DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 1201 Main Street, Suite 7200 One Main Place Dallas, TX 75202-3908 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	10/18-22,25-27/2021; 11/2/2021
	FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. David A. McLennan, owner

FIRM NAME	STREET ADDRESS
Vita Pharmacy, LLC dba Talon Pharmacy of Boerne	1430 South Main Street #105
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Boerne, TX 78006	Producer of 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) (WE) OBSERVED:

OBSERVATION #1

Your facility design may allow the influx of poor quality air into a higher classified area. Specifically,

A. The (b) (4) used to separate the ISO 5 area from the ISO 7 room is attached to the top of the ISO 5 area with double sided mounting strips. A visible gap was observed between the ceiling and the (b) (4) where the mounting strips are attached. There is no assurance that the current configuration prevents the ingress of ISO 7 air into the ISO 5 area.

B. (b) (4) doors are designed with no safeguards in place to detect and notify of changes in differential pressure in the event that the doors are opened simultaneously.

C. A crack was observed in the (b) (4) wall of the ISO 7 cleanroom thereby allowing the possible ingress of air from the ISO 8 area.

D. A power cord from the (b) (4) in the ISO 8 area was connected to an outlet inside the ISO 7 cleanroom through one of the exhaust vent flaps. In this case, the vent was unable to fully close due to obstruction from the cord. In addition, dust was observed in the ISO 8 area in close proximity to the vent flaps thereby allowing possible ingress into the ISO 7 cleanroom.

OBSERVATION #2

You produced hazardous drugs without providing adequate containment and segregation to prevent cross-contamination.

Specifically, your ISO 5 Biological Safety Cabinet used for the compounding of hazardous sterile drug products is

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Stephen D. Brown, Investigator	11/02/2021

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located in the ISO 7 cleanroom in close proximity to the ISO 5 workbench area.

OBSERVATION #3

On 10/27/2021, I observed a dark residue on the plastic grille enclosing the HEPA filter located in the ISO 5 workbench area.

OBSERVATION #4

Materials and supplies were not disinfected prior to entering the aseptic processing areas. Specifically, on 10/25/2021, during the aseptic processing of MIC B12 15/50/100/1 mg/ml Injectable, lot #10252021@1, I observed that the operator sanitized the surface of a package containing a vent needle and placed it on the stainless steel table outside the ISO 5 area. After about 10 minutes, the package containing the vent needle was used in the ISO 5 area without being re-sanitized.

OBSERVATION #5

The certification of the ISO 5 areas was inadequate. Specifically,

A. Smoke studies were not conducted on the ISO 5 Biological Safety Cabinet to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions.

B. Smoke studies within the ISO 5 classified area failed to demonstrate adequate product protection. Specifically, the smoke generator was not positioned properly to allow an assessment of airflow to the critical area where aseptic operations were being simulated.

OBSERVATION #6

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

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	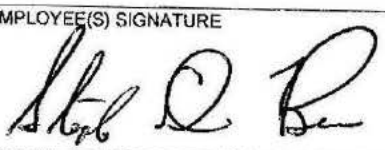	Stephen D. Brown, Investigator	11/02/2021

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Specifically, your current media fill test using a (b) (4) consists of aseptically transferring (b) (4) into a mini bag. Review of media fills conducted since 8/2020 revealed that the media fills were not representative in that your firm failed to simulate actual production processes. For example, a lot of Methylcobalamin 1mg/ml, lot #10132021@4 consisted of (b) (4) ml, or (b) (4) ml vials.

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