DEPARTMENT OF STATE

DIVISION OF PROFESSIONAL REGULATION

2500 Board of Pharmacy

Statutory Authority: 24 Delaware Code, Section 2509 (24 **Del.C.** §2509)
24 **DE Admin. Code** 2500

FINAL

ORDER

The Board of Pharmacy ("Board") was established to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications and such other materials as may be used in the diagnosis and treatment of injury, and prevention of illness and disease. The Board is authorized by 24 **Del.C.** §2509 to make, adopt, amend, and repeal regulations as necessary to effectuate those objectives.

Pursuant to 24 **Del.C.** §2509, the Board proposed broad amendments to its regulation 8.0 Requirements for Obtaining a Permit to Distribute Drugs on a Wholesale Basis. The proposed amendments to regulation 8.0 were prompted by recent changes in the National Association of Boards of Pharmacy's Model Rules for the Licensure of Wholesale Distributors (Model Rules). The proposed amendments incorporate some, but not all, of the changes to the Model Rules. Minor grammatical, typographic, or stylistic amendments are also included.

Pursuant to 29 **Del.C.** §10115, notice of the proposed amendments and public hearing was published in the *Delaware Register of Regulations*, Volume 10, Issue 6, at page 972 on December 1, 2006. However, notice was not published in two (2) Delaware newspapers of general circulation as required by 29 **Del.C.** §10115, so the public hearing could not be conducted on January 17, 2007 as originally scheduled. The public hearing was, therefore, rescheduled for March 21, 2007. Notice of the rescheduled hearing was published in the *Delaware Register of Regulations*, Volume 10, Issue 9, at page 1468 on March 1, 2007.

Summary of the Evidence and Information Submitted

A representative for the Pharmaceutical Research and Manufacturers of America (PhRMA) appeared and provided comment, substantially as follows: PhRMA welcomes the proposed changes to Regulation 8.0, but they are concerned that the requirements for licensing are not strict enough. PhRMA suggests the Board consider requiring a surety bond for wholesalers and a rigorous criminal background check. PhRMA believes the Board should impose a pedigree requirement. Finally, PhRMA is of the opinion that manufacturers that seek wholesale licensure should not be subject to the new, stricter standards but to the federal minimum standards. A more detailed written position statement was provided to the Board and is on file in the Board office.

Findings of Fact

The Board finds that adoption of the proposed amendments is a necessary response to changing wholesale distribution industry practices and is in the best interest of public health, safety, and welfare.

Decision and Effective Date

The Board hereby adopts the proposed amendments to the regulations to be effective 10 days following final publication of this order in the *Register of Regulations*.

Text and Citation

The text of the final regulations is attached hereto as Exhibit A and is formatted to show the amendments. A non-marked version of the regulations as amended is attached hereto as Exhibit B.

IT IS SO ORDERED this 21st day of March, 2007 by the Board of Pharmacy of the State of Delaware.

Don Holst, R.Ph., Chair	Sebastian Hamilton, R.Ph.
Angelo Chiari, R.Ph., Vice Chair	Geoffrey Christ, R.Ph.
Carolyn Calio	David Bonar
Sandra Robinson, R.Ph.	

2500 Board of Pharmacy; 8.0 Requirements for Obtaining a Permit to Distribute Drugs on a Wholesale Basis

(Break in Continuity of Sections)

8.0 Requirements for Obtaining a Permit to Distribute Drugs on a Wholesale Basis

8.1 ~~Purpose. The purpose of this regulation is to implement the provisions of the prescription Drug Marketing Act of 1987 by defining the minimum standards, terms, and conditions for which a permit may be issued to persons who engage in wholesale distribution of (prescription) drugs within the State of Delaware.~~

~~8.2~~ Definitions. Words and terms defined in Title 24, Chapter 25 of the **Delaware Code** are applicable to these regulations. The following additional words and terms, when used within Regulation 8.0, shall have the following meaning unless the context clearly indicates otherwise:

"Authorized agent" means a pharmacist who is trained and qualified to inspect against the Board's standards and has been designated by the Board to conduct inspections on its behalf.

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

~~**"Blood Component"** means that part of blood separated by physical or mechanical means.~~

~~**"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.~~

"Entity" means corporations, companies, associations, firms, partnerships, societies and joint-stock companies, but does not include individuals.

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

~~**"Person"** means an individual, partnership, corporation, business firm, or a sole proprietorship.~~

~~**"Prescription Drug"** means any 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.~~

~~**"Wholesale Distribution"** means distribution of prescription drugs to persons other than a consumer or patient, but does not include:~~

~~**"Intracompany Sales"**, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity:~~

~~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;~~

~~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;~~

~~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;~~

~~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, except that the gross dollar value of such transfers shall not exceed five (5) percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12 consecutive month period;~~

~~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;~~

~~The distribution of drug samples by manufacturers' representatives or distributors' representatives; or~~

~~The sale, purchase, or trade of blood and blood components intended for transfusion.~~

~~**"Wholesale distributor"** means anyone 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.~~

8.1.1 Clarification of Statutory Exceptions from the Definition of Wholesale Distribution.

8.1.1.1 "Common control," as used in 24 **Del.C.** §2502(t)(3), 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.

8.1.1.2 "Emergency medical distributions," as provided for by 24 **Del.C.** §2502(t)(4), may include, but is not limited to: transfers of a drug between a wholesale distributor and pharmacy to alleviate a temporary shortage of the drug arising from delays in or interruption of distribution schedules arranged in the ordinary course of business; or transfers of drugs by a licensed pharmacy or limited services permit holder to another licensed pharmacy or limited services permit holder. In all cases, transfers conducted pursuant to emergency medical reasons may be reviewed by the Board. Such transfers shall not exceed 5.0% of the total drug sales revenue of either the transferor or transferee pharmacy during any 12 consecutive month period.

8.2 Permit Requirements. Wholesale distributors that operate within this state, whether or not the wholesale distributor is physically located within this state, must first be granted a permit by the Board.

8.2.1 Wholesale distributors shall provide information required by a Board-approved application, including but not limited to:

8.2.1.1 All trade or business names used by the permittee, e.g. "doing business as" or "formerly known as." Trade or business names cannot be identical to the name used by another, unrelated wholesale distributor permitted to purchase drugs in the state;

8.2.1.2 Name of the owner or owners and operator or operators of the permittee (if not the same entity), including:

8.2.1.2.1 If an individual: the full name, business address, Social Security number, and date of birth;

8.2.1.2.2 If a partnership: the full name, business address, Social Security number, and date of birth of each partner; the name of the partnership; and the partnership's federal employer identification number;

8.2.1.2.3 If a corporation not publicly traded on a major stock exchange: the full name, business address, Social Security number, date of birth, and title of corporate officers and directors; the corporate name or names; the name of the state of incorporation; the corporation's federal employer identification number; the name of the parent company, if any; and the full name, business address, and Social Security number of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC;

8.2.1.2.4 If a sole proprietorship: the full name, business address, Social Security number, and date of birth of the sole proprietor; and the name and federal employer identification number of the business entity;

8.2.1.3 Assurance that a copy of the wholesale distributor's written policies and procedures, required by Regulation 8.6, will be available at the distributor's site for review prior to licensure and thereafter for inspection;

8.2.1.4 A list of all state and federal licenses, registrations, or permits, including the license, registration, or permit numbers, authorizing the wholesale distributor to purchase, possess, and distribute drugs;

8.2.1.5 A list of all disciplinary actions by state and federal agencies against the

wholesale distributor, as well as any actions against principals, owners, directors, or officers;

8.2.1.6 A plan and full description of each facility and warehouse, including all locations utilized for drug storage, distribution, or both. The description should include the following:

8.2.1.6.1 square footage;

8.2.1.6.2 security and alarm system descriptions;

8.2.1.6.3 terms of lease or ownership;

8.2.1.6.4 quarantined area for damaged, outdated, deteriorated, misbranded, or adulterated drugs; and

8.2.1.6.5 temperature and humidity controls.

8.2.1.7 A copy of the deed or lease for the property on which the wholesale distributor's establishment is located. If leased, the lease must be for an original term of not less than one (1) calendar year.

8.2.2 Changes in any information required by Regulation 8.2.1 shall be submitted to the Board within 30 days after such change.

8.2.3 Wholesale distributors shall submit an application fee to be determined by the Division of Professional Regulation.

8.2.4 Wholesale distribution facilities must undergo an inspection by the Board or its authorized agent prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board.

8.2.5 Wholesale distributors must publicly display or have readily available all permits and the most recent inspection report administered by the Board.

8.2.6 All out-of-state wholesale distributors must comply with all rules, regulations, and laws of the state in which they are physically located and of all states in which they hold permits, including this state.

8.2.7 Information submitted to the Board or its authorized agent that is considered trade secret or proprietary information as defined under Delaware privacy, trade secret, and proprietary information laws shall be maintained accordingly and as required by law and be exempt from public disclosure.

~~8.3 Permit Requirements. Every wholesale distributor located in the State of Delaware who engages in wholesale distribution out of or within this State will be issued a permit by the Delaware Board of Pharmacy in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.~~

~~8.4 Wholesale Distributor Permit Requirement~~

~~8.4.1 The Delaware Board of Pharmacy requires the following from each wholesale drug distributor as part of the initial permit procedure and as part of any renewal of such permit:~~

~~8.4.1.1 The name, full business address, and telephone number of the permittee;~~

~~8.4.1.2 All trade or business names used by the permittee;~~

~~8.4.1.3 Addresses, telephone numbers, and the names of contact persons for the facility used by the permittee for the storage, handling, and distribution of prescription drugs;~~

~~8.4.1.4 The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship); and~~

~~8.4.1.5 The name(s) of the owner and/or operator of the permittee, including:~~

~~8.4.1.5.1If a person, the name of the person;~~

~~8.4.1.5.2If a partnership, the name of each partner, and the name of the partnership;~~

~~8.4.1.5.3If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation, and the name of the parent company, if any;~~

~~8.4.1.5.4If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.~~

~~8.4.1.6 Submission of a policy and procedures manual pertinent to employee qualifications and training.~~

~~8.4.2 Changes in any information in this section shall be submitted to the Board of Pharmacy within 30 days after such change.~~

8.~~5~~3 Minimum Qualifications. The ~~Delaware~~ Board ~~of Pharmacy~~ will consider the following factors in determining eligibility for granting a permit to persons who engage in the wholesale distribution of ~~prescription~~ drugs:

8.~~5~~3.1 Any c~~onvictions of the applicant under any~~ findings by the Board that the appl;icant has violated or been disciplined by a regulatory agency in any state violating Federal, State, or local laws relating t~~o drug samples, wholesale or retail~~ drug distribution~~, or distribution of controlled substances~~;

8.~~5~~3.2 Any ~~felony~~ criminal convictions of the applicant under Federal, State, or local laws;

8.3.2.1 The Board shall consider the results of a criminal and financial background check of the applicant to determine if an applicant or others associated with the ownership, management, or operations of the wholesale distributor have committed criminal acts that would constitute grounds for denial of licensure. The background check shall include all key personnel involved in the operations of the wholesale distributor. Key personnel includes, but is not limited to: the most senior individual or individuals responsible for facility operations, purchasing, and inventory control and the individual or individuals he or they report to; if the applicant is a corporation and not publicly traded on a major stock exchange, key personnel also includes: key company officers, key management, principals, and key owners. The background check will be conducted in compliance with any applicable federal, state, or local laws. The background check will be conducted at the applicant's expense and will be sufficient to include all states of residence since the individuals have been adults. Manufacturers shall be exempt from criminal and financial background checks.

8.~~5~~3.3 The applicant's past experience in the manufacture or distribution of ~~prescription~~ drugs, including controlled substances;

8.~~5~~3.4 The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

8.~~5~~3.5 Suspension,sanction, or revocation by Federal, State, or local government ~~of~~ against any license or permit currently or previously held by the applicant ~~for the manufacture or distribution of any drugs, including controlled substances~~ or any of its owners for violations of any Federal, State, or local laws relating to drugs;

8.~~5~~3.6 Compliance with the requirements of ~~this~~ Delaware regulations under previously granted wholesale distribution permits, if any;

8.~~5~~3.7 Compliance with the requirements to maintain and/or make available to the ~~State~~ Board ~~authority~~ or to Federal, State, or local law enforcement officials those records required to be maintained by wholesale ~~drug~~ distributors.

8.3.8 Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

8.~~6~~4 Personnel. As a condition for receiving and retaining a wholesale drug distributor permit, the permittee shall:

8.4.1 ~~r~~Require each ~~person~~ individual employed in any ~~prescription~~ drug wholesale distribution activity to have any combination of education, training, and experience~~, or any combination thereof,~~ sufficient for that ~~person~~ individual 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~~.~~;

8.4.2 ~~The permittee must m~~Maintain records evidencing that each employee has been trained in accordance with the policy and procedure manual required by Regulation 8.6 ~~approved at the time of the issuance of the permit~~. These records shall be kept for two (2) years from the date of separation of the employee from the company. Records on all current employees shall be available at any time for inspection~~.~~;

8.4.3 Designate a registered agent in this state for service of process. Any permitted wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State of Delaware to be its true and lawful attorney, upon whom may be served all legal processes in any action or proceeding against such permitted wholesale distributor growing out of or arising from its activities in this state. A copy of any such service of process shall be mailed to the wholesale distributor by the Board via certified mail, return receipt requested, postage prepaid, at the address the permitted wholesale distributor has designated on its application for permit in Delaware. If a wholesale distributor is not permitted in Delaware, service on the Secretary of State only shall be sufficient service; and

8.4.4 Ensure that all key personnel have at least an associate’s degree from an accredited institution of higher education acceptable to the Board or a minimum of two (2) years of verifiable full-time managerial or supervisory experience acceptable to the Board in a licensed pharmacy or wholesale distributor where the individual’s responsibilities included, but were not limited to, recordkeeping, storage, and shipment of drugs. Key personnel includes, but is not limited to: the most senior individual or individuals responsible for facility operations, purchasing, and inventory control and the individual or individuals he or they report to; if the applicant is

a corporation and not publicly traded on a major stock exchange, key personnel also includes: key company officers, key management, principals, and key owners.

8.5 Minimum Requirements for the Storage and Handling of Drugs and for Establishment and Maintenance of Drug Records. The following are required for the storage, handling, transport, and shipment of drugs and for the establishment and maintenance of wholesale distribution records by permitted wholesale distributors and their officers, agents, representatives, and employees:

8.5.1 Facilities at which drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

8.5.1.1 Be of suitable construction to ensure that all drugs in the facility are maintained in accordance with each drug's product labeling or in compliance with the *United States Pharmacopeia/National Formulary (USP/NF);*

8.5.1.2 Be of suitable size and construction to allow for cleaning, maintenance, and proper wholesale distribution operations;

8.5.1.3 Have adequate storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions. If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in the USP/NF, to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of drugs;

8.5.1.4 Have a quarantine area for storage of drugs that are: outdated; damaged; deteriorated; misbranded; adulterated; counterfeit, or suspected of being counterfeit; otherwise unfit for distribution; or are in immediate or sealed secondary containers that have been opened;

8.5.1.5 Be maintained in a clean and orderly condition;

8.5.1.6 Be free from infestation of any kind; and

8.5.1.7 Be a commercial location and not a personal dwelling or residence.

8.5.2 Wholesale distributors shall:

8.5.2.1 Provide for the secure and confidential storage of information with restricted access by developing and adhering to policies and procedures to protect the integrity and confidentiality of the information;

8.5.2.2 Maintain records of sources of the drugs, the identity and quantity of the drugs received and distributed or disposed of, and the date of receipt and distribution or other disposition of the drugs;

8.5.2.3 Maintain records of all personnel and their training; and

8.5.2.4 Have records available for inspection and photocopying by the authorized federal, state, or local law enforcement agency officials for a period of three (3) years following the disposition of the drugs. Records shall be kept at the inspection site or must be immediately retrievable by computer or other electronic means. Records may be kept at a central location apart from the inspection site and not electronically retrievable. Such records shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

8.5.3 Wholesale distributors involved in the distribution of controlled substances shall be duly registered with Drug Enforcement Administration (DEA) and the appropriate state agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment, and distribution of controlled substances.

8.6 Written Policies and Procedures. Wholesale distributors shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping, and distribution of drugs. Wholesale distributors shall also establish, maintain, and adhere to written policies and procedures for: identifying, recording, and reporting losses or thefts; for correcting all errors and inaccuracies in inventories; and implementing and maintaining a continuous quality improvement system. Wholesale distributors shall include in their written policies and procedures the following:

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

8.6.1.1 Any action initiated at the request of FDA or any other federal, state, local law enforcement, or other government agency including the Board; or

8.6.1.2 Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

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

8.6.3 A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal, state, or local laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs.

8.6.4 A procedure for reporting criminal or suspected criminal activities involving the inventory of a drug or drugs to the Board, FDA, and, if applicable, DEA and the Office of Narcotics and Dangerous Drugs (ONDD) within three (3) business days.

8.7 ~~Facilities. All facilities at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:~~

~~8.7.1 Be of suitable size and construction to facilitate cleaning, maintenance and proper operations.~~

~~8.7.2 Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.~~

~~8.7.3 Have a quarantined area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated.~~

~~8.7.4 Be maintained in a cleaned and orderly condition; and be free from infestation of insects, rodents, birds, or vermin of any kind.~~

Salvaging and Reprocessing. Wholesale distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to drug product salvaging or reprocessing.

8.8 ~~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).~~ Security and Anti-Counterfeiting. All facilities:

8.8.1 ~~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.~~Shall be secure from unauthorized entry;

8.8.1.1 Access from outside the premises shall be kept to a minimum and be well-controlled,

8.8.1.2 The outside perimeter of the premises shall be well-lighted, and

8.8.1.3 Entry into areas where drugs are held shall be limited to authorized personnel.

8.8.2 ~~Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.~~Shall be equipped with a security system that will provide suitable protection against theft and diversion. Appropriateness of security systems is subject to approval by the Board or its authorized agent. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

8.8.3 Shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting;

8.8.4 Shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other federal, state, or local law enforcement officials; and

8.8.5 May possess and maintain, in good working order, technology and equipment that allows the wholesale distributor to authenticate, track, and trace drugs. The technology and equipment shall satisfy standards set by the Board and shall only be used to conduct tracking, tracing, and authentication of drugs. Wholesale distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

8.9 ~~Record Keeping Requirements. Wholesale drug distributors shall establish and maintain inventory and records. Records shall include the following information:~~

~~8.9.1 Sources of the drugs, the identity and quantity of the drugs received and distributed or disposed of, and the date of receipt and distribution or other disposition of the drugs.~~

8.9.2 Records for all personnel and training.

8.9.3 All 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 the disposition of the drugs.

8.9.4 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.

8.10 Written Policies and Procedures

8.10.1 There shall be written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of drugs including policies for identifying, recording, and reporting losses or thefts, and for correcting all errors, inaccuracies, and inventories. There shall be:

8.10.1.1A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

8.10.1.2A procedure must be established for the handling of recalls and withdrawals of manufacturer/distributor drugs due to any action initiated at the request of the manufacturer, the FDA or other Federal, State, or local enforcement or government agencies.

8.10.1.3A procedure whereby drugs that are outdated, damaged, deteriorated, misbranded or adulterated are physically separated until they are destroyed or returned to their supplier.

8.11 Salvaging and Reprocessing. Compliance with applicable Federal, State, or local law or regulations relating to drug product salvaging is required.

8.12 Security

8.12.1 All facilities shall be secured from unauthorized entry.

8.12.2 The outside of the premises shall be well lighted.

8.12.3 Entry into areas where drugs are held shall be limited to authorized personnel.

8.12.4 All facilities shall be equipped with an alarm system to detect entry after hours subject to approval by the Secretary of the Board.

8.12.5 There must be a security system that will provide suitable protection against theft and diversions. When appropriate, the system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.