DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	8/9/2023-8/29/2023* FEI NUMBER 1000076625

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Wayne C. Sartorio, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Boothwyn Pharmacy LLC	221 Gale Ln
CITY, STATE, ZIP CODE, COUNTRY Kennett Square, PA 19348	TYPE ESTABLISHMENT INSPECTED 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 OBSERVED:

OBSERVATION 1

Smoke studies were inadequately performed under dynamic conditions.

Specifically, unidirectional airflow was not verified under dynamic operational conditions representative of your aseptic processing practices. Air visualization studies ("smoke studies") performed in your ISO 5 classified biological safety cabinet ((b) (4)) and in your ISO5 classified laminar airflow workbench ((b) (4)) in June 2023 do not demonstrate the movement of first air around equipment, supplies, or operator manipulations as observed during sterile product operations. Your technician was observed blocking first air making it difficult to observe its movement within the ISO5 area and did not complete (b) (4) activities which is part of production as observed during the production of Alprostadil/Papaverine HCl/Phentolamine Mesylate (Tri-Mix) lot 080920203@(b) (4)

OBSERVATION 2

The facility design was observed to allow the influx of lesser quality air into a classified area containing higher quality air.

Specifically, your non-hazardous drug preparation room, (b) (4) and your ~~non-~~hazardous **drug** preparation room, (b) (4) share a vent which increases the possibility of cross contamination. For example:

A. **The vent between** (b) (4) **and** (b) (4) increases the possibility of air flow from a lesser quality (ISO 8) area ((b) (4)) into a higher quality (ISO 7) area (b) (4)) to be exhausted through the

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christina K Theodorou, Investigator	X Christina K Theodorou Investigator Signed By: Christina K. Theodorou -S Date Signed: 09-12-2023 11:57:51	9/12/2023

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(b) (4) hoods **where production prep activities such as weighing of hazardous drug** (b) (4) **and blending operations, take place**.

B. The vent between (b) (4) **and** (b) (4) **does not provide adequate segregation to prevent cross contamination between the hazardous drug and non-hazardous drug rooms. There is no continuous differential pressure monitoring in your hazardous drug or non-hazardous drug cleanroom suites or real time alarm to alert staff when there is a change in differential pressures.**

OBSERVATION 3

Use of non-sterile cleaning wipes in the ISO 5 area.

Specifically, your technicians were observed using (b) (4) wipes, during cleaning operations (b) (4) aseptic production which include cleaning of the hard to clean surfaces of the hoods), that were taken from a bulk packet of 300 wipes which is cut open on its side and located outside of the ISO 5 classified area.

For example,

A. On August 9, 2023, technician (b) (5), (b) (7)(C) was observed using the (b) (4) wipes during the aseptic production of Alprostadil/Papaverine HCl/Phentolamine Mesylate (Tri-Mix) lot 080920203@(b) (4).

B. On August 18, 2023, technician ((b) (5), (b) (7)) was observed using the (b) (4) wipes during aseptic production of Altrenogest (20mL) lot 08182023@(b) (4).

OBSERVATION 4

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Use of a sporicidal agent in the facility's ISO 5 areas and classified areas was improper.

Specifically,

A. On August 18, 2023, your technician ((b) (6), (b) (7)) did not clean the (b) (4), located (b) (4) the ISO 8 classified preparation room ((b) (4)) and the ISO 7 classified buffer room (b) (4)), with a sporicidal agent, or any cleaning agent, during direct observation of the (b) (4) cleaning of the sterile suite containing the LAFW.

B. On August 18, 2023, your technician ((b) (6), (b) (7)(C)) was observed to be inconsistently cleaning the walls of the ISO 7 and ISO8 classified rooms as parts of the walls showed no evidence of wetness during the (b) (4) cleaning of rooms (b) (4) – (b) (4).

OBSERVATION 5

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

Specifically,

A. On August 9,2023 your technician ((b) (6), (b) .) did not spray their gloves with a deactivating agent or change their gloves after measuring progesterone (b) (4) and then proceeded to touch other items, such as (b) (4) (lot (b) (4)) and (b) (4) " (Lot (b) (4)), during the production of Progesterone 200mg/ml Cream (lot 08092023@(b) (4)).

B. On August 16, 2023, your technician ((b) (4)) when donning their gowning before preparation operations of Medroxyprogesterone Acetate 200mg/mL lot 08162023@(b) (4) allowed the ties of their sterile smock to touch the ground in (b) (4) during gowning procedures. The ties were then wrapped around their waist, tying them at the front of their waist.

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***DATES OF INSPECTION**
8/09/2023(Wed), 8/10/2023(Thu), 8/14/2023(Mon), 8/15/2023(Tue), 8/16/2023(Wed), 8/17/2023(Thu), 8/18/2023(Fri), 8/29/2023(Tue)

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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 judgment, 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."