

**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 7/23/2018-7/26/2018 FEI NUMBER 3010987875
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alec Gillies, General Manager

FIRM NAME Buffalo Pharmacies Inc	STREET ADDRESS 6035 Transit Rd
CITY, STATE, ZIP CODE, COUNTRY East Amherst, NY 14051-1803	TYPE ESTABLISHMENT INSPECTED Producer of Non Sterile Drug Product

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**

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, on 07/24/2018, I observed a compounding technician use (b) (4) (b) (4) as an ingredient based on your formulation ^{sheet} ~~recipe~~ to produce (b) (4) suppositories. Additionally, the same (b) (4) is used to produce Nystatin Vaginal (b) (4) Units suppositories.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tonia F Bernard, Investigator	<small>Tonia F Bernard Investigator Signed By: 2001837563 Date Signed: 07-26-2018 10:30:48</small> X	DATE ISSUED 7/26/2018