

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 7/22/2019-7/30/2019* FEI NUMBER 3012773475
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jeremy B. Lundevall, Chief Operations Officer		
FIRM NAME Ladd Family Pharmacy LLC	STREET ADDRESS 1109 S Broadway Ave	
CITY, STATE, ZIP CODE, COUNTRY Boise, ID 83706-3626	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 used a non-pharmaceutical grade component in the formulation of a drug product.</p> <p>Specifically,</p> <p>You have not demonstrated that the water used as a component of aqueous drug products meets the minimum requirements for USP Purified Water. For example, the (b) (4) water was used as a component for Acetaminophen [Free] 12mg/mL Liquid lot number 07102019:66@26.</p>		
<p>OBSERVATION 2 You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.</p> <p>Specifically,</p> <p>You failed adequately clean non-dedicated equipment. For example an oxidizing agent was not used to clean non-dedicated equipment following the compounding of a testosterone containing product.</p>		
<p>*DATES OF INSPECTION 7/22/2019(Mon), 7/23/2019(Tue), 7/24/2019(Wed), 7/25/2019(Thu), 7/26/2019(Fri), 7/29/2019(Mon), 7/30/2019(Tue)</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joshua P Wireman, Investigator	DATE ISSUED 7/30/2019
	Joshua P Wireman Investigator Signed By Joshua P. Wireman -S Date Signed 07-30-2019 13:07:46 X _____	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
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