DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Baltimore District Office 6000 Metro Drive, Suite 101 Baltimore, MD 21215 410-779-5455 Industry Information: www.fda.gov/oc/industry	08/06/2018 - 08/17/2018
	FEI NUMBER 3014616172

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Brian H. Trentler, Vice President/Pharmacist in Charge

FIRM NAME	STREET ADDRESS
HV Pharmacy Inc. dba Hunt Valley PharmaLab	10 Warren Road, Suite 220
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Cockeysville, MD 21030	Producer of Sterile and Non-Sterile Drugs

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) (WE) OBSERVED:

1. The cycle parameters (b) (4) used for (b) (4) sterilization of product intended to be sterile are not adequately evaluated to ensure lethality to (b) (4) resistant microorganisms. Specifically,

Your firm places a biological indicator in (b) (4) when (b) (4) sterilizing subcutaneous 12.5mg, 50mg, 92.5mg, 100mg Testosterone pellets and, 6mg, 25mg Estradiol pellets in the (b) (4) for (b) (4) at (b) (4) and (b) (4). The biological indicators are not processed or subjected to the same conditions as the pellets therefore there is no assurance that the (b) (4) cycle parameters utilized to sterilize the pellets are adequate. In addition, there is no documentation available that assesses the impact of (b) (4) sterilization on the compressed pellets. (b) (4) lots of Testosterone pellets and (b) (4) lots of Estradiol pellets have been produced and distributed since May 2018.

2. Personnel were observed conducting aseptic manipulations in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product. Specifically,

On 08/08/2018, during repackaging of one, 4ml vial of Avastin, Lot #3228610, injectable solution into (b) (4) syringes, containing 0.05ml/syringe of Avastin injectable solution, an operator was observed to place his hand(s) directly above the un-capped, open vial of 4ml Avastin single dose injectable solution, blocking unidirectional air flow while in the Class 100 (b) (4) Laminar Air Flow Workstation #1.

3. Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Specifically,

Your firm uses (b) (4) as a component in the production of Benazepril 2.5mg/ml suspension, Methimazole 10mg/ml suspension, Enalapril 5mg/ml suspension, Amlodipine 1.25mg/ml suspension, and Furosemide 10mg/ml suspension.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Marcellinus D. Dordunoo, Investigator	08/17/2018