DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| US Custom House, 200 Chestnut Street, Room 900<br>Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875<br>ORAPHARM1_RESPONSES@fda.hhs.gov<br><br>Industry Information: www.fda.gov/oc/industry | 11/02/2022 - 11/30/2022*<br>**FEI NUMBER**<br>3004858203 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jennifer M. Barlekoff, R.Ph., Pharmacist- in- Charge

| FIRM NAME | STREET ADDRESS |
|---|---|
| Southern Tier Home Infusion, Inc. dba Pharmacy Innovations | 2936 West 17th Street |
| **CITY, STATE AND ZIP CODE** | **TYPE OF ESTABLISHMENT INSPECTED** |
| Erie, PA 16505 | Producer of 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

There is inadequate HEPA filter coverage or airflow over the area to which sterile product was exposed.

Specifically,

1. Your HEPA coverage area in the (b) (4) ISO 5 laminar air flow workbench (LAFW) in the non-hazardous sterile cleanroom has (b) (4) light pod areas that are approximately 6 inches long and surrounded by suspended ceiling tiles that is not sealed around the perimeter of the tile which sits in-between each HEPA filter. On 11/2/2022, we observed your vendor perform a dynamic smoke study which illustrated that the ISO 5 air is turbulent and not unidirectional underneath the light pod areas. Prostaglandin E1 30CC/ML, Lot: t20221103@(b) (4), was prepared in an area that does not have adequate HEPA filter coverage in the ISO 5 LAFW.

2. The ISO 5 LAFW lacks unidirectional airflow in critical areas where drug products intended to be sterile are produced. On 11/2/2022, we observed your vendor perform a dynamic smoke study which showed the air is not unidirectional where drug production is occurring at the LAFW table top. We also observed Prostaglandin E1 30CC/ML, Lot: t20221103@(b) (4), be prepared in an area that did not have ISO 5 HEPA filter coverage.

3. During the walkthrough on 11/2/2022, we observed a rust-like discoloration on the HEPA filter on the left side of your ISO 5 Laminar Flow Air work bench area in the non-hazardous sterile cleanroom. The discolored rust-like HEPA filter supplies air directly to the area where sterile drug products intended to be sterile are produced.

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(Continuation of OBSERVATION 1)

4. During the walkthrough on 11/2/2022, we observed yellowing discoloration on three out of the (b) (4) HEPA filters installed in your (b) (4) ISO 5 LAFW where sterile drug products intended to be sterile are produced.

5. Your HEPA filter on the left side of your (b) (4) ISO 5 LAFW appears to have evidence of (b) (4) (b) (4) on the diffuser screen and HEPA filter. Additionally, there appears to be (b) (4) on the HEPA filter in the ISO 7 (b) (4) cleanroom of the non-hazardous sterile cleanroom suite.

OBSERVATION 2:
Media fills were not performed that closely simulated aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

A. Your media fill program is deficient in that your media fills are not representative of batch sizes and container types. Your media fills are performed in (b) (4) However, your firm prepares (b) (4) using other container types that yield the following: up to (b) (4) filled at (b) (4), up to (b) (4) syringes (filled at (b) (4), up to (b) (4) eye drop-containers (filled at (b) (4), and (b) (4) inhalation tubes (filled at (b) (4)

B. Your media fill program is deficient in that media fills do not include all equipment used in the preparation of drug products intended to be sterile. For instance, a (b) (4) is used to fill an IV bag to dose liquid drug product intended to be sterile into syringes for bladder irrigation prescriptions.

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OBSERVATION 3:
Your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area.

Specifically, the smoke studies performed to demonstrate the (b) (4) laminar air flow in the (b) (4) ISO 5 laminar air flow workbench used to produce drug products intended to be sterile do not have enough smoke to visualize the air flow at critical production areas, do not illustrate unidirectional airflow, and do not reflect all types of operations performed in the areas. Additionally, the (b) (4) airflow from the ISO 5 LAFW was observed bouncing back from the wall along the workbench and exiting at the point where the Plexiglas stopped causing first pass air to not appropriately sweep over and away from drug products intended to be sterile.

OBSERVATION 4:
The facility design was observed to allow the influx of poor quality air into higher classified area.

Specifically,

A. While watching sterile cleanroom activities on 11/07/2022, we observed (b) (4) (b) (4) (b) (4) , remain open simultaneously for (b) (4) to the unclassified non-sterile non-hazardous laboratory area as an employee was leaving the non-hazardous sterile cleanroom suite. Additionally, this occurred while another employee was preparing to enter the ISO 5 LAF workbench for sterile drug production.

B. During the walkthrough on 11/02/2022, we observed a rust-like discoloration on the diffuser of one HEPA filter in your ISO 7 anteroom of your non-hazardous sterile suite, where we observed employees prepare and mix drug products.

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OBSERVATION 5:
Environmental monitoring was not performed in your aseptic processing areas.

Specifically,

1. Your aseptic employee changed their sterile gloves used during the sterile drug production of Prostaglandin E1 30CC/ML, Lot: t20221103@[(b)(4)], with a new pair of sterile gloves outside of the ISO 5 LAF, enter the ISO 5 LAF, sprayed their hands and performed one task prior to completing their (b) (4) monitoring samples. This is not representative of actual processing conditions in the ISO 5 LAFW, and may not provide meaningful results.

2. Your aseptic employee lightly (b) (4) plate rather than roll them side to side when performing personnel monitoring after the sterile drug production of Papaverine/Phentolamine 30MG/3MG/ML injectable, Lot: t20221103@[(b)(4)].

OBSERVATION 6:
Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around uncapped syringes, whether before or after it is filled with sterile product.

Specifically,

1. On 11/04/2022, during the preparation of Prostaglandin E1 30CC/ML, Lot: t20221103@[(b)(4)], we observed your employee's gloved hand directly over an open syringe in a (b) (4) orientation that blocked first pass air in the (b) (4) ISO 5 LAWF.

2. On 11/07/2022, during the preparation of Papaverine/Phentolamine 30MG/3MG/ML injectable, Lot: t20221103@[(b)(4)], we observed your employee holding the (b) (4) drug product filled syringe in (b) (4) position that blocked first pass air in the ISO 5 LAFW. Your employee was also observed removing drug product from the syringe to be placed into a vial in (b) (4) orientation that blocked the critical areas from receiving first pass air flow from the (b) (4) ISO 5 LAWF bench area.

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(Continuation of OBSERVATION 6)

3. On 11/07/2022, during the preparation of Papaverine/Phentolamine 30MG/3MG/ML injectable, Lot: t20221103@(b)(4), your employee was observed working above the syringe of open (b) (4) drug product, having their gloved fingertips touch the hub of the syringe, handle the (b) (4) with their gloved fingertips at the downstream end of the (b) (4), and using their gloved fingertips to touch the filling needle while blocking first pass ISO 5 air flow. Furthermore, your employee was observed placing their gloved hand directly over the sterile vials before drug product intended to be sterile was introduced into the vial.

4. Additionally, on 11/07/2022, we observed your employee moving rapidly in the ISO 5 while producing Papaverine/Phentolamine 30MG/3MG/ML injectable, Lot: t20221103@(b)(4) which caused the syringe to drop back onto the ISO 5 LAFW surface.

5. On 11/07/2022, during the preparation of a hazardous drug, Testosterone injectable, Lot: t20221107@(b)(4), we observed your employee holding the (b) (4) drug product filled syringe (b) (4) position with the filling needle pointing away from first pass air in your ISO 5 Biological Safety Cabinet (BSC). Your employee was observed transferring the (b) (4) drug product from the syringe to another syringe and proceeded to move the (b) (4) syringe in (b) (4) and away from first pass ISO 5 air . Furthermore, we observed your aseptic employee had an excess of materials and a trash on the grill of the biological safety cabinet as they prepared drug products intended to be sterile.

OBSERVATION 7:
The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

1. On 11/09/2022, I observed employees clean the ISO 5 area while wearing non-sterile lab coats.

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(Continuation of OBSERVATION 7)

2. Use of sporicidal agents in the ISO 5 is inadequate. Sporicidal agents are not used on the Plexiglas that extends across the length of the (b) (4) ISO 5 LAFW in the non-hazardous sterile cleanroom. Additionally, there appears to be a crack in the Plexiglas that starts at a nail and runs to the edge of the glass, as well as two gaps in the plexiglass, approximately 10 millimeters in size, which may not be easily cleanable, and may harbor contamination.

3. Your ISO 5 LAFW has 4 nail sized holes in the wall immediately in front of the work space where drugs products intended to be sterile are prepared.

4. (b) (4) plates with rust-like discoloration are sitting in the ISO 5 LAFW of the non-hazardous sterile cleanroom suite. (b) (4) plates can be used to mix prepared media required during the media fill process in the ISO5 LAFW.

5. The return vents below the ISO 5 LAFW bench tops appear to be rusty. According to your firm's employee, they have to access this area when they need to plug in the (b) (4) which is used in the production of sterile drug product.

6. Your hazardous sterile ISO 5 biological safety cabinet had dust and discarded needles, caps, and wrappers underneath the work surface where drugs intended to be sterile are produced.

OBSERVATION 8:
Disinfecting agents and cleaning wipes used in the ISO 5 area aseptic processing areas are not sterile.

Specifically, on 11/04/2022 and 11/07/2022, we observed employees use (b) (4) to clean and sanitize materials entering into the ISO 5 LAFW areas. Your employee was observed spraying a

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(Continuation of OBSERVATION 8)

(b) (4) and then cleaning the work surfaces and equipment inside of the ISO 5 LAFW bench area. Additionally, the (b) (4) was observed moving from the ISO 8 Anteroom/Gown (b) (4) to the ISO 7 (b) (4) cleanroom to be used and placed in the ISO 5 LAFW bench area without being sanitized.

OBSERVATION 9:
Biological indicators were not used to verify the adequacy of the sterilization cycle.

Specifically,

1. Your firm failed to use biological indicators (B.I.s) to ensure cycle effectiveness in (b) (4) cycles intended to sterilize (b) (4) drug products produced from March 2022 to July 2022. For example, your firm produced the following drug products without any biological indicators:
a. Phenol Injection, Lot #s: t20220406@(b) (4), t20220621@(b) (4), t20220505@(b) (4)
b. Vitamin D3, Lot #s: t20220303@(b) (4), t20220304@(b) (4), t20220322@(b) (4), t20220419@(b) (4), t20220504@(b) (4), t20220506@(b) (4), t20220517@(b) (4), t20220613@(b) (4)
c. Glycerin, Lot #s:t20220303@(b) (4), t20220309@(b) (4), t20220421@(b) (4), , t20220603@(b) (4)
d. Prednisolone, Lot #s:t20220519@(b) (4)

Your firm failed to use B.I.s to ensure the cycle effectiveness in (b) (4) of the (b) (4) cycles used to sterilize (b) (4) that is added to sterile drug products and also used to (b) (4) glassware used in drug products intended to be sterile from January 2022 to September of 2022. Additionally, you carry the (b) (4) that is intended to be sterilized through the unclassified area to the ISO 5, lacking assurance of the product being protected.

*Dates of the inspection: 11/02/2022 (Wed.), 11/03/2022 (Thurs.), 11/04/2022 (Fri.), 11/07/2022 (Mon.), 11/08/2022(Tues.), 11/09/2022 (Wed.), 11/21/2022 (Tues.), and 11/30/2022 (Wed.)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."