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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 05/21/2014 - 05/30/2014*<br>FEI NUMBER<br>3010839113 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Robert A. Seik, Pharm D./Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| One Way Drug, LLC dba Partell Specialty Pharmacy | 8751 W Charleston Blvd, Suite 120 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Las Vegas, NV 89117-5480 | Producer of 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 WE OBSERVED:**

## OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, [redacted] (b) (4) used for [redacted] (b) (4) sterilization processes has not been qualified.

a. You use a [redacted] (b) (4) to [redacted] (b) (4) sterilize glass vials, rubber stoppers, metal crimps, and finished injectable drug products. Chapter 1, Section 1. "Product Uses" of the [redacted] (b) (4) user manual states that the [redacted] (b) (4) is designed for **research use only** in [redacted] (b) (4). You have not verified that the unit is suitable for its intended use that is outside the user manual scope. You [redacted] (b) (4) sterilize oil based injectable drug products in this unit.

The modes listed in the user manual of the [redacted] (b) (4) are:

- [redacted] (b) (4)

b. The Quality Assurance/Compliance Supervisor stated that the parameters used for all [redacted] (b) (4) sterilization operations are [redacted] (b) (4). These [redacted] (b) (4) sterilization parameters for components (e.g. glass vials, rubber stoppers, metal crimps) and various finished drug products have never been validated. Finished drug product examples include Testosterone Cypionate in Grapeseed Oil 200mg/mL, Testosterone Cypionate in Sesame Oil 200mg/mL, and Lipoic Acid 50mg/mL.

c. Your SOP 03-07.01, "Personnel Aseptic Media Fill Verification", dated 4/12/13, contains procedures to verify and continuously monitor the aseptic techniques of all individuals involved in compounding of sterile preparations, [redacted] (b) (4) The section entitled "General Information", VIII, states that "Media-Fill tests shall represent the most challenging or stressful conditions actually encountered by the personnel being evaluated" and Section IV (A) states that the "number of manipulations of each unit, and the number of units in each sequence should reflect the most complex and prolonged aseptic

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Ashar P. Parikh, Investigator<br>Jennifer H. Rhyu, Investigator | 05/30/2014 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 05/21/2014 - 05/30/2014*<br>FEI NUMBER<br>3010839113 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert A. Seik, Pharm D./Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| One Way Drug, LLC dba Partell Specialty Pharmacy | 8751 W Charleston Blvd, Suite 120 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Las Vegas, NV 89117-5480 | Producer of Sterile Drug Products |

manipulations likely to be encountered during normal workload production. Your policy states that you use the [redacted] (b) (4) that involves:

[redacted] (b) (4)

This process does not simulate any of the aseptic processes or manipulations performed by your lab personnel during normal sterile filling operations for drug products such as Glutathione 200mg/mL, Testosterone Cypionate in Sesame Oil 200mg/mL, and Lipoic Acid 50mg/mL.

d. Records of the [redacted] (b) (4) sterilization process of components and finished drug product are not always maintained. According to Quality Assurance/Compliance Supervisor, some of the [redacted] (b) (4) sterilization records (i.e. [redacted] (b) (4)) are maintained with the batch record and the rest are discarded. None of the formula worksheets reviewed included a copy of the [redacted] (b) (4) print out.

e. The ISO-5 Laminar Airflow Workbench (LAFW) is a stainless steel table approximately [redacted] (b) (4) feet long under three [redacted] (b) (4) HEPA Filters with a plastic curtain hanging from the ceiling over the back and front edges of the table. We observed that there are no plastic curtains at the side ends of the table. There is no documentation that air flow pattern evaluations (smoke studies) are performed under dynamic conditions in the ISO-5 LAFW and the surrounding ISO-7 clean room to assess the potential impact on drug products by personnel manipulations.

f. According to the Quality Assurance/Compliance Supervisor, your firm uses [redacted] (b) (4) for monitoring your [redacted] (b) (4) sterilization processes. There is no documentation demonstrating that this process has ever been performed. There is no established written procedure on how to conduct the [redacted] (b) (4) test.

g. Your SOP 03-07.01, "Gloved Fingertip Sampling", dated 2/25/13, states in the Policy Section, #V, that the gloved fingertip samples are obtained while the employee is in the ISO-5 environment during preparation of media fill units [redacted] (b) (4). According to your Quality Assurance and Compliance Supervisor, Fingertip Sampling is the only personnel monitoring performed and is only collected during media fills and not after each sterile compounding operation.

h. According to your Quality Assurance/Compliance Supervisor, environmental monitoring and viable and non-viable air sampling of the clean room facility is performed once [redacted] (b) (4) and not conducted during aseptic operations.

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 05/21/2014 - 05/30/2014*<br>FEI NUMBER<br>3010839113 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Robert A. Seik, Pharm D./Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| One Way Drug, LLC dba Partell Specialty Pharmacy | 8751 W Charleston Blvd, Suite 120 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Las Vegas, NV 89117-5480 | Producer of Sterile Drug Products |

## OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

a. You do not have a written procedure for sampling and testing for your finished drug products. Your firm does not conduct laboratory testing for potency, sterility, bacterial endotoxin, and pyrogenicity for all batches of "For Office Use" aseptically filled drug products. The Quality Assurance/Compliance Supervisor stated that his program for testing of aseptically filled drug products is random and there is "no rhyme or reason" to determine which drug products he sends out for testing. The Quality Assurance/Compliance Supervisor also stated that they have not been following the requirements in USP General Chapter <71> Sterility Tests. For example, since May, 2013, approximately (b) lots of Testosterone Cypionate 200 mg/mL (in Sesame Oil or Grapeseed Oil) have been manufactured and used to fulfill "For Office Use" orders. Of these (b) lots, 4 lots were randomly tested for sterility, endotoxin, and potency and an additional 6 lots were tested for potency only. General lot size varies by the amount of bulk drug product manufactured.

b. Aqueous sterile compounded drug products are tested in-house for sterility using (b) (4) test. According to the Quality Assurance/Compliance Supervisor you have not conducted growth promotion or system suitability testing for the (b) (4) test. The calibration for the thermometer used to continuously monitor the incubators for the (b) (4) test expired more than 6 months ago on 11/12/13.

## OBSERVATION 3

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

Specifically, your firm uses (b) (4) glass vials for aseptically filled drug products. These vials are washed in your firm's dishwasher using water from your (b) (4). According to the Quality Assurance/Compliance Supervisor, the water has never been tested to determine the microbial contents or presence of bacterial endotoxin. There is no subsequent wash or final rinse step with Water for Injection (WFI) performed on the glass vials and glass vials are not exposed to a depyrogenation step.

In addition, after the wash cycle and prior to use in sterile filling operations, you (b) (4) sterilize your glass vials in the (b) (4). The user manual for the (b) (4) indicates that the (b) (4) is designed "for research use only". Your (b) (4) has not been qualified by your firm and the (b) (4) sterilization process has not been validated to ensure that glass vials are rendered sterile and non-pyrogenic.

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 05/21/2014 - 05/30/2014*<br>FEI NUMBER<br>3010839113 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Robert A. Seik, Pharm D./Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| One Way Drug, LLC dba Partell Specialty Pharmacy | 8751 W Charleston Blvd, Suite 120 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Las Vegas, NV 89117-5480 | Producer of Sterile Drug Products |

## OBSERVATION 4

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm has no scientific data to justify the Beyond Use Date of 180 days at room temperature for any of the Testosterone Cypionate (100mg/mL and 200mg/mL) injectable drug products. According to the Quality Assurance/Compliance Supervisor, the beyond use date is based on (b) (4) formulas, the earliest expiring ingredient used in the formula, or the firm's stability data.

- The firm does not have any stability data
- (b) (4) formulation (b) (4) has 5 ingredients including (b) (4), your firm's formula has (b) (4) ingredients, (b) (4)
- The beyond use date of (b) (4) formulation (b) (4) is 30 days, your firm's beyond use date is 180 days.

## OBSERVATION 5

Written procedures are lacking for the use of cleaning and sanitizing agents designed to prevent the contamination of equipment, components, drug product containers, and drug products.

Specifically, you do not have written procedures to evaluate the suitability, efficacy, and limitations of your disinfecting agents to ensure that potential contaminants are adequately removed from surfaces. According to your Quality Assurance/Compliance Supervisor, your firm cleans with (b) (4) . It is a bactericidal, virucidal, fungicidal, and tuberculocidal cleaning agent. These cleaning agent have not been qualified. Your disinfectant program does not include a sporicidal agent.

## OBSERVATION 6

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

Specifically,

Personnel performing operations in the LAFW do not don sterile gowns, sleeves, masks, or goggles during sterile operations that involve sterile filtration of High Risk products into open vials.

a. Eyewear/goggles are not cleaned, sanitized, and/or sterilized prior to use. On 5/22/14, I observed that the eyewear is stored

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Ashar P. Parikh, Investigator<br>Jennifer H. Rhyu, Investigator | 05/30/2014 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 05/21/2014 - 05/30/2014*<br>FEI NUMBER<br>3010839113 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Robert A. Seik, Pharm D./Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| One Way Drug, LLC dba Partell Specialty Pharmacy | 8751 W Charleston Blvd, Suite 120 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Las Vegas, NV 89117-5480 | Producer of Sterile Drug Products |

in the ISO 7 Anteroom above the handwashing sink. Lab Technician (b)(6). did not clean or sanitize the eyewear prior to wearing them for sterile filling operations.

b. I also observed that Lab Technician (b)(6) dons shoe covers and a nonsterile gown directly over (b)(6) scrubs and shoes. According to the Laboratory Manager M.H., the scrubs and shoes are worn from the employees residence. Lab Technician (b)(6) was observed to step into the ISO-7 Anteroom while wearing (b)(6) street shoes, place shoe covers on the shoes, and then walked around in the same locations where (b)(6) had previously stood without shoe covers. There is no distinct line indicated in the Anteroom where the employee should only be wearing covered shoes. According to SOP 05-04.01 "Hand Hygiene and Garbing Procedure" Procedure I. Gowning Section C., "The ante area will have a distinct line on the floor separating the 'clean side' from the 'dirty side' ". The section also states that "The shoe cover is never to touch the 'dirty side' of the ante area floor. If it does, a new shoe cover must be used."

c. According to your SOP 02-04.01, "Cleaning and Disinfecting of Sterile Compounding Area", dated 2/28/13, it states that it is your policy to clean all surfaces in the ISO-5 work areas including the Laminar Air Flow Workbench (LAFW) (b)(4) [redacted] On 5/22/14, I observed that after donning a non-sterile gown over scrubs worn from home, Lab Technician (b)(6). reached into the ISO-5 LAFW and cleaned the work surface, exposing the ISO-5 environment to potential contamination from (b)(6) non-sterile gown prior to commencing sterile filter fill operations.

d. We observed that open vials containing sterile drug product are not immediately stoppered but were left open for up to 7 minutes. We also observed Lab Technician (b)(6) remove (b)(6) hands multiple times from the LAFW, reach below the work bench, grab a spray bottle containing (b)(6), spray (b)(6) hands and then resume sterile operations without waiting for the (b)(6) to dry.

## OBSERVATION 7

Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

Specifically, there is a failure to establish and follow consumer complaint handling procedures and a consumer complaint handling log. In addition, there is no documentation of review of the consumer complaint received by the firm for lot 20140409@49 of Testosterone Cypionate in Grapeseed Oil, 200mg/mL. The Quality Assurance/Compliance Supervisor stated there is no documentation of the investigation conducted by the quality control unit.

*** DATES OF INSPECTION:**
05/21/2014(Wed), 05/22/2014(Thu), 05/23/2014(Fri), 05/28/2014(Wed), 05/30/2014(Fri)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Ashar P. Parikh, Investigator<br>Jennifer H. Rhyu, Investigator | 05/30/2014 |