bodies of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. the lack of compliance by the applicant with licensing requirements under previously granted licenses, if any;

G. the lack of compliance by the applicant with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials those records required under this part; and

H. the lack of compliance by the applicant with requirements for the storage and handling of drugs as specified in part 6800.1440.

6800.1430 PERSONNEL.

Each wholesale drug distributor shall establish training programs which, when combined with the education and experience of the personnel, will enable the personnel to assume responsibility for positions related to compliance with state and federal licensing requirements.

6800.1440 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS AND FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS.

Subpart 1. **Application.** The minimum requirements in this part apply to all wholesale drug distributors located in this state and to their officers, agents, representatives, and employees.

Subp. 2. **Incorporation by reference.** "United States Pharmacopeia/National Formulary" means the United States Pharmacopeia/National Formulary published by the United States Pharmacopeial Convention Inc. (Rockville, Maryland, 1990), which is incorporated by reference. The United States Pharmacopeia/National Formulary is subject to frequent change. The book is available for inspection and copying at the Biomedical Library, University of Minnesota, Diehl Hall, 505 Essex Street S.E., Minneapolis, Minnesota 55455, or through the Minitex interlibrary loan system.

Subp. 3. **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

A. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

B. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

C. have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

D. be maintained in a clean and orderly condition; and

E. be free from infestation by insects, rodents, birds, or vermin of any kind.

Subp. 4. **Security.** The requirements in items A to C govern security.

A. All facilities used for wholesale drug distribution shall be secure from unauthorized entry as follows:

(1) access from outside the premises shall be kept to a minimum and be well-controlled;

(2) the outside perimeter of the premises shall be well-lighted; and

(3) entry into areas where prescription drugs are held shall be limited to authorized personnel.

B. All facilities shall be equipped with an alarm system to detect entry after hours.

C. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Subp. 5. **Storage.** Items A to D govern storage of drugs.

A. All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary.

B. If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.

D. The record keeping requirements in subpart 8 shall be followed for all stored drugs.

Subp. 6. **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

The record keeping requirements in subpart 8 shall be followed for all incoming and outgoing drugs.

Subp. 7. **Returned, damaged, and outdated drugs.** Items A to D govern returned, damaged, outdated, deteriorated, misbranded, and adulterated drugs.

A. Drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier.

B. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be physically separated from other drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

D. The record keeping requirements in subpart 8 shall be followed for all damaged, outdated, deteriorated, misbranded, or adulterated drugs.

Subp. 8. **Record keeping.** Items A to C govern record keeping.

A. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

(1) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) the identity and quantity of the drugs received and distributed or disposed of; and

(3) the dates of receipt and distribution or other disposition of the drugs.

B. Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

C. Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Subp. 9. **Written policies and procedures.** Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs. They must include

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." **ADOPTED RULES SECTION** — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include the written policies and procedures described in items A to D.

A. A procedure where the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

B. A procedure to be followed for handling recalls and withdrawals of drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;

(2) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

C. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

Subp. 10. **Responsible persons.** Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Subp. 11. **Compliance with federal, state, and local law.** Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

Wholesale drug distributors shall permit the board of pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect both their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

Wholesale drug distributors who deal in controlled substances shall register with the board of pharmacy and with the Drug Enforcement Administration, and shall comply with all applicable state, local, and Drug Enforcement Administration regulations.

Subp. 12. **Salvaging and reprocessing.** Wholesale drug distributors are subject to any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing, including Code of Federal Regulations, title 21, parts 207, 210, and 211, and *Minnesota Statutes*, section 151.39.

Pollution Control Agency

Proposed Permanent Rules Relating to Water Quality Permit Fees

Notice of Intent to Adopt Rules Without a Public Hearing; and Intent to Adopt Rules With Public Hearing Upon Receiving 25 or More Requests for a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Pollution Control Agency (Agency) intends to adopt the above-entitled rule amendments without a public hearing following the procedures set forth in the Administrative Procedure Act in *Minnesota Statutes* §§ 14.22 to 14.28 (1990). The Agency's authority to adopt the rule is set forth in *Minnesota Statutes* § 116.07., subd. 4d (1990); and *Minnesota Statutes* § 16A.128 (1990).

The proposed rules follow this notice. All persons have until 4:30 p.m. on October 18, 1991, to submit comments on the proposed rule amendments. Comments from all interested or affected parties are encouraged. Any person can submit a written request for a public hearing on the rules within the comment period. Each comment should identify the portion of the proposed rules addressed, reason for the comment, and proposed changes.

If 25 or more persons submit a written request for a public hearing within the comment period a public hearing will be held. The hearing will be canceled if fewer than 25 persons request a hearing.

Comments or written requests for a public hearing must be submitted to:

Scott R. Thompson
Water Quality Division

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Relating to the licensure of drug Manufacturers and Wholesale Distributors

CERTIFICATE OF THE MINNESOTA BOARD OF PHARMACY RESOLUTION ADOPTING THE RULE

I, B. Patricia DeLaPointe, do hereby certify that I am a member and the President of the Minnesota 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 the resolution adopted at a meeting of the Board, duly and properly called and held on the 10th day of December, 1991, that a quorum was present, and that a majority of those present voted for the resolution which has not been rescinded or modified.

> "RESOLVED, that the proposed rule relating to the licensure of drug manufacturers and wholesale distributors be and hereby is approved and adopted pursuant to authority vested in the Board of Pharmacy by Minnesota Statutes 151.06, subdivision 1 (c) and 151.50 and that David E. Holmstrom, Executive Director of the Board of Pharmacy, be and hereby is authorized to sign the Findings of Fact, Conclusion, and Order adopting the rule and further is authorized to modify the rule, if necessary, to obtain the approval of the rule by the Attorney General and is authorized to perform the necessary acts to provide that this rule will have the force and effect of law."

IN WITNESS WHEREOF, I have hereunto subscribed my name this 10th day of Dec, 1991.

B. Patricia DeLaPointe
President of the Board

Attest by one other Board member

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Relating to the Licensing of Drug Manufacturers and Wholesale Distributors.

FINDINGS OF FACT, CONCLUSIONS, AND ORDER ADOPTING RULE WITHOUT PUBLIC HEARING

(1) Notice of the Board's intent to adopt the above-entitled rule was published in the State Register on September 16, 1991 and was sent by United States mail to all persons on the list maintained by the agency pursuant to Minnesota Statutes, sections 14.14, subdivision 1a and 14.22 on September 11, 1991. (3) On August 29, 1991, Notice was sent to the chairs of the Senate Finance and House Appropriations Committees as required by M.S. 16A.128, subd. 2a. (2) The statement of need and reasonableness was prepared before the notice of intent to adopt a rule without a public hearing was mailed to all persons on the rulemaking mailing list and published in the State Register and was available to the public. A copy of the Statement of Need and Reasonableness was mailed to the office of the Legislative Committee to Review Administrative Rules as required by Minnesota Statutes 14.131 and 14.23.

(4) All persons were given the opportunity to submit comment on the rule for 30 days after notice of proposed rulemaking. (5) No requests for a public hearing on the rule were received by the agency.

Only two submissions or comments on the rule were received by the agency. Copies of those submissions are attached hereto. (7) No requests for notice of submission to the attorney general were received by the agency.

Based on the comments and evidence in the record before the agency, I find the following:

The above-captioned rule as it relates to drug Manufacturers and Wholesale Distributors is needed and reasonable. (8)

The Task Force referenced in Minnesota Statutes 151.45 was established with the make-up called for in the statute, and not only reviewed and commented on, but actually drafted the rules herein being proposed and adopted by the Board.

Comments submitted by the National Wholesale Druggists Association recommended changes in parts 6800.1400 and 6800.1430.

The Board believes that the language proposed in 6800.1400 is sufficiently clear to prevent any misunderstanding on the part of drug manufacturers as to the necessity to obtain licensure with the Board. Therefore, the Board declines to make this recommended change.

(6) A minor change was made to part 6800.1430, in response to the comments submitted by the National Wholesale Druggists Association. NWDA proposed that it be made clear that personnel at each licensed wholesale drug distributor be educated and/or trained to be responsible for performing assigned functions relating to the legal requirements for drug quality, safety and effectiveness.

Federal requirements in 21 CFR 205.7 mandate that states develop requirements for education and training of personnel, enabling them to comply with state licensing requirements. It can be argued that providing assurances of drug quality, safety and security, as suggested by NWDA, is incorporated within the "state licensing requirements" through these very rules. Therefore, the Board does not object to the incorporation of the

language proposed by NWDA into the Board's proposed language in section 6800.1430. The Board finds NWDA's comments in this regard were reasonable and helped clarify the Board's intent.

The Board further finds that the change made to 6800.1430 was not a "substantial change" in that the change:

(1) does not affect classes of persons who could not reasonably have been expected to comment on the proposed rule as originally noticed;

(2) does not introduce significant new subject matter which a reasonable person, on the basis of the proposed rule as originally noticed, would not have anticipated would occur during the rulemaking proceeding; and

(3) does not make a major substantive change that was not raised by the proposed rule as originally noticed in such a way as to invite reaction.

NOW, THEREFORE, IT IS ORDERED that the rules identified as Relating to the licensing of drug Manufacturers and Wholesale Distributors are adopted this 10th day of December, 1991, pursuant to authority vested in the Board by Minnesota Statutes, section 151.06. (9)

David Holtzman

Executive Director
Minnesota Board of Pharmacy

Minnesota Wholesale Druggist's Association



October 10, 1991

Mr. David Holmstrom
Executive Director
Minnesota State Board of Pharmacy
2700 University Avenue West
Room 107, Colonial Office Bldg.
St. Paul, Minnesota 55114

Dear David:

I am responding favorably to the Board of Pharmacy Publication of Drug Wholesalers Licensing Rules on behalf of the Minnesota Wholesale Druggist's Association of which I am currently serving the office of President.

Please let this serve as a Policy Statement from MWDA agreeing with the proposed rules and thereby endorse its entirety without need for a Public Hearing.

Very truly yours,

Kent F. Olson/ms
President
Minnesota Wholesale Druggist's Association

Fax Fax Fax Fax Fax

NWDA

Fax Fax Fax Fax Fax

Date 10-10-91

Deliver to:

name David Holmstrom

company

co. fax number 612-643-3530

Number of pages (including cover sheet) 3

Transmitted by Roberta Dean for Sherry Haber

Comments

NWDA fax number: 703/548-2184 (automatic 24 hours)

NWDA phone number: 703/684-6400

National Wholesale Druggists' Association, P.O. Box 238, Alexandria, VA 22313 Phone #703/684-6400 Fax #703/548-2184

TEL No. Oct 10,91 10:21 P.01

Joseph E. Polastri, Chairman
Charles S. Trefrey, President

National Wholesale Druggists' Association

P.O. Box 238, Alexandria, VA 22313 Fax #703/548-2184
105 Oronoco Street, Alexandria, VA 22314 • 703/684-6400

October 9, 1991

David E. Holmstrom
Executive Director
Minnesota Board of Pharmacy
Room 107, Colonial Office Building
2700 University Avenue West
St. Paul, MN 55114-1079

Dear Mr. Holmstrom:

This is in response to the Board of Pharmacy's Proposed Permanent Rules Relating to Drug Manufacturers and Wholesalers Licensing (6800.1400 - 1440) appearing in the State Register dated September 16, 1991.

These will constitute the recommendations of the National Wholesale Druggists' Association (NWDA) located in Alexandria, Virginia. NWDA is the only national trade association for full-line, full-service drug wholesalers. The association represents 84 drug wholesale corporations which operate about 260 distribution centers in the United States. Today, approximately 77 percent of prescription drugs are distributed through drug wholesalers in the U.S and more than 95 percent of those sales are through NWDA members.

In general, NWDA is supportive of the Proposed Rules and finds no need to request a Public Hearing. We do, however, offer comment on two provisions as follows:

- The Proposed Rule 6800.1400 is identified as "DRUG MANUFACTURER OR WHOLESALER LICENSE." The use of the term "or" seems to imply that a manufacturer need only seek licensure as a manufacturer. Under the Prescription Drug Marketing Act (PDMA), a manufacturer is included in the definition of "wholesale drug distributor." The U.S. Food and Drug Administration (FDA) has stated publicly

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MEMBER ASSOCIATION

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on several occasions that a manufacturer must obtain a wholesaler license for its distribution facilities regardless of what other types of licenses or registrations that manufacturer is required to obtain. This should be somehow clarified so that all affected parties are cognizant of their obligations under both federal and state law.

- Proposed Rule 6800.1430, "PERSONNEL," refers to the establishment of "training programs" which we believe implies a formality considerably beyond what is stated in the FDA Guidelines. Our recommendation would be to modify the Proposed Rule as follows:

> "Each wholesale drug distributor shall require each person employed in any prescription drug wholesale activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law," and to assume responsibility for positions related to compliance with state & federal licensing requirements

With the above modifications, NWDA believes the Proposed Rules to be appropriate under the statute and that the State of Minnesota will be in compliance with the PDMA licensing requirements.

NWDA appreciates the opportunity to provide comments for the record on these Proposed Rules. If you need further information or clarification of any the points raised, please do not hesitate to call on me. I may be reached at (703) 684-6400, ext. 233.

Sincerely,

Sherry Haber

Sherry Haber
Director of Government Affairs

TEL NO. Oct 10,91 10:22 P.03

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed
Rule Amendments Relating to the
licensing of Drug Manufacturers
and Wholesale Distributors

DECLARATION OF
COUNSEL

I, Robert T. Holley, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rules, and the supporting rulemaking record, and that, based on my examination, the Administrative Procedures Act and Minnesota Rules, chapter 2010 have been followed. Any exceptions are listed below. For Attorney General billing purposes, the four-digit docket client code is 0484.

Robert T. Holley

Robert T. Holley
Special Assistant
Attorney General

Dated: January 9, 1992

RECEIVED

JAN 09 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg. - Suite 500
525 Park Street
St. Paul, MN 55103