



IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
FAX: 208-334-3536

FACILITY

<Facility Name>
 <Street Address>
 <City, ST Zip Code>
 <Phone Number>
 Owner: <Name>

LICENSE

License No: <License #>
 License Type: Wholesaler of Legend Medical Devices

Inspection Type:	Annual	Inspection Date:	
Result:			

Notes:
Remarks:

Checklist Results

27.01.06.041 - FACILITY REQUIREMENTS	
Question	Answer
27.01.06.041 - Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must:	Not Answered
27.01.06.041.01 - Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;	Not Answered
27.01.06.041.02 - Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;	Not Answered
27.01.06.041.03 - Quarantine. Are Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened;	Not Answered
27.01.06.041.04 - Maintenance Requirements. Be maintained in a clean and orderly condition	Not Answered
27.01.06.041.05 - Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind	Not Answered
27.01.06.042 - FACILITY SECURITY REQUIREMENTS	
Question	Answer
27.01.06.042 - Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:	Not Answered
27.01.06.042.01 - Access from Outside. Access from outside the premises must be kept to a minimum and well controlled;	Not Answered
27.01.06.042.02 - Perimeter Lighting. The outside perimeter of the premises must be well lighted;	Not Answered
27.01.06.042.03 - Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel;	Not Answered
27.01.06.042.04 - Alarm Systems. Facilities must be equipped with an alarm system to detect entry after hours	Not Answered
27.01.06.042.05 - Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering	Not Answered
27.01.06.043 / 044 - DRUG STORAGE & SHIPMENT RQMTS	
Question	Answer
27.01.06.043 - Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs.	Not Answered
27.01.06.044.01 - Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution.	Not Answered
27.01.06.044.02 - Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents.	Not Answered
27.01.06.045 - QUARANTINE	
Question	Answer
27.01.06.045 - Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other	Not

drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor.	Answered
27.01.06.045.01 -Container Adulteration. Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantine	Not Answered
27.01.06.045.02 -Other Conditions Requiring Quarantine. Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.	Not Answered
27.01.06.046 -RECORDKEEPING REQUIREMENTS	
Question	Answer
27.01.06.046 -Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs.	Not Answered
27.01.06.046.01 - Record Contents. The records must include at least:	Not Answered
27.01.06.046.01.a - 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;	Not Answered
27.01.06.046.01.b - The identity and quantity of the drugs received and distributed or disposed of;	Not Answered
27.01.06.046.01.c - The dates of receipt and distribution or other disposition of the drugs.	Not Answered
27.01.06.046.02 - Records Maintenance. Records may be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location.	Not Answered
27.01.06.047.01 - PERSONNEL	
Question	Answer
27.01.06.047.01 - Responsible Person Designees. A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications.	Not Answered
27.01.06.048 - POLICIES AND PROCEDURES	
Question	Answer
27.01.06.048 - Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories, and as necessary to ensure compliance with the following:	Not Answered
27.01.06.048.01 - Distribution of Oldest Approved Stock First. The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation.	Not Answered
27.01.06.048.02 - Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: (a) A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; (b) A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or (c) An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.	Not Answered
27.01.06.048.03 - Crisis Preparation. Wholesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency.	Not Answered

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.

Berk Fraser

Date/Time

Signature of Owner/Representative