May 3, 2022

Case #632383

Via E-Mail
Jessica Sapp
Executive Director
Florida State Board of Pharmacy
4052 Bald Cypress Way Bin C-04
Tallahassee, FL 32399-3258
MQA.Pharmacy@flhealth.gov

Dear Ms. Sapp:

The purpose of this letter is to refer to the Florida State Board of Pharmacy (BOP) for appropriate follow up to 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 Florida BOP, Pharmcore Inc. dba Hallandale Pharmacy, located at 2666 SW 36th St., Fort Lauderdale, FL 33312-5005 (Community Pharmacy License #PH19163 and Special Sterile Compunding Pharmacy License #PH28017).

FDA inspected the firm from September 13, 2021, to September 24, 2021. The Florida State BOP was informed of the inspection and accompanied FDA investigators on Day 1 and during the closeout meeting of the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/154256/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.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
One Main Place, 1201 Main Street, STE 7200
Dallas, TX 75202
www.fda.gov

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 cleaning procedures that were inadequate to prevent cross contamination.

Pharmcore, Inc., committed to FDA in its response to the Form FDA 483 (received on October 15, 2021) 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. Therefore, FDA is referring this matter to the Florida 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 Mr. Thao Ta, Compliance Officer, at thao.ta@fda.hhs.gov or by phone at 214-253-5217.

Sincerely,

Caroline H. Le -S3

Digitally signed by Caroline H. Le -S3
Date: 2022.05.02 22:51:39 -06'00'

CDR Caroline Le, PharmD.
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

cc: **Via E-Mail**
Mr. David G. Rabbani, Owner and President
Pharmcore Inc. dba Hallandale Pharmacy
2666 SW 36th St
Fort Lauderdale, Florida 33312-5005
drabbani@hallandalerx.com