DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE 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	02/26/2018- 03/08/2018
	FEI NUMBER 3011769075

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric L. Sparks, PharmD, Pharmacy Manager

FIRM NAME	STREET ADDRESS
One Way Drug LLC dba Partell Specialty Pharmacy	5835 S. Eastern Ave. Suite 101
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Las Vegas, NV 89119	Producer of Sterile and Non-Sterile Drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

The (b) (4) intended to render final product sterile is not adequate to accomplish sterilization and/or is not pharmaceutical grade.

Specifically,

a. Your firm uses the (b) (4) , when compounding large volume batches of sterile finished product.

The (b) (4) does not appear to be pharmaceutical grade and the labeling for the (b) (4) states "Do not use these systems in direct patient care applications."

There is no (b) (4) testing method for the (b) (4) . The firm releases finished drug product without determining the suitability of (b) (4) . Examples of products, where the (b) (4) has been used as the (b) (4) are Coenzyme Q10, Ascorbic acid, and Vitamin B Complex.

b. There is no assurance that the (b) (4) used to render drug product sterile is adequate to ensure the integrity of such (b) (4) Your firm was unable to confirm what required (b) (4) is used when performing (b) (4) testing on (b) (4) . There is a discrepancy with the required (b) (4) written in the (b) (4) test log and the manufacturers requirement. For example, the log states '(b) (4)' required for the (b) (4) , yet the manufacturer requires (b) (4). Your firm does not document the actual value in the Formula Worksheet and simply enters "PASS or FAIL".

OBSERVATION 2

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	Juanita Versace	Lucila B. Nwatu, Investigator/CSO Juanita P. Versace, Microbiologist	03/08/2018

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The cycle parameter ((b) (4)) used for (b) (4) of product interned to be sterile are not verified to be lethal to (b) (4) microorganisms.

Specifically,

a. Your firm performs all compounding and filling operations for (b) (4) pellet products in an unclassified Biosafety Cabinet, located in an unclassified room. Pellet products include:

- Estradiol, 10mg, 12.5mg, 15mg, 20mg, 25mg, 35mg, 40mg, 50mg, 55mg Pellets
- Naltrexone, 200mg Pellets
- Pregnenolone, 50mg, 100mg Pellets
- Progesterone, 50mg Pellets
- Testosterone/Anastrozole 120/8mg; 180/12mg; 200/20mg; 60/1mg; 60/4mg Pellets
- Testosterone/Estradiol 60/6 mg Pellets
- Testosterone 100 mg, 200 mg, 25 mg, 37.5 mg, 40 mg, 50 mg, 55 mg, 80 mg Pellets
- Testosterone/ Finasteride 60/5 mg, 80/8mg Pellets
- Testosterone/ Finasteride/Anastrozole 120/10/4 mg Pellets

b. Your firm uses the (b) (4) for both (b) (4) sterilization and sterilization of container-closures, such as stoppers and final product vials. Effectiveness of (b) (4) is verified using (b) (4) (b) (4) Biological Indicators. The manufactured recommends incubation conditions of (b) (4) for (b) (4) . Biological Indicator (b) (4) incubator is not calibrated to ensure the temperature can maintain (b) (4) . The (b) (4) does not contain a visual thermometer to monitor the temperature during BI incubation.

c. Your firm conducts (b) (4) sterilization on sealed vials containing pellet products, using an (b) (4) (b) (4) . There is no adequate scientific justification for the (b) (4) used to (b) (4) sterilize implantable pellets, including consideration of (b) (4) and the pellets themselves. There is no assurance that (b) (4) is adequate for pellets in sealed containers.

OBSERVATION 3

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The final containers/closures used for drug product intended to be sterile have not been sterilized or de-pyrogenated.

Specifically,

a. Your firm does not depyrogenate the non-sterile stoppers and vials before conducting filling operation for all aseptically filled drug products.

b. Your firm does not depyrogenate the non-sterile stoppers and vials before conducting filling operation for all (b) (4) sterilized pellet drug products.

OBSERVATION 4

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically,

To clean and disinfect the ISO- 5 Laminar Air Flow Hood (LAFH), the firm uses non-sterile (b) (4) Wipers, non-sterile (b) (4) Dry Wipes, non-sterile (b) (4) non-sterile (b) (4), and sterile (b) (4) (b) (4) spray.

OBSERVATION 5

The use of sporicidal agents in the cleanrooms and/or ISO 5 areas is inadequate.

Specifically,

Your firm has not established sufficient contact time for all disinfectants use in the cleanroom. Your film failed to follow manufacturer's recommended contact times for the disinfectants used in the controlled environments. For example, for non-sterile sporicidal agent (b) (4), the manufacturer recommends a contact surface time of

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(b) (4) . Your daily cleaning/disinfecting log for controlled environments and procedure, does not indicate contact times. Pharmacy Lab Manager and Technicians confirmed that after spraying (b) (4) on the surface, the solution is immediately removed. Demonstration of the effectiveness of the cleaning operations was not assessed due to lack of established contact times.

OBSERVATION 6

You produced hazardous drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm uses non-dedicated glassware and utensils to weigh and mix non-sterile hazardous and non-hazardous ingredients, in preparation for aseptic filling operations. Examples of hazardous ingredients used in your facility include Testosterone Cypionate and Alprostadil.

OBSERVATION 7
Non-sterilized or non-depyrogenated tools or temporary container were used in sterile production.

Specifically,

Your firm uses glassware and utensils to weigh and mix non-sterile ingredients, in preparation for aseptic filling operations. Your firm does not adequately clean the glassware and utensils to prevent cross-contamination. Glassware, spatulas, and mixing bars are washed in a dishwasher using (b) (4) . Your firm has not conducted any testing (microbial and analytical) of the water generated through your (b) (4) system. The glassware is placed in (b) (4) . There is no assurance that these conditions sterilization or depyrogenation these materials prior to use in compounding sterile drug products.

OBSERVATION 8

Environmental monitoring in your aseptic processing areas is not adequate.

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Specifically,

a. Review of the last (b) (4) Environmental Monitoring report, dated 11/30/17, revealed that Micrococus species and Aspergillus was detected when viable air sampling was conducted in the ISO-5 Laminar Air Flow Hood. As a corrective action, your firm performed cleaning (b) (4) times in the controlled environment, and air sampling was repeated. An investigation was not conducted and a root cause was not determined.

b. (b) (4) surface sampling is part of the firm's Environmental Monitoring program. Surface samples are taken with (b) (4), immediately after spraying sterile (b) (4) (b) (4) on the surface.

OBSERVATION 9
Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed. .

Specifically,

a. Sterile drug filling is conducted inside the ISO 5 core of Laminar Air Flow Hood (LAFH). The evaluation of unidirectional airflow (e.g., smoke studies) for microbiological contamination was not performed under dynamic conditions in the ISO 5 LAFH, which is located in an ISO 7 environment.

b. During filling operations, we observed that the doors from the ISO 8 compounding room to the ISO 7 Ante room, and the door from the ISO 7Ante-Room to the ISO 7 aseptic filling room, did not stay consistently closed. We heard multiple alarms during the aseptic filling due to loss in pressure. The firm cannot assure continuous positive pressure during filling operations.

OBSERVATION 10

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

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(b) (4) media fill testing is performed, but are not designed to simulate firm's routine aseptic operation.

a. Your firm conducts Media Fill in (b) (4) . A commercially purchased kit containing (b) (4) (b) (4) , are used to conduct media fills. The content of the (b) (4) of this solution is (b) (4) . This procedure is repeated (b) (4) times. This does not simulate their filling process. The bag is not representative of the container/closures used during routine production.

b. When filling large batch size sterile products, the firm uses a fluid dispensing pump. For example, the fluid dispensing pump is used during filling of Methylcobalamin, 12.5mg/ml injection, whose batch size is (b) (4) into 50 ml vials or 500ml into 5 ml vials. This pump is not included during the media fill simulation.

You have a sterility failure as evidence of production under insanitary conditions. Your firm conducted an inadequate Sterility OOS investigation. Review of OOS Sterility failure investigation revealed Bacillus species was detected in (b) (4) The firm's corrective action includes cleaning and disinfecting the controlled environment (b) (4) times. Demonstration of the effectiveness of the cleaning operations was not assessed because environmental and personnel monitoring was not performed afterward.

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*DATES OF INSPECTION
2/26/2018(Mon), 2/27/2018(Tue), 2/28/2018(Wed), 3/01/2018(Thu), 3/02/2018(Fri), 3/05/2018(Mon), 3/06/2018 (Tue), 3/07/2018(Wed), 3/08/2018(Thu)

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