DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	5/17/2016-5/25/2016* FEI NUMBER 3006899675

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph S. Corgan , Pharmacist In-Charge

FIRM NAME	STREET ADDRESS
Home Care Pharmacy of Palm Coast, Inc.	6 Florida Park Dr, Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Palm Coast, FL 32137-3891	Producer of 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

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. On 05/17/2016, I observed your firm's technician cleaning the ISO 5 (b)(4), which was (b)(4) and the (b)(4). During this cleaning, the technician did not follow procedure "Germfree – (b)(4)" SOP 3.020 which specifies to perform the cleaning process with (b)(4). Instead, the technician cleaned the ISO 5 area with (b)(4) cleanings. In addition, the technician was not wearing any sterile gowning items during this cleaning. The technician had exposed hair that touched the sleeves, gloves, and other parts of the ISO 5 area during the cleaning process. Furthermore, during the cleaning of the ISO 5 area your firm used non-sterile wipes which are stored open in the ISO 8 area.

B. Your firm does not use a sporicidal agent during cleaning of the ISO 5 areas. Per your Pharmacist In-Charge (PIC) the chemicals used to clean are Sterile (b)(4). Furthermore, application times of the cleaning solutions are not well defined in the procedure. Per your firm's technician the application time for (b)(4) is approximately (b)(4), however, per (b)(4) manufacturer's recommendations a minimum of (b)(4) is needed for fungicidal effectiveness. Your firm's cleaning procedure "(b)(4)" SOP 3.010 and "GermFree-Compounding Aseptic (b)(4) SOP 3.020, only addresses hold times for the (b)(4) and not the (b)(4) disinfectant.

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OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Per your procedure "Quality Assurance Program" SOP 9.8 and PIC, environmental monitoring of the ISO 5 area and operators gloves is done (b)(4). During the time between the (b)(4) monitoring periods there are no (b)(4) activities being performed during production of sterile drug products. In addition, there is no form of daily monitoring of the ISO 5 area. For example, during this time period no air monitoring, surface sampling, glove sampling, or particulate sampling is being performed.

OBSERVATION 3

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically,

On 05/17/2016, I observed cleaning of the ISO 5 area during this time the technician wore only non-sterile gloves and a non-sterile face mask, no gowning was worn to prevent particulate shedding and maintain the sterility of the ISO 5 area. For example, the technician was not wearing any sterile hair nets, gowns, gloves or shoe covers.

OBSERVATION 4

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

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On 05/23/2016, your PIC stated that testing of endotoxin levels and bioburden of sterile drug products is only done (b)(4). Review of testing results shows only (b)(4) non-sterile to sterile products are being actively assessed for endotoxin levels or bioburden. Your firm produces the following sterile products from non-sterile components.

- Alprostadil 100 mcg/ml/ (b)(4) (PGE1)
- Papaverine HCL 30 mg/mL/ Phetolamine Mesylate 1.5 mg/mL injection Solution (Bi-Mix)
- Alprostadil 10 mcg/Papaverine HCL 30 mg/Phentolamine Mesylate 0.5 mg/mL Injection Solution (Tri-Mix)
- Dexamethasone Sodium Phosphate
- Papaverine HCL 18.9 mg/mL/Phentolamine Mesylate 0.9 mg/mL/ Atropine Sulfate 0.18 mg/mL/Alprostadil 9 mcg/mL Injection Solution (Quad- Mix)
- Droperidol 2.5 mg/mL Injection Solution
- Glutathione 200 mg/mL Injection Solution
- Hydroxocobalamin 10 mg/mL Injection Solution
- Sodium Hydroxide 0.1N/ (b)(4)

OBSERVATION 5
Written records are not made of investigations into unexplained discrepancies.

Specifically,

A. On (b)(4), your technician had positive growth during media fill testing, yet there is no record of investigation or retesting. A note on the test record says "possible vial contamination", however, no further information is provided in support of the finding or impact to products using the same lot of vials. Furthermore, this media fill was considered as a passing media fill.

B. On 05/18/2016, I observed your technician perform a (b)(4) test which

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resulted in a failing test result (below (b)(4) This failing test result and the initial processing of the sterile product were not recorded in any manner, including on documents associated with aseptic processing. There was no investigation conducted to determine the root cause of the failure. However, the technician did mark the product with an "X" and remake the order. The PIC was not notified until after the product was remade and (b)(4) test passed.

OBSERVATION 6

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing and processing.

Specifically,

On 05/24/2016, I requested the production records for prescription number (b)(6) and (b)(6) Your PIC was unable to locate the records associated with this aseptically produced drug product. A logbook is used to record production of sterile products; this logbook does not contain the records for either prescription requested.

OBSERVATION 7

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

The ISO 8 room in-which the ISO 5 (b)(4) is located, does not have HEPA filter units at the air supply vents for the area. The filter located in the return air grate is not sufficient to ensure adequate filtration of the air circulating through the area.

***DATES OF INSPECTION**

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5/17/2016(Tue),5/18/2016(Wed),5/19/2016(Thu),5/20/2016(Fri),5/23/2016(Mon),5/24/2016(Tue),5/25/2016(Wed)

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