

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 22215 26th Ave SE, Suite 210 Bothell, WA 98021 (425) 302-0340 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 4/25-28; 5/2-3; 5/17/2016
	FEI NUMBER 3006317860

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: William G. Ewing, RPh, Owner

FIRM NAME Ballard Plaza Pharmacy I, Inc.	STREET ADDRESS 1801 NW Market St, Suite 104
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CITY, STATE AND ZIP CODE Seattle, WA 98107	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
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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) (WE) OBSERVED:

OBSERVATION 1

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

Specifically, on April 25, 2016 during the production of Cataract Block Solution (Bupivacaine-Lidocaine and Epinephrine-Hyaluronidase) 3.52 mg-9.38 mg-9.4 u/mL, Lot number 04252016@1:

A) A piece of thin, wood paneling was observed to be partially detached from the underside of the work surface of the (b) (4) ISO 5 (b) (4) laminar flow hood (LFH), exposing a un-cleanable yellow fibrous material along the length of the work surface.

B) Non-sterile wipes were used to clean and wipe down the surfaces of the ISO 5 LFH, ISO 7 clean room, and ISO 8 anteroom.

C) Apparent soiled material was observed on the metal grate covering the pre-filter of the (b) (4) # (b) (4) ISO 5 LFH.

D) Apparent rust was observed on the following parts of a mobile cart stored in the ISO 7 clean room: the lower wire basket; the wheel casters; and the screw heads connecting the legs of the mobile cart to the top work surface.

E) Apparent soiled material was observed on the handset surface of a telephone installed in the ISO 7 clean room.

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AMENDMENT 1

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	Gerard P. Deleon -S <small>Digitally signed by Gerard P. Deleon 5 DN: cn=Gerard P. Deleon, o=FDA, ou=CDER, email=gerard.p.deleon@hhs.gov, c=US</small>	Gerard P. De Leon, Investigator	6/10/2016
	Christopher R. Czajka -S <small>Digitally signed by Christopher R. Czajka 5 DN: cn=Christopher R. Czajka, o=FDA, ou=CDER, email=christopher.czajka@hhs.gov, c=US</small>	Christopher R. Czajka, Investigator	
		Gary C. Peecic, Analyst Lisa T. Michel, Analyst	

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Bothell, WA 98021
(425) 302-0340

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Producer of Sterile Drug Products

F) Apparent residue was observed on the classified area sides of the glass windows of the ISO 8 anteroom and ISO 7 clean room.

G) An approximately eight inch crack was observed on the glass window directly above the (b) (4) between the ISO 8 anteroom and ISO 7 clean room.

OBSERVATION 2

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

Specifically,

A) No (b) (4) bioburden limits have been established in order to determine if it exceeds the maximum capability of the (b) (4). For example, the following sterile drug products were produced with the (b) (4):

- 1) The (b) (4) Unit, Lot # (b) (4) (b) (4) used in the (b) (4) sterilization of Cataract Block Solution (Bupivacaine-Lidocaine and Epinephrine-Hyaluronidase) 3.52 mg-9.38 mg-9.4 u/mL, Lot number 04252016@1.
- 2) The (b) (4) Unit, Lot # (b) (4) used in the (b) (4) sterilization of Vancomycin HCl (PF) 50 mg/mL Ophthalmic Solution, Lot number t05022016@43.
- 3) The (b) (4) Unit, Lot # (b) (4) used in the (b) (4) sterilization of Apomorphine HCl 3 mg/mL Injectable Solution, Lot number 04052016@14.

B) The (b) (4) has not been validated for its intended purpose. For example,

- 1) The (b) (4) was installed prior to April 2015 and was not validated following installation to confirm

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the following:

a) Effective sterilization of the following items through the designated sterilization (b) (4) (b) (4): oils; ophthalmic base solutions; glass bottles; and lab glassware used in sterile drug production.

b) Effective depyrogenation of lab glassware used in sterile drug production through the depyrogenation time and temperature cycle.

2) The Log Instructions & Notes for final sterilization of Hydroxyprogesterone Caproate (Sesame Oil Solution) 250 mg/mL Injectable requires to **** (b) (4) the oil solution in (b) (4) until the contents of the vial have (b) (4) (b) (4) (b) (4). (b) (4) (b) (4) is used for each sterilization (b) (4) (b) (4); however, there is no documentation to show (b) (4) was used during the sterilization (b) (4) for the following:

- a) Hydroxyprogesterone Caproate (Sesame Oil Solution) 250 mg/mL, Lot number 061815-ZZ.
- b) Hydroxyprogesterone Caproate (Sesame Oil Solution) 250 mg/mL, Lot number 042215-RR.
- c) Hydroxyprogesterone Caproate (Sesame Oil Solution) 250 mg/mL, Lot number 040115-VV.

C) The (b) (4), S/N # (b) (4), was installed prior to April 2015 and was not validated following installation to confirm effective sterilization of the following items through the designated sterilization time and temperature cycle: empty ointment tubes; metal utensils; and ophthalmic base caps and stoppers.

D) An in situ air pattern analysis (smoke study) of the (b) (4) ISO 5 LFH and ISO 7 clean room has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions.

E) (b) (4) used in sterile drug production are sterilized by (b) (4) for (b) (4) (b) (4).

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OBSERVATION 3

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

Specifically,

A) The following inadequate aseptic techniques were observed:

1) An operator was observed working at the (b) (4) ISO 5 (b) (4) laminar flow hood (LFH) with parts of the non-sterile garbing materials exposed inside and in direct contact with the ISO 5 LFH work surface. For example,

a. On April 25, 2016 an operator was observed manipulating components for the preparation of Cataract Block Solution (Bupivacaine-Lidocaine and Epinephrine-Hyaluronidase) 3.52 mg-9.38 mg-9.4 u/mL, Lot number 04252016@1 with the elbows of the non-sterile disposable lab coat resting in direct contact with the work surface of the ISO 5 LFH.

b. On May 2, 2016 an operator was observed manipulating components for the preparation of Tobramycin 14 mg/mL Ophthalmic Solution, Lot number t05022016@42 and Vancomycin (PF) 50 mg/mL Ophthalmic Solution, Lot number t05022016@43 with the waist of the non-sterile disposable lab coat in direct contact with the wood paneling that was observed to be partially detached from the underside of the work surface of the ISO 5 LFH with exposed yellow fibrous material.

2) On May 2, 2016 an operator was observed bringing in a non-sterile white trash receptacle from the ISO 8 anteroom into the ISO 7 clean room while wearing sterile latex gloves with the surface of the receptacle in direct contact with the non-sterile disposable lab coat. The non-sterile surface of the receptacle was not sanitized with sterile (b) (4) prior to entering the ISO 7 clean room and the operator did not change the non-sterile disposable lab coat prior to the production of Tobramycin 14 mg/mL Ophthalmic Solution, Lot number t05022016@42 and Vancomycin HCl (PF) 50 mg/mL Ophthalmic Solution, Lot number t05022016@43.

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the media fill test were also not recorded.

2) Media Fill Test Formula Worksheet, Date made: (b) (4), indicates a start date of (b) (4), (b) (4) °C at (b) (4) days with no date written, and (b) (4) °C at (b) (4) days on (b) (4). The operator indicated that the results were a "Pass" at (b) (4) days (b) (4) without allowing for the required (b) (4)-day incubation period.

3) Media Fill Test Formula Worksheet, Date made: 6/15/15, indicates a "start incubation (b) (4) @ (b) (4) C" and (b) (4) checks only from "(b) (4)". The operator indicated that the results were a "pass as of (b) (4)". The start and stop time of the media fill test were also not recorded.

4) Media Fill Test Formula Worksheet, the operator does not indicate a date made for the media fill or the dates when the media was placed under incubation for the required (b) (4) day incubation period. The operator indicated that the results as a "pass (b) (4)".

5) Media Fill Test Formula Worksheet, the operator only indicates the start date of (b) (4), the dates at (b) (4) temperature "(b) (4)" and the dates at (b) (4) °C "(b) (4)". The operator indicated that the results were a "PASS (b) (4)". The start and stop time of the media fill test were also not recorded.

OBSERVATION 4

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

Specifically,

A) Your environmental monitoring procedure SOP 3.030 Environmental Monitoring of the Clean Room Facility is deficient in that there is no scientific rationale to support the frequency and methodology of testing:

1) Surface sampling for microbiological monitoring is not performed each day in the (b) (4) (b) (4) ISO 5 LFH when sterile drugs are produced. SOP 3.030 – Section 9.5.2 states in part
*** (b) (4)

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(b) (4). The most recent (b) (4) surface sampling was conducted on April 21, 2016.

2) Viable air monitoring is not performed in the (b) (4) ISO 5 LFH when sterile drug products are produced. SOP 3.030 - Section 9.4 states in part ****(b) (4) (b) (4).

3) Non-viable air monitoring is not performed in the (b) (4) ISO 5 LFH when sterile drug products are produced. Non-viable air monitoring is only performed (b) (4) during (b) (4) (b) (4). The most recent (b) (4) non-viable air sampling was performed on February 5, 2016.

4) Personnel monitoring of operators is conducted per SOP 3.030 - Section 9.7 which states in part ****(b) (4) (b) (4), (b) (4) (b) (4). No other surface samples of the operator, including (b) (4), are sampled (b) (4).

B) The positive air pressure differential was not being monitored continuously between the ISO 7 clean room and ISO 8 ante room, and the ISO 8 ante room and unclassified hallway during the production of sterile drug products prior to the (b) (4). Monitoring and recording of the positive air pressure differential began on November 12, 2015.

OBSERVATION 5

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

Specifically, sterility testing is not performed on each finished batch or representative finished batches of filled sterile drug products. For example, sterility testing is not performed on batches of the following sterile drug products: (1) Tobramycin 14 mg/mL Ophthalmic Solution, Lot number t05022016@42 (BUD 30 days refrigerated)

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; and (2) Vancomycin HCl (PF) 50 mg/mL Ophthalmic Solution, Lot number t05022016@43 (BUD 14 days refrigerated).

OBSERVATION 6

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, potency studies have not been conducted to support the shelf life claimed and potency testing is conducted according to SOP 9.120 Sterile Compounding Finished Preparation Testing - Section 9.5.4 which states in part "****(b) (4), samples shall be tested for potency using the appropriate method or samples shall be sent to a contract lab for testing."

For example, there is no potency study data for Alprostadil (b) (4) to support the purported beyond-use date (BUD) of (b) (4). The following finished sterile drug products with the same BUD (b) (4) were produced with Alprostadil (b) (4), were observed under (b) (4) storage, and have been distributed:

- Alprostadil-E1 (Prostaglandin) Lot number 012016-QQ Expires 30 days after thawed and refrigerated or 7/20/2016 frozen [Alprostadil (b) (4) Lot number (b) (4), Exp. date 6/27/16]
- Alprostadil-Papaverine HCl-Phentolamine MES (Triple Mix #1) Lot number 020916-TT Expires 30 days after thawed and refrigerated or 06/27/216 frozen [Alprostadil (b) (4) Lot number (b) (4), Exp. date 6/27/16]
- Alprostadil/Chlorpromazine HCl (ED-2) Lot number 02162016@14 Expires 30 days after thawed and refrigerated or 06/27/16 frozen [Alprostadil (b) (4) Lot number (b) (4), Exp. date 6/27/2016]

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- Alprostadil-Papaverine HCl-Phentolamine MES (Triple Mix #5) Lot number 03072016@61 Expires 30 days after thawed and refrigerated or 07/11/16 frozen [Alprostadil (b) (4) Lot number (b) (4) (b) (4), Exp. date 8/28/2016]
- Alprostadil-Papaverine HCl-Phentolamine MES (Triple Mix #21) Lot number 03092016@29 Expires 30 days after thawed and refrigerated or 08/28/2016 [Alprostadil (b) (4) Lot number (b) (4) (b) (4), Exp. date 8/28/2016]
- Alprostadil-E1 (Prostaglandin) Lot number 04042016@80 Beyond use date: 10/1/2016 180 days after compounding date [Alprostadil (b) (4) Lot number (b) (4) (b) (4), Exp. date 8/28/2016]

OBSERVATION 7

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

Specifically, the attire worn by an operator on April 25, 2016 during the production of Cataract Block Solution (Bupivacaine-Lidocaine and Epinephrine-Hyaluronidase) 3.52 mg-9.38 mg-9.4 u/mL, Lot number 04252016@1 and on May 2, 2016 during the production of Tobramycin 14 mg/mL Ophthalmic Solution, Lot number t05022016@42 and Vancomycin HCl (PF) 50 mg/mL Ophthalmic Solution, Lot number t05022016@43 was inadequate as follows:

- A) An operator was observed working in the (b) (4) ISO 5 LFH wearing a disposable non-sterile head cover, non-sterile surgical mask, non-sterile lab coat, and non-sterile shoe covers.
- B) The disposable non-sterile surgical mask and non-sterile head cover worn by an operator did not provide adequate coverage to the forehead, neck or face. The operator was also not wearing protective eyewear.

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C) Prior to donning sterile latex gloves in the ISO 5 LFH, an operator donned non-sterile latex gloves that were loosely stored outside of its original packaging on a shelf in the ISO 8 anteroom.

D) Non-sterile scrubs that are worn under the non-sterile disposable lab coat during sterile drug production are personally laundered by the operators.

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