U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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August 23, 2019

VIA UPS Next Day Air
Ms. Deena Speights-Napata
Executive Director
Maryland State Board of Pharmacy
PO Box 1991
Baltimore, MD 21203

Dear Ms. Speights-Napata:

The purpose of this letter is to refer to the Maryland State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Maryland BOP, HV Pharmacy, Inc. dba Hunt Valley PharmaLab, located at 10 Warren Road, Suite 220, Cockeysville, MD 21030 (License# PW0507; Expiration date: 05/31/2020).

FDA inspected the firm from August 6, 2018, to August 17, 2018. FDA investigators were accompanied by Maryland state investigators for one day. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/120717/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Hunt Valley PharmaLab and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

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.

2. An operator was observed to place their hands directly above an un-capped, open vial inside the LAFW.

3. The firm used (b) (4) water for non-sterile compounding.

Hunt Valley PharmaLab committed to FDA in its responses to the Form FDA 483, dated September 6, 2018 and October 1, 2018, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Maryland State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Compliance Officer, CDR Liatte Closs, at 973-331-4933, or by email at Liatte.Closs@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000115 79, cn=Diana Amador-toro -S
Date: 2019.08.26 09:36:15 -04'00'

Diana Amador-Toro
Program Division Director/District Director
Office of Pharmaceutical Quality Operations, Division I

Cc: Mr. Brian H. Trentler
Pharmacist in Charge
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