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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 22215 26th Ave SE, Suite 210<br>Bothell, WA 98021<br>(425) 302-0340<br><br>Industry Information: www.fda.gov/oc/industry | 7/17-7/21; 7/25-7/26; 7/31; 8/1/2017 |
| | FEI NUMBER<br>3013436443 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Scott D. Herzog, PharmD, Chief Operating Officer, Vice President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Kelley-Ross Compounding Pharmacy | 805 Madison St, #702 |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Seattle, WA 98104 | Producer of Sterile and 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) (WE) OBSERVED:

OBSERVATION 1
Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, on 7/17/2017 a non-sterile plastic bag containing in-process materials, containers and closures used for the production of Tri-Mix (Prost/Pap/Phent 10 mcg/30 mg/1 mg/mL) injectable, Lot number (b) (6) were placed directly into the ISO-5 (b) (4) biological safety cabinet (BSC), Serial Number (b) (4) without adequate disinfection or sanitation of the outer surface.

OBSERVATION 2
The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment.

Specifically, on 7/17/2017 during the production of Tri-Mix (Prost/Pap/Phent 10 mcg/30 mg/1 mg/mL) injectable, Lot number (b) (6) :

A) Apparent residue was observed on the metal HEPA filter screens installed in the ceiling of the ISO 7 Prep Area and ISO 7 Anteroom.

B) After being wiped with a non-sterile paper towel and non-sterile (b) (4), apparent residue was observed on the exterior surface of the (b) (4) balance located in the (b) (4) (b) (4), Serial Number (b) (4), used for weighing in-process non-sterile drug materials in the ISO 7 Prep Area.

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AMENDMENT 1

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|---|---|---|---|
| | Gerard P. De Leon<br>Kenneth O. Gee | Gerard P. De Leon, Investigator<br>Kenneth O. Gee, Investigator | 8/2/2017 |

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C) Three cracks each measuring approximately 2.5 inches, 8 inches, and 3.5 inches respectively were observed on the bottom of a glass window installed between the ISO 7 Anteroom and ISO 7 Positive Pressure Room.

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OBSERVATION 3

ISO-5 classified areas were not certified under dynamic conditions.

Specifically,

A) From 6/2/2017 to 7/19/2017 72 sterile drug products were made; however, certification of the following units expired on 06/2017:

i. The ISO-5 (b) (4) biological safety cabinet, Serial Number (b) (4) located in the Negative Pressure Room; and

ii. The ISO-5 (b) (4), Serial Number (b) (4) located in the Positive Pressure Room.

B) An in situ air pattern analysis (smoke study) of the following has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions:

i. The ISO-5 (b) (4) biological safety cabinet, Serial Number (b) (4) located in the Negative Pressure Room; and

ii. The ISO-5 (b) (4), Serial Number (b) (4) located in the Positive Pressure Room.

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OBSERVATION 4

Environmental monitoring was not performed in your aseptic processing areas.

Specifically, gloved fingertip sampling was not performed by Operator (b)(6), (b)(7)(C) from 10/17/2014 to 6/27/2017. Per your sampling schedule, sterile drug production operators are required to perform gloved fingertip sampling every (b) (4).

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OBSERVATION 5
Sporicidal agents are not used in your facility's cleanroom.

Specifically, your (b) (4) cleaning procedures require the use of a (b) (4) solution and non-sterile (b) (4) (b) (4). The concentration of each batch of the (b) (4) solution is not verified prior to use and a disinfectant efficacy study has not been conducted for this solution. The (b) (4) solution and non-sterile (b) (4) is applied on (b) (4) basis to the following:

A) The exterior surfaces of the ISO-5 (b) (4) biological safety cabinet, Serial Number (b) (4).

B) The exterior surfaces of the ISO-5 (b) (4), Serial Number (b) (4).

C) The floors, walls and ceilings of the Sterile Drug Production Room.

OBSERVATION 6
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.

Specifically,
A) Media fills have not been performed for Operators (b)(6),(b)(7)(C) to simulate sterile drug production operations in the ISO-5 (b) (4) biological safety cabinet (BSC), Serial Number (b) (4). From 4/17/2017 to current, the ISO-5 (b) (4) BSC has been designated as the primary unit for performing sterile drug production and approximately (b) (4) sterile drug products have been made.

B) From 4/9/2014 to 6/17/2016 Operator (b)(6), (b)(7)(C) did not perform a high-risk media fill recertification test every (b) (4) (b) (4) per SOP 8.090 "Evaluation of Compounding Personnel for Aseptic Technique and Manipulation Procedures". Operator (b)(6), (b)(7)(C) was designated as a responsible sterile drug production operator. In addition, Operator (b)(6), (b)(7)(C) performed recertification on 6/17/2016 with a (b) (4)

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(b) (4) Test Kit that expired on 6/18/2016, prior to the 14-day read of the media plates conducted on 7/1/2016.

OBSERVATION 7

Non-microbial contamination was observed in your production area.

Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room:

A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6), the following was observed in the (b) (4), Serial Number (b) (4):
i. Apparent dried white residue in the airfoil holes;
ii. Apparent dried buildup in the center of the air filter screen; and
iii. Apparent staining and buildup on the (b) (4) balance used to weigh in-process non-sterile drug materials.

B) A crack approximately ¼ inch by 6 inches was observed on the light shield installed in the (b) (4) (b) (4), Serial Number (b) (4).

C) The following was observed in the (b) (4) Hood, Serial Number (b) (4)
i. Apparent dried white residue in the airfoil holes; and
ii. Apparent dried residue on the interior ceiling surface of the hood.

D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6), apparent dust particles were observed on the top surface of the (b) (4) light fixtures installed above (b) (4) hoods and stored chemicals used in the manufacture of non-sterile drug products.

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