State of Utah
Department of Commerce

Division of Occupational and Professional Licensing
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CLASS C Wholesaler/Distributer Manufacturer

INSPECTION

☐ New Opening ☐ Regular

INFORMATION

(Please print clearly or type information)

Facility Name: _____ Date: _____

Facility Owner(s): _____
(owner/sole proprietor name or names of all partners/LLC partners or name of corporation and state of incorporation, attach a separate sheet if necessary)

Facility License Number: _____ Expiration Date: _____

Controlled Substance License Number: (if applicable) _____ Expiration Date: _____

FDA Registration Number: (if applicable) _____ Expiration Date: _____

DEA Registration Number: (if applicable) _____ Expiration Date: _____

Facility FEIN Number: _____

Facility Telephone: _____ Facility Fax: _____

Facility Street Address: _____

City: _____ State: _____ Zip: _____

Hours: (Monday-Friday) _____ (Saturday) _____ (Sunday) _____

Responsible Person: _____ Telephone Number: _____
(responsible person must be 21, must have 3 years pharmacy/wholesaler experience, must be in a full-time manager position, must be actively involved in and aware of daily operations, must be physically present at the facility during business hours, and must only be a designated representative of one licensee at a time)

INSPECTION

	Yes	No	
1.	☐	☐	Every pharmaceutical wholesaler or manufacturer that engages in the wholesale distribution and manufacturing of drugs or medical devices located in this state shall be licensed by the Division. The facility will/has obtained a separate license for each separate location engaged in the distribution or manufacturing of prescription drugs. (Manufacturers distributing only their own FDA-approved prescription drugs or co-licensed product shall satisfy this requirement by registering their establishment with the FDA pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205, including any amendments thereto, to the Division.) [UAC R156-17b-615 (1-2)]
2.	☐	☐	The facility will be/is of suitable size and construction to facilitate cleaning, maintenance and proper operations. [UAC R156-17b-615 (7) (a)]
3.	☐	☐	The facility will/does have storage areas are provided with adequate lighting, ventilation, sanitation, space, equipment, and security conditions. [UAC R156-17b-615 (7) (b)]
4.	☐	☐	The facility will/does have the ability to control temperature and humidity within tolerances required by all prescription drugs and prescription drug precursors handles or used in the distribution or manufacturing activities. [UAC R156-17b-615 (7) (c)]

	Yes	No	
5.	☐	☐	The facility will/does have a quarantine area for storage of prescription drugs and prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, opened or unsealed containers that have once been appropriately sealed or closed or in any other way unsuitable for use or entry into distribution or manufacturing. [UAC R156-17b-615 (7) (d)]
6.	☐	☐	The facility will be/is maintained in a clean and orderly condition. [UAC R156-17b-615 (7) (e)]
7.	☐	☐	The facility will be/is free from infestation by insects, rodents, birds or vermin of any kind. [UAC R156-17b-615 (7) (f)]
8.	☐	☐	The facility will be/is secure from unauthorized entry. [UAC R156-17b-615 (8) (a)]
9.	☐	☐	The facility will/does limit access from the outside to a minimum in conformance with local building codes, life and safety codes and control access to persons, to ensure unauthorized entry is not made. [UAC R156-17b-615 (8) (b)]
10.	☐	☐	The facility will/does limit entry into areas where prescriptions drugs or prescription drug precursors are held to authorized persons who have a need to be in those areas. [UAC R156-17b-615 (8) (c)]
11.	☐	☐	The facility will be/is well lighted on the outside perimeter. [UAC R156-17b-615 (8) (d)]
12.	☐	☐	The facility will be/is equipped with an alarm system to permit detection of entry and notification of appropriate authorities at all times when the facility is not occupied for the purpose of engaging in distribution or manufacturing of prescription drugs. [UAC R156-17b-615 (8) (e)]
13.	☐	☐	The facility will be/is equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors. [UAC R156-17b-615 (8) (f)]
14.	☐	☐	The facility provides for the storage of prescription drugs and prescription drug precursors in accordance with the following: [UAC R156-17b-615 (9)] ☐ All prescription drugs and prescription drug precursors are stored at the appropriate temperature, humidity and other conditions in accordance with labeling of such prescription drug or prescription drug precursors or with the requirements in the USP-NF; ☐ If no storage requirements are established for a specific prescription drug or prescription drug precursor, the products shall be held in a condition of controlled temperature and humidity as defined in the USP-NF to ensure that its identity, strength, quality and purity are not adversely affected; and ☐ There is an established system of manual, electromechanical or electronic recording of temperature and humidity in the areas in which prescription drugs or prescription drug precursors are held to permit review of the record and ensure that the products have not been subjected to conditions which are outside of established limits.
15.	☐	☐	The facility engaged in pharmaceutical wholesale distribution of prescription drugs for human use that leave, or have ever left, the normal distribution channel will/does, before each pharmaceutical wholesale distribution of such drug, provide a pedigree to the person who receives such drug. The pedigree shall be maintained by the purchaser and the pharmaceutical wholesaler for five years from the date of sale or transfer and be available for inspection or use upon a request of an authorized officer of the law; and include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any pharmaceutical wholesaler, until sale to a pharmacy or other person dispensing or administering the prescription drug. At minimum, the necessary chain of distribution information shall include: [UAC R156-17b-615 (10)] ☐ name, address, telephone number, and if available, the email address of each owner of the prescription drug, and each pharmaceutical wholesaler of the prescription drug; ☐ name and address of each location from which the product was shipped, if different from the owner's; ☐ transaction dates; ☐ name of the prescription drug; ☐ dosage form and strength of the prescription drug; ☐ size of the container;

- ☐ number of containers;
- ☐ lot number of the prescription drug;
- ☐ name of the manufacturer of the finished dose form; and
- ☐ National Drug Code (NDC) number.

	Yes	No	
16.	☐	☐	The facility will/does establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel. [UAC R156-17b-615 (11) (a)]
17.	☐	☐	The facility will/does ensure that upon receipt, each outside shipping container containing prescription drugs or prescription drug precursors shall be visibly examined for identity and to prevent the acceptance of prescription drugs or prescription drug precursors that are contaminated, reveal damage to the containers or are otherwise unfit for distribution. [UAC R156-17b-615 (11) (b)]
18.	☐	☐	The facility will/does ensure that prescription drugs or prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated or in any other way unfit for distribution or use in manufacturing shall be quarantined and physically separated from other prescription drugs or prescription drug precursors until they are appropriately destroyed or returned to their supplier. [UAC R156-17b-615 (11) (b) (i)]
19.	☐	☐	The facility will/does ensure that any prescription drug or prescription drug precursor whose immediate sealed or outer secondary sealed container has been opened or in any other way breached shall be identified as such and shall be quarantined and physically separated from other prescription drugs and prescription drug precursors until they are appropriately destroyed or returned to their supplier. [UAC R156-17b-615 (11) (b) (ii)]
20.	☐	☐	The facility will/does ensure that 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. [UAC R156-17b-615 (11) (c)]
21.	☐	☐	The facility will/does ensure that if the conditions or circumstances surrounding the return of any prescription drug or prescription drug precursor cast any doubt on the product's safety, identity, strength, quality or purity, then the drug shall be appropriately destroyed or returned to the supplier, unless examination, testing or other investigation proves that the product meets appropriate and applicable standards related to the product's safety, identity, strength, quality and purity. [UAC R156-17b-615 (11) (c) (i)]
22.	☐	☐	Returns of expired, damaged, recalled, or otherwise non-saleable prescription drugs will be/are distributed by the receiving pharmaceutical wholesale distributor only to the original manufacturer or a third party returns processor that is licensed as a pharmaceutical wholesale distributor under this chapter. [UAC R156-17b-615 (11) (c) (ii)]
23.	☐	☐	Returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving pharmaceutical wholesaler, shall not be subject to the pedigree requirements, so long as they are exempt from the pedigree requirement under the FDA's Prescription Drug Marketing Act guidance or regulations. [UAC R156-17b-615 (11) (c) (iii)]
24.	☐	☐	As a facility authorized by law to dispense or administer prescription drugs for use by a patient, the facility is accountable for administering their returns process and ensuring that all aspects of their operation are secure and do not permit the entry of adulterated and counterfeit prescription drugs. [UAC R156-17b-615 (11) (d)]
25.	☐	☐	The facility will/does only furnish prescription drugs to a person licensed by the Division or to another appropriate state licensing authority to possess, dispense, or administer such drugs for use by a patient. [UAC R156-17b-615 (12)]
26.	☐	☐	Prescription drugs furnished by the facility shall be delivered only to the business address of a person described in Subsection R156-17b-615(13), or to the premises listed on the license, or to an authorized person or agent of the licensee at the premises of the manufacturer or pharmaceutical wholesaler if the identity and authority of the authorized agent is properly established. [UAC R156-17b-615 (13)]

Yes No

27. ☐ ☐ The facility shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following: [UAC R156-17b-615 (14)]

☐ there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

☐ there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped or otherwise disposed of by specific product and strength;

☐ there shall be a record of the dates of receipt and distribution or other disposal of any product;

☐ there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver and the address of the location to which the products were shipped;

☐ inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities;

☐ required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities and such records shall be maintained for a period of two years following disposition of the products; and

☐ records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

28. ☐ ☐ The facility shall establish, maintain and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, manufacturing, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following: [UAC R156-17b-615 (15)]

☐ a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first with a provision for deviation from the requirement if such deviation is temporary and appropriate;

☐ a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the FDA or other federal, state or local law enforcement or other authorized administrative or regulatory agency;

(ii) any voluntary action to remove defective or potentially defective drugs from the market; or (iii) any action undertaken to promote public health, safety or welfare by replacement of existing product with an improved product or new package design;

☐ a procedure to prepare for, protect against or 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;

☐ a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed; and

☐ a procedure for providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state or local authorities for a period of two years after disposition of the product.

☐ a procedure for identifying, investigating and reporting significant drug inventory discrepancies (involving counterfeit drugs suspected of being counterfeit, contraband, or suspect of being contraband) and reporting of such discrepancies within three business days to the Division and/or appropriate federal or state agency upon discovery of such discrepancies; and

☐ a procedure for reporting criminal or suspected criminal activities involving the inventory of drugs and devices to the Division, FDA, and if applicable, Drug Enforcement Administration (DEA), within three business days.

	Yes	No	
29.	☐	☐	The facility shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors, managers and other persons in charge which lists shall include a description of their duties and a summary of their background and qualifications. [UAC R156-17b-615 (16)]
30.	☐	☐	The facility will/does comply with laws including: [UAC R156-17b-615 (17)] ☐ operating within applicable federal, state, and local laws and regulations; ☐ permitting the state licensing authority and authorized federal, state, and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and ☐ obtaining a controlled substance license from the Division and registering with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacturing of controlled substances and shall comply with all federal, state, and local regulations applicable to the distribution or manufacturing of controlled substances.
31.	☐	☐	The facility will be/is subject to and abides by applicable federal, state, and local laws that relate to the salvaging or reprocessing of prescription drug products. [UAC R156-17b-615 (18)]
32.	☐	☐	The facility is not licensed in the same location as both a Class C pharmacy and any other classification of pharmacy. [UAC R156-17b-615 (19)]

COMMENTS

Signature of Responsible Person: _____ Date of Signature: ____/____/____

Signature of Division Investigator: _____ Date of Signature: ____/____/____

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