State of Connecticut
Department of Consumer Protection Drug Control Division
DCP.DrugWholesalers@ct.gov
www.ct.gov/dcp/dcd

CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION

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

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)) ○ Yes ○ No ○ Advised — Comments

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) ○ Yes ○ No ○ Advised — Comment

B. Facility

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

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 Does the facility have a quarantine area for storage of drugs, medical devices, and/or cosmetics that are outdated, damaged, deteriorated, misbranded, adulterated or that are in immediate or sealed secondary containers that have been opened?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

E. Materials

1. Upon receipt, is each outside shipping container visibly examined for identity? (21a-115-32(d)(1))	○ Yes	○ No	○ Advised	Comment
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
3. Is each outgoing shipment carefully inspected for identity of the drugs products? (21a-115-32(d)(2))	○ Yes	○ No	○ Advised	Comment
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
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

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
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
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
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

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

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

Comment

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

State of Connecticut
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Inspection Report for Wholesalers with Controlled Substances

Individuals Responsible for Controlled Substances

Drug Enforcement Administration Registration #

Controlled Substances Used

- ☐ Schedule I
- ☐ Schedule II
- ☐ Schedule III
- ☐ Schedule IV
- ☐ Schedule V

Names of Controlled Substances Used

Name of Wholesaler Providing Controlled Substances

Controlled Substance Units (Sec. 21a-262-1(e))

#100 tablets or capsule = 1 unit
1 pint of a liquid = 1 unit
1/8 ounce of a powder, crystal, flake, or granule= 1 unit
1 multiple use vial = 1 unit
10 suppositories = 1 unit
10 single dose ampules, tubexes, dosettes, hyporettes or other single dose package forms for injection whether powder or in solution = 1 unit

Partial containers of controlled substances shall be considered as being full when determining the total quantity of controlled substance stock. Larger package sizes shall be counted according to the number of controlled substance units they contain. Packages sizes less than a full controlled substance unit shall be counted as the fraction of controlled substance unit which the package size contains, i.e. #50 tablets = 0.5 unit

A.STORAGE (21a-262-4)

1. Does the facility store greater than 250 Controlled Substance Units? (21a-262-4(a))
   If yes, see vault requirements
   If no, see safe requirements
   ○ Yes ○ No ○ Advised
   Comments

2. Are all Schedule III, IV, V stock stored in an: (21a-262-4(b))
   ○ Approved Vault
   ○ Approved safe equipped with a separate effective electrical alarm system
   ○ Separate secure locked caged area or enclosure equipped with a separate effective electrical alarm system
   Comments

3. If a separate secure locked caged area is used, is the construction heavy gauge wire mesh with openings smaller than the smallest controlled substance containers stocked?(21a-262-4(b))
   ○ Yes ○ No ○ Advised
   Comments

4. Are all controlled substances: (21a-262-4(c))
   ☐ Stored in such a manner to prevent diversion?
   ☐ Accessible only to the minimum number of specifically authorized personnel essential for efficient operation
   ☐ Returned to the required security location immediately after completion of the procedure or at the end of the scheduled business day
   Comments

B. SAFE REQUIREMENT (Sec. 21a-262-1)

Is a safe required? (21a-262-4a) ○ Yes ○ No ○ Advised **If no, please skip this section.**

Manufacturer	Model #	Serial Number	Weight

1. Does the safe have a minimum of a "B" Burglary rate? (21a-262-1(f)1) ○ Yes ○ No ○ N/A Comments

2. Is the safe equipped with a re-locking device? (21a-262-1(f)2) ○ Yes ○ No ○ N/A Comments

3. Does the safe weigh at least 750 pounds or is it rendered immobile by being securely anchored to a permanent structure of the building? (21a-262-1(f)3) ○ Yes ○ No ○ N/A Comments

4. Does the safe have adequate interior space to store all controlled substances required to be kept within the safe? (21a-262-1(f)4) ○ Yes ○ No ○ N/A Comments

C. VAULT REQUIREMENTS (Sec. 21a-262-1)

Is a vault required? ○ Yes ○ No **If no, please skip this section.**

1. Are the walls, floors, and ceilings constructed of:
   - ☐ At least 8 inches of reinforced concrete or other substantial masonry
   - ☐ Reinforced vertically and horizontally with ½ inch steel rods tied 6 inches on center or the structural equivalent to such reinforced walls floors and ceilings

   Comments

2. Does the door of the vault contain: . (The GSA Class 5 rated steel door meets all the qualifications for the vault door.)
   - ☐ A multiple-position combination lock or the equivalent
   - ☐ A re-locking device or equivalent and steel plate with a thickness of at least ½ inch

   Comments

3. Does the vault have a "day gate"? ○ Yes ○ No Comments

Day Gate - If operations require it to remain open for frequent access, must be equipped with a "day gate" which is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove raw material in the morning and return raw material at night, and is always re-locked immediately after use, a "day gate" is not required.

4. Are the walls, floor, and ceiling of the vault equipped with an alarm which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has legal responsibility to respond, or a 24-hour control station operated by the registrant? ○ Yes ○ No Comments

Note: If necessary due to local conditions or other problems, holdup buttons shall be placed at strategic points or entry to the perimeter area of the vault.

5. Is the vault door equipped with a contact switch? ○ Yes ○ No Comments

6. Does the vault have at least one of the followings:

- ☐ Complete electrical lacing of the walls, floor and ceiling
- ☐ Sensitive ultrasonic equipment within the vault
- ☐ Sensitive sound accumulator system
- ☐ Such other device designed to detect illegal entry a may be approved by the Commissioner of Consumer Protection

Comments

7. Is there an electrical alarm system certified as being Underwriters Laboratories approved for system and installation? ○ Yes ○ No

Comments

C. SECURITY (Sec. 21a-262-2)

1. Does the registrant have other safeguards (i.e. watchman service, full electrical protection of the building, electric alarms, etc.)? (21a-262-2(a)) ○ Yes ○ No ○ Advised

Comments

2. Are all stocks of controlled substances in all schedules in a secure area or location accessible only to specifically authorized personnel? (21a-262-2(b)) ○ Yes ○ No ○ Advised

Comments

3. Are all equipment used for the storage of controlled substances securely locked except for the actual time required to remove or replace needed items? (21a-262-2(c)) ○ Yes ○ No ○ Advised

Comments

4. Are locks in good working order with keys removed from them? (21a-262-2(c)) ○ Yes ○ No ○ Advised

Comments

5. Are keys accessible to personnel that are not authorized to obtain controlled substances? (21a-262-2(c)) ○ Yes ○ No ○ Advised

Comments

D. RECORD KEEPING (21a-254)

Receipt

Schedule I and II

1. Are the records readily available? (21a-254(f)) ○ Yes ○ No ○ Advised

Comments

2. Are the forms kept separate from all other records? (21a-254(f)) ○ Yes ○ No ○ Advised

Comments

3. Are the order forms kept securely? (CFR 1304.04) ○ Yes ○ No ○ Advised

Comments

4. Have the forms been properly executed? (CFR 1305.12) ○ Yes ○ No ○ Advised

Comments

Schedule III-V

1. Do the receipt records contain the following? (Must have all) (21a-254(f))

- ☐ Date of Receipt
- ☐ Name and address of person from whom received
- ☐ Kind and quantity of controlled substances received

Comments

2. Are the receipt records kept separate from all other records? (21a-249(k)) ○ Yes ○ No ○ Advised

Comments

E. DISPOSITION RECORD

1. Are the disposition records readily available? ○ Yes ○ No ○ Advised

Comments

2. Are the disposition records for Schedule I + II and Schedule III-V separately maintained? (21a-254(f) ○ Yes ○ No ○ Advised

Comments

3. Are records of all controlled substances, compounded, mixed, cultivated, or grown, or by any other process produced or prepared and of all controlled substances received and disposed of by them maintained? (21a-254(d)) ○ Yes ○ No ○ Advised

Comments

F. BIENNIAL INVENTORY (21a-254(h))

1. Was a biennial inventory conducted? ○ Yes ○ No ○ Advised

Comments

2. Is the biennial inventory readily available? ○ Yes ○ No ○ Advised

Comments

3. Was the biennial inventory properly executed?

- ☐ Date Conducted
- ☐ Time of Day Completed
- ☐ Schedule I + II Separate from Schedule III-V
- ☐ Signature
- ☐ Complete Listing

Comments

Other Safeguards/Comments

Wholesaler of controlled substance application approved? ○ Yes ○ No

Is a re-inspection required? ○ Yes ○ No

If Yes, why?

Drug Control Agent Signature Date Representative Signature Date