DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	9/12/2016-9/23/2016*
	FEI NUMBER 3012773475

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeremy B. Lundevall , Chief Operating Officer and Certified Pharmacy Technician

FIRM NAME	STREET ADDRESS
Ladd Family Pharmacy LLC	1109 S Broadway Ave
CITY, STATE, ZIP CODE, COUNTRY Boise, ID 83706-3626	TYPE ESTABLISHMENT INSPECTED Manufacturer

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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

The firm has not implemented a stability program to scientifically determine appropriate expiration dates to assign to the manufacturing of non-sterile drug products, and does not assign expiration dates based on product-specific documented standards. For example, Bezocaine/Lidocaine/Tetracaine 20/10/4% gel, lot 08172016:84@2, manufactured for "(b) (4)" per Rx (b) (4), (b) (6), was assigned a beyond-use date (BUD) of 30 days per a documented standard for all water-containing topical semisolid formulations. Cantharidin topical liquid 0.7% solution, lot 07262016:27@8, manufactured for "(b) (4)" per Rx (b) (4), (b) (6) was assigned a BUD of 180 days per documented standard guidelines for all non-aqueous formulations. Both of these products were manufactured to fill non-patient specific prescriptions.

OBSERVATION 2

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

The (b) (4) hoods that are used to manufacture non-sterile drug products for human and veterinary use are not being cleaned in a manner that is effective in removing residues from previous manufactured products from joints and surfaces on the inside of the hoods. On 09/12/16, we observed that white powder residue was present in the welded joint between the work surface and back panel, and in the

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joint between the plastic front panel and pivot hinge of (b) (4) Hood # (b) (4) in the "Compounding Area". This residue was observed on the inside of the hood before and during the manufacturing of prescription drug products.

OBSERVATION 3

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

The firm's SOP 1.30, version 3.0, titled "Compounding Area Requirements (Nonsterile)", states that garb may include "(b) (4)" for employees working in the "Compounding Area", but does not define the areas to (b) (4) to reduce the risk of product contamination. On 09/12/16, we observed an employee performing manufacturing of lot 09122016:31@7 of Estradiol (PGF) 1mg/gm Lipo and lot 09122016:98@18 of Itraconazole/buprofen 1/2% DMSO nail solution (b) (4). We observed this employee exit the "Compounding Area" into the general pharmacy area and return to the "Compounding Area" without (b) (4).

OBSERVATION 4

Determinations of conformance to appropriate written specifications for acceptance are not made and deficient for drug products.

Specifically,

Finished product testing is not performed on every lot of non-sterile manufactured drug product produced by the firm. The firm sends out (b) (4) for potency testing by a contract laboratory every (b) (4) or so, but does not have an established schedule or system for choosing which products to test. For example, the following non-sterile products were manufactured to fill multiple non-patient specific prescriptions between 06/12/16 and 09/12/16, none of which were tested prior to release:

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Boise, ID 83706-3626	Manufacturer

- Bezocaine/Lidocaine/Tetracaine 20/10/4% gel, manufactured to fill (b) (4) non-patient specific prescriptions between 06/12/16 and 09/12/16.
- Cantharidin topical liquid 0.7% solution, manufactured to fill (b) (4) non-patient specific prescriptions between 06/12/16 and 09/12/16.
- Diethylstilbestrol (VET) 1 mg capsule manufactured to fill (b) (4) non-patient specific prescriptions between 06/12/16 and 09/12/16. This is a veterinary product.

***DATES OF INSPECTION**

9/12/2016(Mon),9/13/2016(Tue),9/14/2016(Wed),9/15/2016(Thu),9/22/2016(Thu),9/23/2016(Fri)

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