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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| U.S. Food & Drug Administration<br>New England District<br>One Montvale Avenue, 4th Floor<br>Stoneham, MA, 02180 Phone: 781-587-7500<br>Industry Information: www.fda.gov/oc/industry | 08/09-12/2016, 08/18/2016 |
| | FEI NUMBER<br>3011911677 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ryan D. Dyer, Pharmacist, Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| Bayview Pharmacy, Inc. | 3045 Towerhill Road |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Saunderstown, RI | Producer of Sterile and Non-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 (I) (WE) OBSERVED:

## OBSERVATION 1

**Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.**

Specifically:

1. Personnel engaged in sanitization and aseptic processing in the ISO 5 zone reach with their arms, head, and upper torso into the (b) (4) Laminar Flow Hood to manipulate equipment and components while wearing a non sterile cleanroom frock, dust mask and hair cover. Additionally, the face and eyes of personnel engaged in aseptic practices is exposed between the dust mask and hair cover. For example:

a. On 08/09/2016 we observed that the Pharmacists upper body and head broke the plane of the ISO 5 (b) (4) Laminar Flow Hood during aseptic filling of Acetylcysteine 10% (PF) [Nebulizer] INH SOLN, Lot # 08082016@10. The lot was discarded based on inspectional comments and your firm's subsequent investigation.

b. On 08/10/2016 we observed that during aseptic filling of TRI-MIX (b) (4) Lot # (b) (4), the Pharmacist compromised the sterility of vial stoppers (for primary packaging) by placing them with the drug contact surface down and in contact with a wipe lining the ISO 5 (b) (4) Laminar Flow Hood bench top. The wipe (received commercially sterile) was compromised as the Pharmacist was observed working over the wipe, blocking first pass air, prior to placing the stoppers with the material contact surface contacting the wipe thus potentially contaminating the stoppers. The lot was discarded based on inspectional comments and your firm's subsequent investigation.

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|---|---|---|---|
| | | Edmund F. Mrak Jr., Investigator<br>NEALIE C. NEWBERGER, INVESTIGATOR | 08/18/2016<br>08/18/2016 |

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2. Personnel engaged in aseptic processing of sterile drugs in the ISO 5 (b) (4) Laminar Flow Hood place the Logged Formula Worksheet (b) (4) ) leaning against the back left wall of the (b) (4) laminar flow hood where it may deflect airflow and cause disruption of first pass air over materials intended to be sterile. For example:

a. On 08/09/2016 we observed that the Pharmacist placed the Logged Formula Worksheet (b) (4) ) leaning against the back left wall of the ISO 5 (b) (4) Laminar Flow Hood during aseptic processing and filling of Acetylcysteine 10% (PF) [Nebulizer] INH SOLN, Lot # 08082016@10. The lot was discarded based on inspectional comments and your firm's subsequent investigation.

b. On 08/10/2016 we observed that the Pharmacist placed the Logged Formula Worksheet (b) (4) leaning against the back left wall of the ISO 5 (b) (4) Laminar Flow Hood during aseptic processing and filling of TRI-MIX (b) (4) , Lot # (b) (4) . The lot was discarded based on inspectional comments and your firm's subsequent investigation.

3. The temperature in the ISO 7 Cleanroom (buffer room) housing the ISO 5 Hood was observed at 79° F on 08/09/2016 causing the the Pharmacist to visibly perspire during processing of sterile drugs Temperature logs indicate that the temperature of the room exceeded 78° F on twelve days during the period May 2016 to present including a high of 81° F on 05/12/2016, 06/06/2016, and 06/13/2016.

OBSERVATION 2
The facility design was observed to allow the influx of poor quality air into a higher classified area.

Specifically:

There is no dynamic air flow pattern assessment of the ISO 5 (b) (4) Laminar Flow Hood, used to produce sterile drugs, to assure that lesser quality air will not enter the higher classified area of the hood.

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| | | HERBIE C. NEUBERGER, INVESTIGATOR | 08/18/2016 |

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OBSERVATION 3

Highly potent drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, you handle potent drug substances including hormones without providing adequate containment, segregation, and cleaning of work surfaces, utensils, and personnel to prevent cross-contamination. The following objectionable conditions were observed relating to control and containment of hormone drug substances including, progesterone, estradiol, and testosterone, and prevention of cross contamination of non-hormone drugs produced in the general pharmacy within containment Hood #1:

1. There were visible particulate residues remaining in Hood #1 after cleaning and proceeding to the next batch from encapsulation of drug product containing testosterone; Progesterone/Estradiol/Testosterone 300-2-30mg capsules – Lot No. 08092016@2.

2. The technician sanitized (b)(6), (b)(7)(C) gloves with (b) (4) but did not change gloves between batches during the making and filling of Progesterone/Estradiol/Testosterone 300-2-30mg capsules – Lot No. 08092016@2, Testosterone 60mg/mL topical gel cream - Lot No. 08102016@13 and non-hormone containing product; Alkalinzation Compound [CA/K/MG/P/NA] 38-9-28-13-0.13mg Capsule Lot No. 08092016@7 in Hood #1. Additionally, Hood #1 was wiped down with (b) (4) between the subject batches however you do not have data to support that (b) (4) will effectively neutralize potent drug residues.

3. The technician's lab coat was noticeably soiled in the front and on the sleeves – sleeves were observed contacting powder residues on the Hood #1 bench surface during capsule filling of Progesterone/Estradiol/ Testosterone 300-2-30mg capsules – Lot No. 08092016@2 and Alkalinzation Compound [CA/K/MG/P/NA] 38-9-28-13-0.13mg Capsule Lot No. 08092016@7 – and the lab coat was not changed between batches of various products produced.

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| | | NEALIE C. NEUBERGER, INVESTIGATOR | 08/18/2016 |

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4. (b) (4), used to (b) (4), stored in the open cabinet beneath Hood #1 and said to be clean was observed to have visible white powder residue in the crevices where the (b) (4) seats on the base.

5. The containment Hood #1 plenum and duct were observed to have visible buildup of powder residues.

OBSERVATION 4

Disinfecting agents used in the ISO 5 area [aseptic processing areas] are not sterile.

Specifically, (b) (4) and (b) (4) used to sanitize the ISO 5 (b) (4) Laminar Flow Hood at the end of each work day are not sterile.

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| | | Edward F. Mrak Jr., Investigator | 08/18/2016 |
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