DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	6/25/2018-6/27/2018
	FEI NUMBER 3012289984

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marcelino P. Casal, President/CEO

FIRM NAME	STREET ADDRESS
Well Care Discount Pharmacy, LLC	3300 W. Charleston Blvd., Suite A
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89102	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug 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 I OBSERVED:

OBSERVATION 1

Drug products failing to meet established specifications are not rejected.

Specifically,

Your firm failed to reject Testosterone 2mg/gram cream, lot 02092017:71@29 after you received potency testing results with a result of 126%, outside your range of (b) (4)%. This lot was distributed to (b) (4) patients and your pharmacist was unable to determine if the patients were notified of the superpotent drug product.

In addition, your firm does not routinely perform potency testing on your drug products and has not tested any drug products produced since August 2017.

OBSERVATION 2

Failure to reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ashar P Parikh, Investigator	X Ashar P Parikh Investigator Signed By: Ashar P. Parikh -S Date Signed: 06-27-2018 14:22:00	6/27/2018

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Your firm received (b) (4) shipments of Domperidone BP lot #(b) (4) in (b) (4) 2017. The Domperidone BP label states the bulk drug substance is "FOR VETERINARY USE ONLY." Your firm used lot #(b) (4) to produce (b) (4)- 20mg capsules on March 27, 2017 and June 27, 2017 and (b) (4)- 10mg capsules on December 8, 2017. These capsules were intended for human consumption and distributed to patients as part of prescriptions #(b) (6) and (b) (6) .

OBSERVATION 3

Laboratory controls do not include determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components used in the manufacture, processing, packing, or holding of drug products.

Specifically,

Your firm does not utilize compendial grade purified water for the production of drug products. For example, your firm utilizes non-compendial grade (b) (4)(b) (4) water purchased from (b) (4) stores to use in the production of drug products including but not limited to Dyclonine 1% Oral Solution as shown on the logged formula worksheet for lot #04202018:35@19 produced on 4/23/2018.

In addition, your firm has not performed any microbial testing on the store bought (b) (4) water.

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