

Wholesaler of Drugs, Medical Devices, and/or Cosmetics Mobile Inspection Form

The Drug Control Division is utilizing all-inclusive mobile inspection forms that encompass multiple inspection types and business models. Inspection sections and/or inspection fields may intentionally remain blank when such sections and/or fields do not apply to the inspection type and/or business model for which the mobile inspection forms are being utilized. Please contact the Drug Control Agent who conducted your inspection if you feel an inspection section and/or inspection field was inadvertently left blank.

Wholesaler of Drugs, Medical Devices, and/or Cosmetics

Type(s) of Business Conducted in Connecticut	
	Cosmetics
	Drugs - Non-Legend
	Drugs - Legend Non-Controlled
	Drugs - Legend Controlled
Schedules	Schedule II
	Schedule III
	Schedule IV
	Schedule V
	Wholesalers of Legend Controlled Drugs Must Also Complete the "Wholesaler of Legend Controlled Drugs Mobile Inspection Form"
	Durable Medical Equipment
	Medical Devices
	Medical Gases
	Reverse Distributor
	Third Party Logistics
	Other

General Questions		Yes	No	Advised
1	Does the wholesaler hold a Connecticut pharmacy license?			
2	Does the wholesaler operate a facility or facilities at more than one location?			
3	Does the wholesaler have joint ownership and control of each facility operated at another location?			
4	Does the wholesaler store or distribute products from a facility operated at another location?			
5	Does the wholesaler store or distribute legend controlled drugs from a facility operated at another location? [Section 21a-115-30]			

Personnel		Yes	No	Advised
1	Did the wholesaler provide a list of officers, directors, managers, and other persons in charge of wholesale distribution, storage, and handling, including a description of their duties and a summary of their qualifications? [Section 21a-115-32(h)]			
2	Have wholesaler personnel been provided with appropriate education and/or experience to assume responsibility for the positions related to compliance with registration requirements? [Section 21a-115-31]			

Facilities		Yes	No	Advised
1	Are all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed of suitable size and construction to facilitate cleaning, maintenance, and proper operations? [Section 21a-115-32(a)(1)]			
2	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate lighting? [Section 21a-115-32(a)(1)]			
3	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate ventilation? [Section 21a-115-32(a)(2)]			
4	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate temperature? [Section 21a-115-32(a)(2)]			
5	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate sanitation? [Section 21a-115-32(a)(2)]			
6	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate humidity? [Section 21a-115-32(a)(2)]			
7	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate space? [Section 21a-115-32(a)(2)]			
8	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate equipment? [Section 21a-115-32(a)(2)]			
9	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate security conditions? [Section 21a-115-32(a)(2)]			
10	Do all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed have a quarantine area for storage of products that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened? [Section 21a-115-32(a)(3)]			

11	Are all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed maintained in a clean and orderly condition? [Section 21a-115-32(a)(4)]			
12	Are all facilities at which products are stored, warehoused, handled, offered, marketed, or displayed free from infestation by insects, rodents, birds, or vermin of any kind? [Section 21a-115-32(a)(5)]			

Facility Security		Yes	No	Advised
1	Is the wholesaler required to have additional security measures due to theft?			
2	Is the wholesaler's facility secure against any unauthorized entry? [Section 21a-115-32(b)(1)]			
3	Is access from outside of the wholesaler's premises kept to a minimum and well controlled? [Section 21a-115-32(b)(2)]			
4	Is the perimeter of the wholesaler's facility well-lighted? [Section 21a-115-32(b)(3)]			
5	Is entry into areas where the wholesaler holds products limited to authorized personnel only? [Section 21a-115-32(b)(4)]			
6	Is the wholesaler's facility equipped with an alarm system to detect entry after business hours? [Section 21a-115-32(b)(5)]			
7	Is the wholesaler's 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? [Section 21a-115-32(b)(6)]			

Facility Storage		Yes	No	Advised
1	Does the wholesaler store all products at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such products, or with requirements in the current edition of an official compendium? [Section 21a-115-32(c)(1)]			
2	Are storage requirements established for all products stored by the wholesaler?			
3	Does the wholesaler hold products at "controlled" room temperature, as defined in an official compendium, to help ensure that each product's identity, strength, quality, and purity are not adversely affected? [Section 21a-115-32(c)(2)]			
4	Does the wholesaler undertake the appropriate measures to ensure that products are stored under conditions of proper temperature and humidity? [Section 21a-115-32(c)(4)]			
5	Does the wholesaler adequately document temperature and humidity? [Section 21a-115-32(c)(4)]			

Examination of Materials		Yes	No	Advised
1	Does the wholesaler, upon receipt, visibly examine each outside shipping container for identity? [Section 21a-115-32(d)(1)]			
2	Does the wholesaler, upon receipt, visibly examine each outside shipping container to prevent the acceptance of contaminated products or products that are otherwise unfit for distribution? [Section 21a-115-32(d)(1)]			
3	Does the wholesaler carefully inspect each outgoing shipment for identity of the products? [Section 21a-115-32(d)(2)]			
4	Does the wholesaler carefully inspect each outgoing shipment to ensure that there is no delivery of products that have been damaged in storage or held under improper conditions? [Section 21a-115-32(d)(2)]			

Returns, Damages, Outdates		Yes	No	Advised
1	Does the wholesaler quarantine and physically separate products that are outdated, damaged, deteriorated, misbranded, or adulterated from other products until they are destroyed or returned to the supplier? [Section 21a-115-32(e)(1)]			
2	Does the wholesaler quarantine and physically separate products whose immediate containers have been identified as opened or used from other products until they are either destroyed or returned to the supplier? [Section 21a-115-32(e)(2)]			
3	Does the wholesaler quarantine and physically separate products whose sealed outer containers have been identified as opened or used from other products until they are either destroyed or returned to the supplier? [Section 21a-115-32(e)(2)]			
4	Does the wholesaler quarantine and physically separate products whose sealed secondary containers have been identified as opened or used from other products until they are either destroyed or returned to the supplier? [Section 21a-115-32(d)(2)]			
5	Has the wholesaler experienced any situations in which the conditions under which a product was returned cast doubt on the product's safety, identity, strength, quality, or purity?			
6	Did the wholesaler handle product appropriately when the conditions under which product was returned cast doubt on the product safety, identity, strength, quality, or purity? [Section 21a-115-32(e)(3)]			

Policies and Procedures		Yes	No	Advised
1	Does the wholesaler have a written procedure in which the oldest stock or product is distributed first? [Section 21a-115-32(g)(1)]			

2	Does the wholesaler have a written procedure for handling product recalls and product 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? [Section 21a-115-32(g)(2)]			
3	Does the wholesaler have a written 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? [Section 21a-115-32(g)(3)]			
4	Does the wholesaler have a written procedure to ensure that any outdated products are segregated from other products and either returned to the manufacturer or destroyed? [Section 21a-115-32(g)(4)]			

Records		Yes	No	Advised
1	Do the inventory and record of receipt, distribution, and other disposition bear the NAME OF THE SELLER or transferor? [Section 21a-115-32(f)(1)]			
2	Do the inventory and record of receipt, distribution, and other disposition bear the PRINCIPAL ADDRESS OF THE SELLER or transferor? [Section 21a-115-32(f)(1)]			
3	Do the inventory and record of receipt, distribution, and other disposition bear the ADDRESS of the location FROM WHICH products were SHIPPED or in the case of distribution the name and address of the purchaser? [Section 21a-115-32(f)(1)]			
4	Do the inventory and record of receipt, distribution, and other disposition bear the IDENTITY OF PRODUCTS received and distributed or disposed of? [Section 21a-115-32(f)(1)]			
5	Do the inventory and record of receipt, distribution, and other disposition bear the QUANTITY OF PRODUCTS received and distributed or disposed of? [Section 21a-115-32(f)(1)]			
6	Do the inventory and record of receipt, distribution, and other disposition bear the DATES of receipt and distribution or other disposition of the products? [Section 21a-115-32(f)(1)]			
7	Where does the wholesaler keep the inventories and records of all transactions regarding the receipt and distribution or other disposition of products?			
	Inspection site [Section 21a-115-32(f)(3)]			
	Immediately retrievable by computer or other electronic means [Section 21a-115-32(f)(3)]			
	Central location apart from inspection site and not electronically retrievable [Section 21a-115-32(f)(3)]			
	Other			
	Are the wholesaler's records of all transactions regarding the receipt and distribution or other disposition of products kept at a central location apart from the inspection site and not electronically retrievable made available for inspection within two working days of a request by an authorized official of a Federal, State, or local agency during the retention period? [Section 21a-115-32(f)(3)]			

8	Does the wholesaler make inventories and records of receipt, distribution, and other disposition available for inspection and photocopying by authorized Federal, State, or local officials for three years following the disposition of products? [Section 21a-115-32(f)(2)]			
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Additional Comments		Yes	No	Advised
1	Does the inspecting agent have any additional comments with respect to this wholesaler inspection?			

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