DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| US Custom House, Room 900<br>200 Chestnut Street<br>Philadelphia, PA 19106<br>(215) 597-4390 | 05/12/2025 -06/09/2025*<br>FEI NUMBER<br>1000076625 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John W. Howell Sr., Executive Vice President of Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Boothwyn Pharmacy LLC | 221 Gale Lane |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Kennett Square, PA 19348 | 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.

**OBSERVATION 1**

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, your firm released drug products that failed sterility or potency testing. Your firm failed to notify patients of the out of specification (OOS) results. For example, lot 04072025@(b)(4) TIRZEPATIDE/GLYCINE/METHYLCOBALAMIN, was produced from 04072025@(b)(4) TIRZEPATIDE 17 MG/ML / GLYCINE 5 MG/ML / METHYLCOBALAMIN 5 MG/ML (STOCK SOLUTION) on 04/07/2025 and dispensed to patents on 04/09/2025 – 04/12/2025. Your firm received preliminary testing results on 04/11/2025 from your contracted testing laboratory indicating that there was a delay with the processing of your samples and the results were under investigation. On 04/28/2025 your firm was notified by your contract testing laboratory that the samples failed and were subsequently placed on hold pending an OOS investigation from the contract testing laboratory.

The following table contains examples of some additional lots of products that were distributed to patients with failing OOS results.

| Product | Lot Number | Type of Test | Specifications | Result |
|---|---|---|---|---|
| ACETYL-D-GLUCOSAMINE | 12112024@(b)(4) | USP <85> Bacterial Endotoxin Test | | Fail |
| ACETYL-D-GLUCOSAMINE 200 mg/mL | 12202024@(b) | Assay - Acetyl-D-Glucosamine | (b) (4) | 87.6227 |
| TIRZEPATIDE 10 MG/ML | 01172025@(b) | Assay - Tirzepatide | | 86.779 |
| HA/CHONDROITIN/ACETYL-D-GLUCOSAMINE | 01232025@(b)(4) | USP <85> Bacterial Endotoxin Test | | Fail |
| SEMAGLUTIDE 2.5 MG/ML (2ML) INJ | 01282025@(b) | ScanRDI Sterility Test | | Fail |
| SEMAGLUTIDE 2.5mg/ml (1.6ml Vial) | 01292025@(b) | ScanRDI Sterility Test | | Fail |
| TIRZEPATIDE 10 MG/ML | 02112025@(b) | Assay - Tirzepatide | (b) (4) | 89.132 |
| SEMAGLUTIDE 2.5 MG/ML | 03042025@(b) | Assay - Semaglutide | | 79.876 |
| FLUOXETINE 5MG | 03212025@(b)(4) | Assay - Fluoxetine HCl | | 69.522 |
| FLUORESCEIN 2% OPHTH SOLN | 03272025@(b)(4) | Assay - Fluorescein | | 75.855 |
| TIRZEPATIDE/GLYCINE/METHYLCOBAL | 04072025@(b)(4) | ScanRDI Sterility Test | | Fail |

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (PRINT OR TYPE) | DATE ISSUED |
|---|---|---|---|
| | Christina K. Theodorou | Christina K. Theodorou, Investigator<br>Evan Tong, Investigator | 06/09/2025 |

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| US Custom House, Room 900<br>200 Chestnut Street<br>Philadelphia, PA 19106<br>(215) 597-4390 | 05/12/2025 -06/09/2025*<br>FEI NUMBER<br>1000076625 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

John W. Howell Sr., Executive Vice President of Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Boothwyn Pharmacy LLC | 221 Gale Lane |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Kennett Square, PA 19348 | 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.

**OBSERVATION 2**

Drug held under environmental conditions whereby it may have been rendered injurious to health.

Specifically, the labels on your Semaglutide and Tirzepatide drug formulations state "store frozen" when no studies have been conducted to indicate these drugs are stable under this storage condition. The labeling for the approved drug products states, "Do not freeze and do not use if it has been frozen".

**OBSERVATION 3**

Sterile drugs and materials were exposed to lower than ISO 5 quality air.

Specifically,

A. Technician (b) (6), was observed opening a pre-sterilized pack of vials outside of the ISO 5 area. These vials were then used to fill lot 05122025@(b) (4
B. There were multiple instances observed of Technician (b) (6), (b) resting their right-hand wrist on the front vent of BSC ID 01983 during filling operations. Technician (b) (6), (b) rested their wrist on the vent while using the filling needle to fill vials. Once filling of a vial was completed, they would use their right hand to place stoppers, thereby removing their arm off the vent. This action of resting their right-hand wrist on the vent, removes their hand outside of ISO 5 air, which is then reintroduced into the ISO5 without sanitization.
C. Technician (b) (6), (b) was observed with their hand partially outside of the BSC asset number 01984 Serial#(b) (4) when capping the first row of vials and continuing to place caps moving further back into the ISO 5 zone without sanitization.
D. Compounding Helper (b) (6), (b) was observed opening the first layer of packaging over pre-sterilized vials outside the ISO 7 zone but there is no way to determine how long this vial pack was left open during processing.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (PRINT OR TYPE) | DATE ISSUED |
|---|---|---|---|
| | Christina K. Theodorou | Christina K. Theodorou, Investigator<br>Evan Tong, Investigator | 06/09/2025 |

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| US Custom House, Room 900<br>200 Chestnut Street<br>Philadelphia, PA 19106, (215)-597-4390 | 05/12/2025 – 06/09/2025 |
| | FEI NUMBER<br>1000076625 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John W. Howell Sr., Executive Vice President of Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Boothwyn Pharmacy LLC | 221 Gale Lane |
| CITY, STATE, ZIP CODE, COUNTRY<br>Kennett Square, PA 19348 | TYPE ESTABLISHMENT INSPECTED<br>Producer of s |

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.

**OBSERVATION 4**

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

Specifically, your production technician failed to follow aseptic technique during the production of Lot 05122025@(b) Tirzepatide/Glycine/Methylcobalamin injection solution. For example, Technician (b) (6), (b) was observed moving their left hand to the right, over the first row of uncovered vials to pick up a filling needle. Additionally, there were multiple instances where first air over open vials were blocked by the paper that is included as part of your sterile vials packaging. When Technician (b) (6), introduced the pack of vials into the ISO 5 zone, they blocked first pass air over the open packet of pre-sterilized (b) (4)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (PRINT OR TYPE) | DATE ISSUED |
|---|---|---|---|
| | Christina Theodorou | Christina K. Theodorou, Investigator<br>Evan Tong, Investigator | 06/09/2025 |

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| US Custom House, Room 900<br>200 Chestnut Street<br>Philadelphia, PA 19106, (215)-597-4390 | 05/12/2025 – 06/09/2025*<br>FEI NUMBER<br>1000076625 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| John W. Howell Sr., Executive Vice President of Operations | |
| FIRM NAME<br>Boothwyn Pharmacy LLC | STREET ADDRESS<br>221 Gale Lane |
| CITY, STATE, ZIP CODE, COUNTRY<br>Kennett Square, PA 19348 | TYPE ESTABLISHMENT INSPECTED<br>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.

**OBSERVATION 5**

Smoke Studies were inadequately performed under dynamic conditions.

Specifically, review of your firm's air visualization "smoke" study videos, shows insufficiencies. For example:

A. All smoke study videos provided do not adequately illustrate that there is no air entering from the ISO 7 into the ISO 5 zone.
B. All smoke study videos provided do not truly represent operations under current production practice. For example, the smoke studies include a second person assisting in transfer of material into the ISO 5 area and the primary operator does not exist the ISO 5 environment. Your firm is unable to identify which production processus utilized the services of secondary assistants that enters the ISO 5 zone.
C. All the smoke study videos provided do not show the movement of air inside the BSC specifically where the bulk solution beakers and the sterilized packets of caps and stoppers are placed.
D. In video CEC#01983, there are instances where stagnant air is observed on the deck, instances where there is no first pass air over the vials and instances where the air is arching over the vials and stoppers and immediately leaving the zone. Improper technique is used to remove the caps on the filer, and on the tubing and connections, thereby preventing first pass air. There are instances of air dragging over the vials and over stoppers.
E. In video CEC#02166, there are instances where the air is arching to the front grill which makes it difficult to visualize if first pass air is going over the droptainers. There are instances of turbulence and back flow of air over the vials. The angle of the camera makes it difficult to see first pass air while filling is taking place.

The items identified above are examples of some of the instances observed during the review and do not indicate that the other videos not identified do not contain insufficiencies.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (PRINT OR TYPE) | DATE ISSUED |
|---|---|---|---|
| | Christina K. Theodorou | Christina K. Theodorou, Investigator<br>Evan Tong, Investigator | 06/09/2025 |

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| US Custom House, Room 900<br>200 Chestnut Street<br>Philadelphia, PA 19106<br>(215) 597-4390 | 05/12/2025 -06/09/2025*<br>FEI NUMBER<br>1000076625 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

John W. Howell Sr., Executive Vice President of Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Boothwyn Pharmacy LLC | 221 Gale Lane |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Kennett Square, PA 19348 | 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.

**OBSERVATION 6**

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically,

A. Your firm's ceiling tiles in PS-112 (ISO 7) where your human sterile preparations are produced, appear to be recessed so the central portion or tile is much higher than the framing making it difficult to clean. Floors, walls, and ceilings should be constructed of smooth, hard surfaces that can be easily cleaned. In addition, one of the ceiling tiles in PS-112 appears to have numerous tiny pores within the material. These factors make it difficult to clean and allow contaminants to accumulate and potentially spread. Furthermore, there are gaps in the ceiling framing that were not sealed allowing non-HEPA filtered air from the ceiling plenum to enter the ISO 7 cleanroom, where (b) (4) ISO 5 BSCs are located and used to product drug products intended to be sterile.

B. The walls in PS-112 and PS-112A are constructed of drywall with a layer of epoxy paint. This has left the walls with an unsmooth surface which makes them difficult to clean appropriately. Walls should be constructed of smooth hard surfaces that can be easily cleaned.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (PRINT OR TYPE) | DATE ISSUED |
|---|---|---|---|
| | Christina K. Theodorou | Christina K. Theodorou Investigator<br>Evan Tong Investigator | 06/09/2025 |

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."