

State of Connecticut

Department of Consumer Protection Drug Control Division

DCP.DrugWholesalers@ct.gov

www.ct.gov/dcp/dcd



Inspection Report for Wholesalers of Drugs, Medical Devices and/or Cosmetics

Wholesaler Name

Inspecting Agent

Inspection Date

Registration Number

Person In Charge

E-mail

Phone Number

Fax Number

Secondary Contact

E-mail

Primary Location Address

Mailing Address

Products Distributed

Controlled substances
Rx Legend Drugs
Non-Legend Drugs
Medical Gases
Medical Devices
Cosmetics
Durable Medical Equipment
Reverse Distributor

Customer

Department Store
Grocery/Variety Store
Hospitals
Nursing Homes
Pharmacies
Practitioners
Wholesalers
Other

Other Information

A. Personnel

- | Question | Yes | No | Advised | Comments |
|--|-----|----|---------|----------|
| 1. Has the facility provided you with a list 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? (21a-115-32(h)) | | | | |
| 2. Have the personnel been provided with appropriate education and/or experience to assume responsibility for the positions related to compliance with registration requirements? (21a-115-31) | | | | |

B. Facility

- | Question | Yes | No | Advised | Comment |
|---|-----|----|---------|---------|
| 1. Is the facility of suitable size and construction to facilitate cleaning, maintenance and proper operations? (21a-115-32(a) (1)) | | | | |

2. Does the facility have storage areas designed to provide adequate lighting, ventilation, temperatures, sanitation, humidity, space, equipment, and security conditions? (21a-115-32(a)(2))	Yes	No	Advised	Comment
3. Does the facility have a quarantine area for storage of drugs, medical devices, and/or cosmetics that are outdated, damaged, deteriorated, misbranded, adulterated or that are in immediate or sealed secondary containers that have been opened? (21a-115-32(a)(3))	Yes	No	Advised	Comment
4. Is the facility maintained in a clean and orderly condition? (21a-115-32(a)(4))	Yes	No	Advised	Comment
5. Is the facility free from infestation by insects, rodents, birds or vermin of any kind? (21a-115-32(a)(5))	Yes	No	Advised	Comment

C. Security

1. Is this facility also licensed as a pharmacy? If yes, questions 3 and 5 shall only apply to the area where legend drugs are stored. (21a-115-32(b)(7))	Yes	No	Advised	Comment
2. Is the facility secure against any unauthorized entry? (21a-115-32(b)(1))	Yes	No	Advised	Comment
3. Is access from outside of the premises kept to a minimum and well controlled? (21a-115-32(b)(2))	Yes	No	Advised	Comment
4. Is the perimeter of the facility well –lighted? (21a-115-32(b)(3))	Yes	No	Advised	Comment
5. Is entry into areas where drugs are held limited to authorized personnel only? (21a-115-32(b)(4))	Yes	No	Advised	Comment
6. Is the facility equipped with an alarm system to detect entry after business hours? (21a-115-32(b)(5))	Yes	No	Advised	Comment
7. Is the facility equipped with a security system that will provide suitable protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records? (21a-115-32(b)(6))	Yes	No	Advised	Comment

D. Storage

1. Are all drugs 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? (21a-115-32(c)(1))	Yes	No	Advised	Comment
2. If no storage requirements are established for a drug, is it 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? (21a-115-32(c)(2))	Yes	No	Advised	Comment
3. Are appropriate measures undertaken to ensure that drugs are stored under conditions of proper temperature and humidity? ((21a-115-32(c)(4))	Yes	No	Advised	Comment

4. Are the temperature and humidity adequately documented? (21a-115-32(c)(4))	Yes	No	Advised	Comment
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E. Materials

1. Upon receipt, is each outside shipping container visibly examined for identity? (21a-115-32(d)(1))	Yes	No	Advised	Comment
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2. Upon receipt, is each outside shipping container visibly examined to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution? (21a-115-32(d)(1))	Yes	No	Advised	Comment
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3. Is each outgoing shipment carefully inspected for identity of the drugs products? (21a-115-32(d)(2))	Yes	No	Advised	Comment
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4. Is each outgoing shipment carefully inspected to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions? (21a-115-32(d)(2))	Yes	No	Advised	Comment
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5. Is each outgoing shipment packaged to ensure proper storage conditions of the drugs within the package during shipment? (21a-115-32(d)(2))	Yes	No	Advised	Comment
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F. Returned, Damaged, And Outdated Drugs

1. Are drugs that are outdated, damaged, deteriorated, misbranded, or adulterated quarantined and physically separated from other drugs until they are destroyed or returned to their supplier? (21a-115-32(e)(1))	Yes	No	Advised	Comment
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2. Are drugs whose immediate outer containers have been opened or used identified as such and quarantined and physically separated from other drugs until they are either destroyed or returned? (21a-115-32(e)(2))	Yes	No	Advised	Comment
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3. Are drugs whose sealed secondary containers have been opened or used identified as such and quarantined and physically separated from other drugs until they are either destroyed or returned? ((21a-115-32(d)(3))	Yes	No	Advised	Comment
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4. Are drugs that have been returned under circumstances where the safety, identity, strength, quality, and purity are in doubt destroyed, or returned unless examination, testing, other investigation proves that the drug meets the appropriate standards of safety, identity, strength, quality and purity? (21a-115-32(e)(3))	Yes	No	Advised	Comment
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G. Record Keeping

1. Does the wholesale establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs? (21a-115-32(f)(1))	Yes	No	Advised	Comment
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2. Do the records include the following information: (All are required) (21a-115-32(f)(1))

Name and Principle address of the seller/transferor
Address of the location from which the drugs were shipped
Name and address of the purchaser
Date of receipt
Date of distribution
Other disposition of the drugs

3. Are inventories and records made available for inspection and photocopying by authorized Federal, State or local officials for 3 years following the disposition of the drugs? (21a-115-32(f)(2))

Yes No Advised Comment

4. Are records kept at the inspection site readily available at the inspection site or immediately available by computer? (21a-115-32(f)(3))

Yes No Advised Comment

5. Are records kept at a central location available for inspection within 2 working days of a request by a Federal, State, or local official? (21a-115-32(f)(3))

Yes No Advised Comment

H. Written Policies And Procedures (Does not apply to licensed pharmacies)

1. Are there written 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 and for correcting all errors and inaccuracies in inventory? (21a-115-32(g))

Yes No Advised Comment

2. Is there a procedure where the oldest stock or drug product distributed first? (21a-115-32(g)(1))

Yes No Advised Comment

3. Is there a procedure for handling recalls and drug withdrawals due to the U.S. Food and Drug Administration or other Federal, State, or local law enforcement or government agency, voluntary action by the manufacturer? (21a-115-32(g)(2))

Yes No Advised Comment

4. Is there a procedure to ensure that the wholesaler prepare for, protect against and handle any crisis that affects security or operation in the event of strike, fire, flood or other natural disaster, or other situations of local, state, or national emergency? (21a-115-32(g)(3))

Yes No Advised Comment

5. Is there a procedure to ensure that any outdated drugs are segregated from other drugs and either returned to the manufacturer or destroyed? (NOTE: The procedure should provide for written documentation of the disposition of outdated drugs which shall be maintained for 3 years after disposition) (21a-115-32(g)(4))

Yes No Advised Comment

I. Other Safeguards/Comments

Wholesaler application recommended for approval?

Yes No

Is a re-inspection required?

Yes No Why?

Drug Control Agent Signature

Date

Representative Signature

Date