DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	7/26/2018-8/3/2018* FEI NUMBER 3009192575

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronda M. Wenzel, Pharmacist

FIRM NAME	STREET ADDRESS
Talon Compounding Pharmacy	2950 Thousand Oaks Dr Ste 25
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78247-3347	Compounding Pharmacy

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

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, during a review of your firm's 8/14/2017 Cleanroom Certification, your firm's cleanroom contract certifier reported an ISO 7 Cleanroom differential pressure as + 0.026". The differential pressure in the ISO 8 Anteroom was reported as +0.029. Your firm failed to document, investigate, and implement a corrective action to correct poor quality air from flowing from the Anteroom into the higher quality ISO 7 Cleanroom. Within the ISO 7 cleanroom is the ISO 5 aseptic processing area. On 8/14/2017, your firm aseptically compounded (b) (4) sterile patient-specific finished drugs products.

OBSERVATION 2

Personnel engaged in aseptic processing were observed with exposed hair.

Specifically, on 7/26/2018 while observing your firm's pharmacy technician aseptically compounding 2 lots of sterile Tri-Mix Injection (Lot 07252018:91, BUD 1/21/2019; and Lot 07262018:52, BUD 1/22/2019), I observed your pharmacy technician hair sticking out from underneath the hairnet. On more than eight occurrences, your pharmacy technician entire head extended into your ISO 5 area while aseptically processing both sterile drug lots.

OBSERVATION 3

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	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 08-03-2018 21:35:28	8/3/2018

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Personnel did not disinfect to prevent contamination.

Specifically, your firm's pharmacy technician failed to disinfect gloves to prevent contamination. For example, while conducting visual observations on 7/26/2018, 7/31/2018, and 8/1/2018, I observed your firm's pharmacy technician while aseptically manipulating a sterile finished drug product leave the ISO 5 classified area to select additional processing components within the ISO 7 classified area and return without re-disinfecting sterile gloves prior to reentering the aseptic processing area on too many to count occasions.

OBSERVATION 4

Equipment was not disinfected prior to entering the aseptic processing areas.

Specifically, equipment and materials and/or supplies were not disinfected prior to placing these items into to the ISO 5 aseptic processing area. For example, while conducting visual observations on 7/26/2018, 7/31/2018, and 8/1/2018, I observed your firm's pharmacy technician placing drug components into the cleanroom (b) (4) without disinfecting with sterile (b) (4) . Drug components were then transferred from your firm's ISO 7 to the ISO 5 aseptic processing area without disinfecting with sterile (b) (4) and used to aseptically process sterile patient-specific drug products.

OBSERVATION 5

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worse-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's media fill simulation fails to represent the worst-case scenario and simulate actual production conditions. For example, You firm's media fill simulation consists of aseptically (b) (4) (b) (4) . Your firm PIC reported the potential maximum

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number of vials aseptically processed can be (b) (4) for a specific sterile drug lot. Your firm's aseptic processing does not include the filling of IV bags. Instead, your firm aseptic processing includes vial and syringe filling only for sterile drug compounding.

OBSERVATION 6

There is a lack of adequate controls to prevent mix-ups.

Specifically, Incident Report dated 10/10/2017, reported Rx (b) (6), Lot # 08292017:77 was incorrectly labeled as Testosterone 4% Topical CRM and was dispensed. The correct label should have been Testosterone 4mg/mL Topical CRM. Your firm failed to detect the labeling error for approximately 1 year, until your technician was typing a new prescription for the patient.

OBSERVATION 7

Cleanroom certification for your ISO classified areas are inadequate.

Specifically, your firm's cleanroom certifications are documented as being performed in the dynamic (operational) condition. Your firm fail to include the use of the (b) (4) as part of your firm's ISO 5 cleanroom smoke study and certification.

OBSERVATION 8

There is a lack of adequate separation within facility design and equipment placement within the ISO classified and non-classified areas to prevent contamination.

Specifically,

A. Your cleanroom is designed with plastic flaps along the floor which function as air exhausts for the ISO 5

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classified area which vents into the ISO 8. Your firm's cleanroom design failed to prevent contamination of your ISO 5 sterile drug compounding area.

This is a repeat observation.

B. Your firm has a refrigerator/freezer within your firm's ISO 5 classified area used as part of your firm's (b) (4) process. Your firm failed to prevent contamination from the refrigerator/freezer and transferred into the ISO 5 sterile compounding area.

C. Your firm placement of the (b) (4) is located within your ISO 8 classified area. The (b) (4) location is on the opposite side of the wall where your firm has designated as ISO 5. There is a plastic flap along the floor which separate both areas and remains open. Your firm failed prevent the introduction of contamination from the (b) (4) from entering your ISO 5 classified area.

***DATES OF INSPECTION**

7/26/2018(Thu), 7/27/2018(Fri), 7/30/2018(Mon), 7/31/2018(Tue), 8/01/2018(Wed), 8/02/2018(Thu), 8/03/2018(Fri)

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