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,

There was no analytical data to support the label claim potency of multiple products at the time of dispensing or throughout the labeled six month beyond use date. The dispensed products were for medical office use and not patient specific.

This included:

a. Hydroxyzine Pamoate 25mg/5ml Suspension for Human use; this preparation was dispensed on (b) (4), (b) (6)

b. Gabapentin 50mg/ml Fixed Oil Suspension for Animal use; this preparation was dispensed on (b) (4), (b) (6)

c. Ondansetron 4mg/ml Suspension for Animal Use, this preparation was dispensed on (b) (4), (b) (6)
d. Piroxicam 5mg Capsules for Animal Use, this preparation was dispensed (b) (4) (b) (4), (b) (6). The preparation instruction for this preparation listed a 6 month beyond use date, but the prescription label actually listed a one year beyond use date of 10/12/2016. No explanation was provided for this discrepancy.

*DATES OF INSPECTION
6/14/2016(Tue),6/16/2016(Thu),6/21/2016(Tue),6/22/2016(Wed)

X Nancy M Espinal
Nancy M Espinal
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Signed by: Nancy Espinal - 5

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DATE ISSUED 6/22/2016

INSPECTIONAL OBSERVATIONS