

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax: (425)302-0404		DATE(S) OF INSPECTION 8/12/2019-8/16/2019 FEI NUMBER 3005374721
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Anne L. Henriksen, Owner/Pharmacist in Charge		
FIRM NAME Columbia River Pharmacy LLC (DBA Malley's Compounding Pharmacy)	STREET ADDRESS 1906 George Washington Way	
CITY, STATE, ZIP CODE, COUNTRY Richland, WA 99354-2308	TYPE ESTABLISHMENT INSPECTED Producer of Nonsterile Drug Products	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.</p> <p>Specifically,</p> <p>A. Hazardous bulk drug substances (ie: hormones) are stored together with non-hazardous bulk drug substances within your compounding lab.</p> <p>B. A deactivating agent is not used to clean non-dedicated equipment (ie: hoods and utensils) to prevent cross-contamination.</p> <p>C. Non-dedicated (b) (4) hoods are designed in a way that the exhaust is vented back into the compounding room.</p> <p>D. Glassware (ie: graduated cylinders, mortar and pestles) is stored on open shelves by the end of the compound lab with no door present.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joshua P Wireman, Investigator	DATE ISSUED 8/16/2019
	Joshua P Wireman Investigator Signed By: Joshua P. Wireman -S Date Signed: 08-16-2019 12:16:49 X	
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 2 PAGES		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404		DATE(S) OF INSPECTION 8/12/2019-8/16/2019	
		FEI NUMBER 3005374721	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Anne L. Henriksen, Owner/Pharmacist in Charge			
FIRM NAME Columbia River Pharmacy LLC (DBA Malley's Compounding Pharmacy)		STREET ADDRESS 1906 George Washington Way	
CITY, STATE, ZIP CODE, COUNTRY Richland, WA 99354-2308		TYPE ESTABLISHMENT INSPECTED Producer of Nonsterile Drug Products	
OBSERVATION 2			
Your facility design allowed the influx of poor quality air into a higher classified area.			
Specifically,			
A. The compounding lab has two doorways. The door to one of the doorways was observed propped open leading to the hallway and storage area. The other doorway had no door present and a fan was observed blowing air from the general pharmacy area into the compounding lab.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joshua P Wireman, Investigator		DATE ISSUED 8/16/2019
	<small>Joshua P Wireman Investigator Signed By: Joshua P. Wireman -S Date Signed: 08-16-2019 12:18:49</small> X		