

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 4/23/2018-4/25/2018
	FBI NUMBER 3006899675

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

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

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**

You produced hazardous drugs without providing adequate containment, segregation and cleaning of work surfaces to prevent cross-contamination.

Specifically,

On 04/24/2018, I observed the production of prescription (b) (6) (estrogen and testosterone vaginal cream) and Methimazole 2.5mg/0.1mL, Lot 042418A, used in the filling of prescription # (b) (6). The scale was not cleaned in between the weighing of ingredients, including the active ingredients: methimazole, estrogen, and testosterone. In addition, the hood used to produce these drug products was not cleaned in its entirety in between the production of each drug product.

OBSERVATION 2

You produced beta-lactam drugs without providing adequate containment, segregation and cleaning of work surfaces to prevent cross-contamination.

Specifically,

Beta-lactam drug products are produced in the same hood as other drug products without appropriate segregation and cleaning of the hood and equipment. For example, on 04/17/18, your firm produced prescription # (b) (6) for Amoxicillin 125mg/mL followed by prescription # (b) (6) for Progesterone,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jennifer L Huntington, Investigator	Investigator Signed By: Jennifer L. Huntington X Date Signed: 04-25-2018 13:33:52	DATE ISSUED 4/25/2018

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Estrogen, and Testosterone cream without cleaning the hood and equipment in between the production of each drug product.

OBSERVATION 3

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

Your firm has not conducted any testing (microbial and analytical) of the water (b) (4) (b) (4) system. This water has been used as a component during the production of various drug products. For example, (b) (4) water was used in the formulation for Potassium Bromide 250mg/mL, prescription # (b) (6) and Glutaraldehyde 5% Aqueous Solution, prescription # (b) (6)

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	Jennifer L Huntington Investigator Signed By: Jennifer L. Huntington -3 Date Signed: 04-25-2018 11:33:52 X	