DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	9/13/2021-9/24/2021* FEI NUMBER 3014480778

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David G. Rabbani, President

FIRM NAME	STREET ADDRESS
Pharmcore Inc. dba Hallandale Pharmacy	2666 SW 36th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Lauderdale, FL 33312-5005	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 OBSERVED:

OBSERVATION 1

Cleaning procedures are inadequate to prevent cross contamination.

Specifically,

Your firm cleans and disinfects the sterile compounding suites for hazardous and non-hazardous drug products on (b) (4) basis prior to aseptic activities. Your current procedure is to clean the sterile hazardous suite first before cleaning the sterile non-hazardous suite. The order in which you clean inappropriate because it may potentially cross contaminate and introduce hazardous materials into the non-hazardous suite. Furthermore, your QA Director stated that while the technician will change sterile gloves and sterile booties, he/she does not re-gown in-between.

OBSERVATION 2

You did not take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

Your QA Director stated that a thorough "(b) (4) " clean is conducted when an objectionable microorganism is found during environmental monitoring of your ISO classified areas. However, your firm failed to thoroughly clean and disinfect the sterile hazardous and sterile nonhazardous rooms containing the ISO5 biosafety cabinet

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 09-24-2021 14:39:11	9/24/2021

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David G. Rabbani, President	
FIRM NAME Pharmcore Inc. dba Hallandale Pharmacy	STREET ADDRESS 2666 SW 36th St
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(BSC) and ISO5 laminar air flow hood (LAFH) after actionable microbial contamination was recovered whether or not objectionable microorganisms were found. For example:

- *Staphylococcus epidermidis* was isolated during the active air sampling conducted on March 29, 2021 in the ISO5 BSC during the aseptic production of Gonadorelin HCl 2mg, Lot #97145.
- *Staphylococcus epidermidis* was isolated during the post process surface sampling of Ipamorelin 9mg, Lot #97277 conducted on March 29, 2021 in the ISO5 LAFH.
- *Micrococcus luteus* was isolated during the active air sampling conducted on April 26, 2021 in the ISO5 BSC during the aseptic production of HCG 5000IU, Lot #100385.
- *Bacillus megaterium* was isolated during the post process fingertip sampling of Testosterone Cypionate (b) (4) 200mg/ml, Lot #98400 conducted in the ISO5 BSC on April 8, 2021.

OBSERVATION 3

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

On 9/15/2021, I observed your sterile technician fail to properly disinfect the plastic bag containing the sterile (b) (4) and sterile (b) (4) used to (b) (4) and collect the mixture of Gonadorelin, Lot #117356 prior to placement in the ISO5 Laminar Flow Hood which is located in your firm's ISO7 Mixing/Weighing room for sterile non-hazardous compounded drug products.

***DATES OF INSPECTION**

9/13/2021(Mon), 9/14/2021(Tue), 9/15/2021(Wed), 9/17/2021(Fri), 9/20/2021(Mon), 9/21/2021(Tue), 9/24/2021(Fri)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."