

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875		DATE(S) OF INSPECTION 07/08/2019-07/17/2019	
		FEI NUMBER 1000121499	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Rosemary E. Mihalko, Owner			
FIRM NAME Hieber's Pharmacy		STREET ADDRESS 3500 5 th Avenue; Suite 100	
CITY, STATE, ZIP CODE, COUNTRY Pittsburgh, PA 15213-3337		TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile drug products	
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
OBSERVATION 1			
Procedures designed to identify and prevent insanitary conditions are not established and followed by your firm.			
Specifically,			
Your firm did not perform appropriate environmental monitoring in your aseptic processing areas. For example, pressure differentials between areas with different air classifications were not monitored before or during sterile drug production.			
The air pressure differential between the ISO 5 (b) (4) and the ISO 7 clean room is not monitored. Instead personnel perform a (b) (4) visual inspection of the pressures on the (b) (4) and the clean room gauge, and record the pressures on the Cleaning and Calibration Log. Additionally, there is no pressure gauge to monitor the pressure or pressure differential between the ISO 7 clean room and the uncontrolled environment in the vestibule.			
This is a repeat observation from the 2017 inspection.			
SEE REVERSE OF THIS PAGE		Digitally signed by Lisa Orr -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Lisa Orr -S, 0.9.2342.19200300.100.1.1=2001665590 Date: 2019.07.17 12:01:22 -0400	DATE ISSUED 07/17/19
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