DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	05/02/2016 - 05/12/2016
	FEI NUMBER 3012289984

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Marcelino Casal, President/CEO

FIRM NAME	STREET ADDRESS
Well Care Discount Pharmacy LLC DBA Well Care Compounding Pharmacy DOE 5/3/16	3430 E Tropicana Ave Ste 9
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89121-7345	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically,

A. Your firm has not performed smoke studies under dynamic conditions to demonstrate unidirectional air flow patterns in the (b) (4) where sterile injectable drug products are prepared. According to the Lab Manager, smoke studies have been performed; however, your firm does not have any documented evidence of these studies.

B. The (b) (4) has not been correctly performed for all batches of sterile injectable drugs ever produced at your firm. On 05/02/2016 and 05/04/2016, we observed the Lab Manager performing (b) (4) The Lab Manager (b) (4) (b) (4) . He was unable to (b) (4) . Without (b) (4) , your firm lacks sterility assurance of sterile injectable drugs produced at your firm. Between 04/01/2014 and 05/10/2016, approximately (b) (4) batches of sterile injectable drugs were prepared by your firm.

C. Your firm's Lab Manager was repeatedly observed performing sterile manipulations that blocked the HEPA unidirectional air flow. On 05/02/2016 and 05/04/2016, we observed the aseptic preparations of TESTOSTERONE CYP Lot # 04292016:35@11 and METHYLCOBALAMIN Lot # 05042016:98@11, respectively. We observed the Lab Manager blocking the unidirectional air flow to the product vials by placing his right hand directly over the open vial while performing sterile (b) (4) . We also observed the Lab Manager blocking unidirectional air flow to the open sterile vials with his arms directly over the open vials.

D. There is a lack of frequent disinfection of gloves used for sterile drug process. On 05/02/2016 and 05/04/2016, we observed the (b) (4) gloves disinfected with sterile (b) (4) only (b) (4) . In addition, on 05/02/2016, we observed the Lab Manager (b) (4) but did not allow the (b) (4) . The gloves appeared to be sticky after applying the (b) (4) to the point

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where the product vials were sticking to the gloves during manipulations.

E. On 05/02/2016 and 05/04/2016, we observed the aseptic preparations of TESTOSTERONE CYP Lot # 04292016:35@11 and METHYLCOBALAMIN Lot # 05042016:98@11, respectively. We observed the Lab Manager touching the product contact surface of the sterile rubber stopper when removing them from the vial. We also observed the product contact surface of the sterile rubber stopper touching the work bench of the ISO 5 (b) (4)

F. On 05/02/2016 and 05/04/2016, we also observed the Lab Manager stoppered the product vials by gloved hand after sterile (b) (4) . We observed the Lab Manager having difficulty picking up each sterile rubber stopper by the rim (a non-product contact surface), we observed him grabbing and touching the product contact surface part of the stopper with his (b) (4) gloves.

G. Your firm performs media fills (MF) using the (b) (4) (b) (4) ". However, the (b) (4) did not simulate the actual production solution preparation of (b) (4) Also, the largest batch prepared by your firm was about (b) (4) are prepared following MF (b) (4)

OBSERVATION 2

Aseptic processing areas are deficient in that walls and ceilings are not smooth and/or hard surfaces that are easily cleanable.

Specifically, on 05/02/2016 and 05/04/2016, we observed the aseptic preparations of TESTOSTERONE CYP Lot # 04292016:35@11 and METHYLCOBALAMIN Lot # 05042016:98@11, respectively. During the production of these lots we observed the following:

A. We observed exposed wood-like material underneath the (b) (4) of the ISO 5 (b) (4) . The ISO 5 (b) (4) made (b) (4) Underneath the (b) (4) we observed a (b) (4) that exposes the wood-like material. The (b) (4) The wood-like material is particle shedding, difficult to clean and disinfect, and may harbor microbial contamination.

B. In the ISO 8 clean room where the ISO 5 (b) (4) is located, we observed a countertop/work bench and several storage shelving are made of laminated particle board. We observed exposed wood-like material on the underneath sides of the countertop/work bench and the shelving.

C. In addition, your firm's ISO 8 clean room ceiling is made of pop-up tiles. We observed numerous gaps in the ceiling tiles and unsmooth caulking along the edges where the ceiling meets the walls. We also observed 3 vertically

aligned nail holes on the right side of the ISO 8 clean room wall above the (b) (4) . In addition, your firm's Lab Manager stated that the ISO 8 clean room ceiling and the storage shelving, with exception of the countertop/work bench, are not routinely cleaned.

OBSERVATION 3

The flow of components, drug product containers, closures, in-process materials, and drug products though the building is not designed to prevent contamination.

Specifically,

A. On 05/02/2016, we observed the aseptic preparation of TESTOSTERONE CYP Lot # 04292016:35@11. We observed the Lab Manager moving components and materials from the non-ISO classified area and also from ISO 8 room to the ISO 5 (b) (4) without disinfecting them. The components and materials were placed (b) (4) (b) (4) without being wiped down with any disinfectant. Once (b) (4) , they were only sprayed with sterile (b) (4) . We noted not all component and material surfaces were exposed to the sterile (b) (4)

B. We observed the Lab Manager used his bare hands to open the plastic curtains and entered the ISO 8 clean room head first. We observed Lab Manager's bare hands and facial skins touching the plastic curtains.

C. Weighing and mixing of non-sterile APIs and excipients for sterile preparations were not done in an ISO classified area. On 05/04/2016, we observed the aseptic preparation of METHYLCOBALAMIN Lot # 05042016:98@11. We observed the weighing and mixing of non-sterile API and excipients were performed in the non-ISO classified area. We also observed that the (b) (4) , including the (b) (4) were visibly stained, crusty, and dirty.

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, your firm does not adequately perform sterility and endotoxin testing on each lot of your firm's sterile products. Your firm's testing is in adequate for the following:

A. Your firm does not routinely perform sterility and endotoxin testing on your firm's sterile products. Since January 1st, 2016, your firm has not performed endotoxin testing on any sterile products and performed sterility testing on (b) (4) of sterile product. Your firm has produced (b) (4) lots of sterile product during that time period. Also, the Lab Manager has explained that approximately (b) (4) of sterile products produced before January 1st, 2016 were

tested for sterility.

B. According to the (b) (4) of sterility testing results from your contract testing laboratory, the sterility tests performed are not compliant to compendial standards because the "suitability of the method for the product has not been documented."

C. Your firm combines (b) (4) to make a combination product. However, your firm does not perform sterility, endotoxin, or potency on the new combination product.

D. Your firm's sterile drug products are only tested for potency (b) (4) (b) (4) Your firm has only performed potency testing on (b) (4) lots of sterile product produced (b) (4).

OBSERVATION 5

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

Specifically, environmental monitoring operations are inadequate for the following:

A. Pressure differential (PD) of the clean room facility is not monitored. Your firm lacks documented evidence that the PD is monitored on each day a batch of sterile drug is prepared in the ISO 5. Also, your firm has no pressure gauge installed to monitor the PD between the ISO 8 clean room and the unclassified area.

B. Your firm's environmental and personnel monitoring are not performed each day that a batch of sterile drug is produced in the ISO 5 (b) (4) Instead, they are performed on a (b) (4) basis.

C. Your firm has no written description, or justifications for how each environmental monitoring location was determined.

D. Growth promotion was not performed for each lot of (b) (4) for surface and gloved fingertip sampling.

E. Media suitable for the detection of yeast and mold species are not used in the environmental and personnel monitoring of your firm's clean room facility.

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OBSERVATION 6

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

Specifically,

A. Non-sterile lint-free wipes and non-sterile disinfectants, specifically, non-sterile (b) (4) and non-sterile (b) (4) are used to clean your firm's clean room facility including the ISO 5 (b) (4)

B. Recommended disinfectant contact time is not followed. Manufacturer labelings for (b) (4) and (b) (4) state to allow treated surfaces to (b) (4). In addition, (b) (4) labeling states that the contact dwell time is (b) (4) Your firm's Lab Manager stated that (b) (4) contact time was applied for the above (b) (4) disinfectants..

C. On 05/04/2016, we observed your firm's Lab Manager performing (b) (4) cleaning of the ISO 5 (b) (4) using sterile (b) (4) and non-sterile wipe. The Lab Manager indicated that he could not (b) (4) (b) (4). In addition, we observed the Lab Manager cleaning the (b) (4) r with his upper body leaning (b) (4). The Lab Manager wore non-sterile gown, non-sterile hair net, and non-sterile beard cover. The bare skin on his face was exposed.

D. On 05/02/2016, we observed reddish/orange spots on the (b) (4) surface of the (b) (4). Your firm's Lab Manager stated that the reddish/orange spots were probably spills from stopping or capping methylcobalamin (B12) vials.

E. On 05/02/2016, we observed an oily film covering most of the (b) (4) surfaces of the ISO 5 (b) (4) (b) (4) In addition, we observed white crystal-like structures along the (b) (4) surfaces of the (b) (4) near the (b) (4) work bench. Your firm's Lab Manager stated that the oil and white crystal-like structures were probably from sterile (b) (4) and they had been there for about a year.

F. During the inspection of your firm's clean room facility, we observed a piece of yellowish debris-like material on the ISO 5 (b) (4) Your firm's Lab Manager stated it was likely due to a (b) (4) (b) (4)

G. On 05/04/2016, we observed stains on the plastic curtains next to the ISO 5 (b) (4) The stains were on the lower half sections of the curtains close to the floor. On 05/10/2016, your firm's Lab Manager confirmed that they were on both sides of the curtains and were from mopping and splashing of the floor cleaning agents. The Lab Manager stated that he had attempted to clean the plastic curtains one time but the curtain panels became sticky after cleaning.

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There is no documentation showing that the curtains have been cleaned.

H. Your firm lacks documented evidence that the cleaning and disinfecting of the clean room facility has been performed (b) (4) . For example, your firm only has cleaning logs for the month of 02/2016, 03/2016, and 05/2016.

OBSERVATION 7

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

A. Your firm's has no justifications for assigning Beyond-Use Dates on the finish drug product beyond the expiration date of its ingredients. However, your firm routinely assigns Beyond-Use Dates that are longer than the expiration date of its ingredients. For example, the finish sterile product, ESTRADIOL VALERATE, Lot # 03092016:30@19 had a Beyond-Use Date of 06/07/2016. This lot was prepared using (b) (4) which had an expiration date of 02/28/2016.

(b) (4) lots reviewed of HCG Injection Solution which were produced in the last 6 months contained ingredients that expired before the finished product's Beyond-Use Date. (b) (4) lots of Estradiol Valerate 10 mg/mL Injection Solution which were produced in the last 6 months contained ingredients that expired before the finished product's Beyond-Use Date.

B. Your firm's Beyond-Use Date testing program for your sterile products consists of (b) (4) The testing program does not include sterility or endotoxin testing.

C. Your firm does not have written procedures for your Beyond-Use Date testing program.

D. Your firm relies on (b) (4) for a 6 month Beyond-Use Date for your sterile product, M.I.C. with Cobalamin. However, your firm also extends this (b) (4) of a 6 month Beyond-Use Date to two other products, M.I.C. with Methylcobalamin/Folic Acid and M.I.C. with Methylcobalamin/Vitamin C without any additional Beyond-Use Date testing.

E. Your firm's sterile products are marketed for multi-dose use. Your firm has not performed any studies to support that your container closure systems are able to adequately protect the product from contamination during multi-dose use.

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OBSERVATION 8

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, glassware used in the mixing and heating of API for sterile drug processing is not adequately depyrogenated. We observed glassware was depyrogenated (b) (4) . Your firm's SOP 8.010, entitled, "Sterilization and Depyrogenation", version 1.0, effective 08/26/2013, section 9.6.2 specifies (b) (4) in order to achieve depyrogenation.

OBSERVATION 9

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm does not review any unexplained discrepancies or failures of any batches. For example:

A. Your firm has experienced failed batches due to (b) (4) failures. The Lab Manager explained that the failures occur approximately (b) (4) . These batch failures were not investigated. The Lab Manager stated that the batch records were destroyed. However, there is no documented evidence showing that the batches were discarded.

B. On 05/02/2016 and 05/04/2016, we observed the aseptic preparations of TESTOSTERONE CYP Lot # 04292016:35@11 and METHYLCOBALAMIN Lot # 05042016:98@11. We observed a failure in the (b) (4) during the production of sterile product. No investigation was performed on the failed (b) (4)

OBSERVATION 10

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically, there is a lack of equipment/instruments calibration. For example, your firm has not calibrated the following equipment/instruments.

- Pressure gauges for the ISO 5 (b) (4) have never been calibrated.
- (b) (4) for the (b) (4) have never been calibrated
- Incubator used for the incubation of environmental monitoring (EM), personnel monitoring (PM), and media

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fills (MF) tests have never been calibrated.

- The (b) (4) pH meter is calibrated every (b) (4) with no log record of calibrations.
- Thermometers and probes for the refrigerator and freezer used in the storage of quarantine and released finished sterile drug products have never been calibrated.

OBSERVATION 11

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, the garments and protective apparel worn by your Lab Manager is inadequate. Your firm's clean room gowning consists of non-sterile shoe covers, non-sterile hair net, non-sterile face mask, non-sterile beard cover, non-sterile lab coat, and sterile gloves.

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