

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax: (973)331-4969	<small>DATE(S) OF INSPECTION</small> 7/23/2018-7/26/2018  <small>FBI NUMBER</small> 3010987875	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Alec Gillies, General Manager		
<small>FIRM NAME</small> Buffalo Pharmacies Inc	<small>STREET ADDRESS</small> 6035 Transit Rd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> East Amherst, NY 14051-1803	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Non Sterile Drug Product	
<p>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.</p>		
<p><b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b>  <b>OBSERVATION 1</b></p> <p>You used a non-pharmaceutical grade component in the formulation of a drug product.</p> <p>Specifically, on 07/24/2018, I observed a compounding technician use (b) (4) as an ingredient based on your formulation <sup>sheet</sup> <del>recipe</del> to produce (b) (4) suppositories. Additionally, the same (b) (4) is used to produce Nystatin Vaginal (b) (4) Units suppositories.</p>		
<p><b>SEE REVERSE OF THIS PAGE</b></p>	<small>EMPLOYEE(S) SIGNATURE</small> Tonia F Bernard, Investigator	<small>DATE ISSUED</small> 7/26/2018  <small>Tonia F Bernard Investigator Signed By: 2001837563 Date Signed: 07-26-2018 10:30:48</small> X
<small>FORM FDA 483 (09/08)      PREVIOUS EDITION OBSOLETE      INSPECTIONAL OBSERVATIONS      PAGE 1 of 1 PAGES</small>		