



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

Customer

Other Information

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

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

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 Does the facility have a quarantine area for storage of drugs, medical devices, and/or cosmetics that are outdated, damaged, deteriorated, misbranded, adulterated or that are in immediate or sealed secondary containers that have been opened?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/transferrer			Comment
	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	<input type="text"/>	Representative Signature
				Date <input type="text"/>

State of Connecticut

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



Inspection Report for Wholesalers with Controlled Substances

Individuals Responsible for Controlled Substances

Drug Enforcement Administration Registration #

Controlled Substances Used	Names of Controlled Substances Used	Name of Wholesaler Providing Controlled Substances
Schedule I		
Schedule II		
Schedule III		
Schedule IV		
Schedule V		

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	
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	
5. Is the vault door equipped with a contact switch?	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.

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

7. Is there an electrical alarm system certified as being Underwriters Laboratories approved for system and installation?	Yes	No		Comments
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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			Comments
	Name and address of person from whom received			
	Kind and quantity of controlled substances received			
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			Comments
	Time of Day Completed			
	Schedule I + II Separate from Schedule III-V			
	Signature			
	Complete Listing			

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