DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	8/14-8/18/17
	FEI NUMBER FEI: 3010404505

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mina M. Banoub, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
United Pharmacy, LLC	3951 N. Haverhill Rd. Suite 120-121
CITY, STATE AND ZIP CODE West Palm Beach, FL 33417	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1: Actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production without adequate product evaluation and remedial action.

Specifically, on 11/29/16 during viable air monitoring conducted by your vendor an Out of Specification (OOS) of (b) (4) (specification (b) (4)) of Aspergillus versicolor was observed in the Negative Pressure Clean Room at location (b) (4) of the (b) (4) Your firm failed to conduct an adequate investigation and as a result attributed the OOS to be vendor related without any supporting evidence. During this time, your firm released (b) batches based solely on passing sterility testing between 11/30/16-12/15/16. The following batches were distributed:

1. Testosterone Cypionate 210mg/ml 5ml injection ((b) (4) vials), lot # TC-27 BUD: 5/30/17
2. Testosterone 200mg pellets ((b) (4) pellets), lot # PT200-5, BUD: 6/6/17
3. Testosterone 100mg pellets (pellets), lot # PT100-4, BUD: 6/6/17
4. Testosterone Propionate 5ml 100mg/ml injection (b) (4) vials), lot # TP-10, BUD: 5/30/17
5. HCG 5,000 unit injection (b) (4) units), lot # HCG5-23, BUD: 6/9/17
6. HCG 6,000 unit injection (b) (4) units), lot # HCG6-24, BUD: 6/15/17

Observation 2: 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 and distributed approximately (b) (4) Testosterone 50mg subcutaneous pellets (compounded 4/21/16), lot # PT50-2, BUD: 10/21/16 despite receiving failing potency test results (dated: 5/27/16) numerous times for low assay (83.4%, 86%, 78.3%) from your firm's contract testing laboratory. The specification for assay by HPLC is (b) (4). The same day, 5/27/16 your firm's contract testing laboratory tested the sample a fourth time and received a passing result of 96.2%. Your firm failed to evaluate the four test results for the same sample (3 failing, 1 passing) and shipped the product without conducting an investigation to invalidate the three OOS results based on scientific rationale.

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	Jessica L. Pressley	Jessica L. Pressley, Drug Investigator	08/18/2017

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Observation 3: Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, on 8/16/17 during gowning within the ISO 5 certified positive anteroom, adjacent to the negative pressure clean room, two operators were observed touching their sterile sleeves against both the door handle leading to the clean room and powder hood located within the anteroom. The ISO 5 certified positive anteroom contains a powder hood, sink and shelving with gowning materials, tubing, glassware, etc. leaving little room for the operators to adequately don sterile gowning.

Observation 4: Personnel failed to disinfect or change gloves frequently enough to prevent contamination.

Specifically, on 8/16/17 during the compounding operations for Testosterone Cyp./Anast. 200mg-0.5mg/mL 5mL injectable, lot # TCA0.5-4, BUD: 1/30/18 within the negative pressure clean room your firm's (b) (4) employees failed to disinfect or change gloves frequently during the following observed instances:
1. The operator sprayed his gloves with sterile (b) (4) then touched the drapes leading to the (b) (4) (b) (4), the front of the (b) (4) and the chair that he was sitting on and continued his aseptic technique.
2. The same operator during stoppering of the vials dropped the stopper, picked it up with his gloved hand and (b) (4) stoppered the vial containing sterile product.
3. At the completion of (b) (4) and prior to filling of the individual vials, the operator was observed moving equipment from the (b) (4) to a stainless steel workbench outside of the draped area therefore touching the drapes, equipment and workbench and without re-sanitizing or changing gloves began to fill the individual vials.

Observation 5: Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, on 8/16/17 prior to the compounding operations for Testosterone Cyp./Anast. 200mg-0.5mg/mL 5mL injectable, lot # TCA0.5-4, BUD: 1/30/18 within the negative pressure clean room your firm's (b) (4) operators failed to clean/disinfect the following equipment and supplies:
1. The operator failed to clean and sanitize the ceiling and front shield of the (b) (4)
2. The operator failed to wipe down the tray containing sterilized vials before placing it within the (b) (4)

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3. The operator failed to wipe down the (b) (4) containing non-sterile product before placing it within the (b) (4)
4. The operator failed to wipe down the tubing package before placing it within the (b) (4)
5. The operator failed to wipe the bottom of the repeater pump before placing it within the (b) (4)

Observation 6: Environmental monitoring was not adequately performed in your aseptic processing areas.

Specifically, on 8/16/17 at the completion of compounding operations for Testosterone Cyp./Anast. 200mg-0.5mg/mL 5mL injectable, lot # TCA0.5-4, BUD: 1/30/18 within the negative pressure clean room your firm's operator failed to adequately conduct surface sampling. When conducting his surface sample (b) (4) of the (b) (4) he was observed not applying pressure to the plate therefore the media was not coming in direct contact with the surface. Instead he tapped the edges of the plate and upon removal of the media plate an impression of a ring remained therefore the center of the plate failed to come in contact with the work surface of the (b) (4)

Observation 7: 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, your firm's media fills fail to demonstrate your current compounding process. For example, there is no documentation of the simulated filling and (b) (4) process. In addition, (b) (4) units were filled, but only 60 units were incubated and inspected for growth and turbidity. Your firm failed to provide scientific justification for not incubating and inspecting all units. Your firm also lacks documentation of growth promotion testing for the media used.

Observation 8: Post (b) (4) testing to the (b) (4) was not performed adequately.

Specifically, on 8/17/17 your firm's operator conducted a (b) (4) test on the (b) (4) (b) (4) used to (b) (4) Testosterone Cyp./Anast. 200mg-0.5mg/mL 5mL injectable, lot # TCA0.5-4, BUD: 1/30/18 (compounded on 8/16/17). During the (b) (4), your operator opened the (b) (4) completely instead of (b) (4) the (b) (4) as stated in your firm's SOP # 3.086, Rev. 1 titled, (b) (4), dated 5/1/17. The (b) (4) on the tank was closed, therefore when he opened the (b) (4) the (b) (4). The operator performed the (b) (4) and it failed at (b) (4) (specification is a minimum of (b) (4)). Your firm stated that this was the first time a (b) (4) has failed the (b) (4).

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In addition, your firm failed to provide scientific rationale and supporting documentation to demonstrate that the (b) (4)) can adequately sterilize the Testosterone Cyp./ Anast. 200mg-0.5mg/mL 5mL injectable which is an oil base product.

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