

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	DATE(S) OF INSPECTION 6/14/2016-6/22/2016* FEI NUMBER 3007537202
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Ann Ervin , Pharmacist in Charge

FIRM NAME Village Pharmacy	STREET ADDRESS 1280 Yardville-Allentown Rd
CITY, STATE, ZIP CODE, COUNTRY Allentown, NJ 08501-1830	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 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 **(b) (4)**

(b) (4), (b) (6)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Paul L Bellamy, Investigator Nancy M Espinal, Investigator	<input checked="" type="checkbox"/> Paul L Bellamy <small>Paul L Bellamy Investigator Signed by: Paul L. Bellamy D-5</small>	DATE ISSUED 6/22/2016

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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)
6/22/2016

Nancy M Espinal

Nancy M Espinal
Investigator
Signed by: Nancy Espinal -5

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