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
5/28/2019-6/13/2019*

PEI 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 (b) (4) 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 (b)(4) that is not labeled as pharmaceutical or FCC grade. The label of the (b) (4) you used lists ingredients in addition to (b) (4).

*DATES OF INSPECTION

Andrew K Haack, Investigator
Peter S Kessler, Investigator

SEE REVERSE OF THIS PAGE

Andrew K Haack
Peter S Kessler

DATE ISSUED
6/13/2019

FORM FDA 482 (08/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 1 PAGES