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)%.

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,
Your firm received 3 shipments of Domperidone BP lot #44 in 4444. The Domperidone BP label states the bulk drug substance is "FOR VETERINARY USE ONLY." Your firm used lot #4444 to produce 30mg capsules on March 27, 2017 and June 27, 2017 and 10mg capsules on December 8, 2017. These capsules were intended for human consumption and distributed to patients as part of prescriptions 3333 and 3333.

**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 water purchased from 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 water.