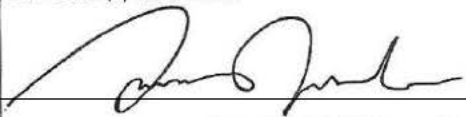


DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Baltimore District Office 6000 Metro Drive, Suite 101 Baltimore, MD 21215 410-779-5455 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 11/04/2019 - 11/07/2019	
		FEI NUMBER 3012958560	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Dr. David S. Elefterion, Owner/Pharmacist in Charge			
FIRM NAME Apex Pharmacy, LLC.		STREET ADDRESS 165 Ragland Road	
CITY, STATE AND ZIP CODE Beckley, WV 25801		TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs	
<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>DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:</p>			
<p>1. Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Specifically,</p> <p>Your firm uses non-pharmaceutical grade (b) (4) as a component in the production of various strengths of Tretinoin Topical Cream, gel, ointments and, Omeprazole 5mg/mL oral suspension (b) (4) was used in the production of (b) (4) lots of the compounded drug products, produced between May 10, 2019 and November 7, 2019.</p>			
<p>2. Non-microbial contamination was observed in your production area. Specifically,</p> <p>The (b) (4) analytical balance, Serial No (b) (4), used to weigh components of your firm's non-sterile compounded drug products, was observed to have compromised structural integrity of the back-panel of the inner balance chamber. Although the back-panel is not an intended product contact surface, there is potential for particulate shedding of the back-panel material (paint chips, fibers, etc.) to enter and contaminate the non-sterile components during weighing activities.</p>			
<p>3. Personnel engaged in aseptic processing were observed with exposed hands. Specifically,</p> <p>On 11/04/19, your firm's Pharmacist in Charge (PIC) was observed verifying (re-weighing) components, weighed out by the pharmacy technician, during compounding of Lidocaine/Tetracaine, 23/7% Ointment, Lot No. 10252019@2, without gloves.</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Marcellinus D. Dordunoo, Investigator	DATE ISSUED 11/07/2019