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	5/28/2019-6/13/2019*
	FEI NUMBER 3006089725

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Hee Joo Park, President and CEO	
FIRM NAME Puget Sound Drug Corporation dba Key Pharmacy and Compounding Center	STREET ADDRESS 530 S 336th St
CITY, STATE, ZIP CODE, COUNTRY Federal Way, WA 98003-6383	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile products

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

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

Your firm uses non-pharmaceutical grade corn syrup in the production of veterinary drug products. For example, on 5/21/2019, your firm produced Potassium Bromide (vet) Beef 250 mg/mL soln, lot 05/20/2019@72 using corn syrup that is not labeled as pharmaceutical or FCC grade. The label of the corn syrup you used lists ingredients in addition to corn syrup.

---

*DATES OF INSPECTION

5/28/2019(Tue), 5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri), 6/03/2019(Mon), 6/04/2019(Tue), 6/05/2019(Wed), 6/06/2019(Thu), 6/07/2019(Fri), 6/13/2019(Thu)

X Peter S Kessler
Investigator
Signed By: Peter S. Kessler -S
Date Signed: 06-13-2019 07:26:26

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Andrew K Haack, Investigator Peter S Kessler, Investigator	X Andrew K Haack Investigator Signed By: Andrew K. Haack -S Date Signed: 06-13-2019 07:27:43	6/13/2019