Oregon
Kate Brown, Governor

Oregon Board of Pharmacy
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E-mail: pharmacy.board@state.or.us
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Inspector Signature: _____

Date: _____ Deficiency Notification: _____

2018 OREGON WHOLESALER SELF-INSPECTION REPORT

All Wholesale Distributors MUST complete this inspection report and have it available for Inspection by ***September 1, 2018*** *pursuant to OAR 855-065-0009(7). DO NOT MAIL TO THE BOARD OFFICE.*

Print Name: _____

☐ *Check here if you are a Designated Representative (required for WHSE I) –or–* ☐ *Check here if you are a Contact Person (WHSE II and III)*

Business Name: _____

License No. _____

Address: _____

City, State, Zip: _____

Tel: _____ Normal Business Hours: _____

DEA No: _____ Expiration Date: _____

1. Has this wholesale distributor been granted any exceptions by the Board or DEA to any laws or rules? If yes, please attach a copy. Please note that rule changes may invalidate an old waiver and waivers are valid for a maximum of 5 years. ☐ Yes ☐ No

2. Has any disciplinary action been taken against this wholesale distributor, its owner, principal or designated representative, or any other wholesale distributor under common ownership or control, in connection with the drug laws or regulations of any state or the federal government? If yes, please attach a statement explaining why. ☐ Yes ☐ No

3. Go to the last page. Write where your Self-Inspection Report and Law Book are located, and hang this slip next to the distributor's registration on the wall in the outlet.

4. Where are the following items located inside the outlet: (Be as specific as possible, there can be many filing cabinets and "North" is hard to find without a compass.)

   - Current written Policies and Procedures: _____
   - Invoices for the last 3 years: _____
   - Pedigree records for the last 3 years (*if applicable*): _____
   - Self-Inspection Reports for the last 3 years: _____
   - List of responsible individuals and their qualifications/duties: _____

5. How many employees does wholesaler employ? _____

6. In which states does wholesaler have a license? _____

7. Whom does wholesaler purchase from? _____

8. What are procedures when wholesaler is asked to ship into a state they are not licensed in? _____

_____

_____

CAREFULLY CONFIRM WHETHER OR NOT WHOLESALER IS COMPLIANT AND MARK THE APPROPRIATE BOX TO THE LEFT OF EACH ITEM. IF YOU FIND ITEMS THAT NEED CORRECTING, RECTIFY THE DEFICIENCY AND WRITE THE DATE OF CORRECTION AND THEN MARK THE "YES" BOX. DO NOT MARK "YES" UNLESS THE ANSWER IS "YES." NOTE: THE CORRECT ANSWER TO SOME QUESTIONS IS "NO."

Compliant		**RECORD KEEPING AND INVENTORY ANAGEMENT**
Yes	No	
		9. OAR 855-065-0005 and 855-065-0010 Are your records compliant with state and federal laws? *(Note: The Drug Supply Chain Security Act - DSCSA- is federally implemented and the Oregon Board of Pharmacy adopted new rules, eff. 1 July 2015)* a. Do your pedigree records contain all required elements, such as Transaction Information, Transaction History & Transaction Statement? b. Where are they stored? _____ c. If no, please explain: _____ _____ _____
		10. OAR 855-065-0010 (2-4) Are records and invoices readily maintained for a minimum of three years? (Records less than 13 months old must be kept at the inspection site or immediately retrievable by computer or electronic means for immediate inspection.)
		11. Is inventory monitored? a. Who monitors inventory adjustments? _____ b. What is the threshold to initiate an investigation for controlled substance and non-controlled substance adjustments? _____
		c. Are DEA and Board notified of losses?
		d. How long do you retain records? How are these stored? _____
		e. Does computer inventory match actual inventory?

Yes	No	
		12. Do you examine items upon receipt and compare shipping documents to what was received? If a box appears opened, what do you do? _____
		13. OAR 855-065-0010(6)(d) Do you have a policy and procedure for identification and quarantine of suspect/illegitimate product? a. Where are quarantined products stored? _____ b. Do you notify the Board, the FDA and all affected trading partners of illegitimate product within 24 hours?
		14. Do you have criteria for returning products to inventory when received from a pharmacy? • Seals inspected - inner and outer • Expiration Date • Cold items returned cold. Does customer certify item was maintained at proper temperature?
		15. Do you verify active Oregon licensure of trading partners/affiliates/customers/vendors prior to receiving or distributing products? How is this done? _____
		16. Do you maintain records offsite? Which ones? _____ How long does it take to get from offsite location? _____

Compliant		**POLICIES AND PROCEDURES**
Yes	No	
		17. OAR 855-065-0010 Are you able to produce, at the time of inspection, your facility's written procedures for the following?
		• The oldest approved stock is distributed first.
		• Handling of recalls.
		• Any action initiated by the FDA, or other federal or state agency (including OBOP).
		• Handling of epidemic or emergency preparedness.
		• Outdates.
		• Disposition or destruction of outdates.
		• Investigation of discrepancies.
		• Documentation of temperature and humidity, and storage conditions.
		• Policy for identifying suspect product, such as suspicious labels and containers?
		• Quarantine of suspect or illegitimate, adulterated, misbranded, contaminated, contraband, counterfeit, damaged or otherwise unfit for distribution medications. (In such cases, you must notify the FDA, immediate trading partners, and the OBOP within 24 and conduct an investigation to authenticate each distribution of the drug back to the wholesaler from which the drug was purchased.)

Compliant		**STORAGE OF DRUGS**
Yes	No	
		18. OAR 855-065-0012 (1)(a) and (b) Is your facility of suitable construction and size to facilitate cleaning, maintenance, and proper distribution operations?
		19. OAR 855-065-0012 (1-2) Does your facility have adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions?
		20. Temperature and humidity
		a. How many monitors? (Are they temperature and/or humidity?) _____
		b. Where are the monitors? _____
		c. Do you look at monitors and see past graphs? _____
		d. What happens if temperature goes out of range? _____
		e. How frequently do you calibrate monitors? Who calibrates? _____
		21. OAR 855-065-0012(3) Is there a security system?
		a. Are there controls that restrict access to areas where drugs are held to authorized personnel only?
		b. Entry to drug area • Who has access? _____ • Who has keys to cage (controlled substances)? _____
		c. Computer system
		• Password protected?
		• Are there different levels of access? _____
		• Are transactions monitored? How often? _____
		d. Policies and procedures for detection of diversion/losses.
		• How are suspected losses handled? Are the police, DEA and Board notified?
		e. An after hours central alarm or a comparable entry detection system.
		Security - who monitors (example - ADT) _____
		○ Fenced?
		○ Cameras?
		○ Cages?
		○ Outside lighting?
		○ Skylights caged?
		22. OAR 855-065-0012(1) Is your facility clean and in orderly condition? (i.e. free from insects, rodents, etc.)
		Pest Control
		a. Traps?
		b. Service - how frequent? _____
		23. Do you receive cold storage items?
		a. How is this handled? (Do you check temperature when it arrives, how is it shipped (in Styrofoam cooler with ice?), it is moved immediately to cooler?) _____
		b. How do you pack cold items for shipment? (In cooler with cold pack?) _____
		24. OAR 855-065-0012 (3)(c) Is there adequate outside perimeter lighting?

Compliant		**PROHIBITED PRACTICES - OAR 855-065-0013**
Yes	No	
		25. Are you aware that purchasing drugs from a closed door pharmacy is illegal?
		26. Do you understand that your facility may not sell, distribute, or transfer drugs to customers not appropriately registered by the Oregon Board of Pharmacy?
		PERSONNEL ***(applicable only to WHSE, Category I)***
		27. OAR 855-065-0009(1) Are you the Designated Representative or Board Contact Person for more than one wholesale distributor? (Note: You must have a Board approved exception.)
		28. Are you employed full time by the wholesale distributor?
		29. OAR 855-065-0009(4) Are you actively involved in and aware of the daily operations of the wholesale distributor?
		30. OAR 855-065-0009(6) Are you physically present at the wholesale distributor during normal business hours (as listed above)?

I hereby certify that I have verified this facility is in compliance with all laws and rules, have read and verified written policies and procedures reflect current practices, and the answers marked on this report and true and correct.

_____ _____

Designated Representative Signature Date

Website resources available at: http://www.oregon.gov/pharmacy/Pages/Laws_Rules.aspx

Cut on this line, fill in location of each item, and post next to outlet license on the wall.

Post next to outlet license on the wall.

DO NOT SEND ANY PART OF THIS REPORT TO THE BOARD OFFICE. KEEP IN THE BOARD OF PHARMACY LAW BOOK, COPIES SENT TO THE BOARD WILL BE DISCARDED.

Location of Wholesaler Self-Inspection Report: _____

Location of Board of Pharmacy Laws and Rules: _____