DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	3/11-12,14-15,18,21,25-26,28-29/2019;4/2/2019; 5/9/2019
	FEI NUMBER 3014613445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. David S. Centanni, Owner

FIRM NAME	STREET ADDRESS
Total Vein Pharmacy LLC dba Total Vein Pharmacy	2428 Yale Street Suite B
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Houston, TX 77008	Producer of Sterile and Non-Sterile Drugs

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

The ISO 5 classified areas were not certified under dynamic conditions. Specifically, unidirectional air flow was not verified under operational conditions.

I reviewed the smoke study dated 11/7/18 and observed significant air turbulence inside the ISO 5 area. The failure to maintain unidirectional airflow was not investigated by your firm.

OBSERVATION #2

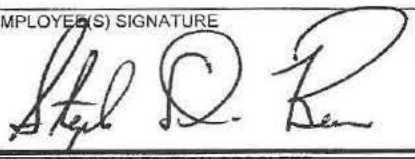
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst case activities and conditions that prove a challenge to aseptic operations.

Specifically, review of your media fill dated 9/28/18 revealed that a total of (b) (4) vials were sterile filled. However, during actual production, your firm routinely fills at least (b) (4) vials per batch.

For example, on 2/18/19, your firm produced Polidocanol 5% for Injection, lot #5P021819 which consisted of (b) (4) or approximately (b) (4) vials.

OBSERVATION #3

Your firm uses the following disinfectants in the ISO 5 area, (b) (4) Cleaner and (b) (4) (b) (4). The contact time of (b) (4) (b) (4) minutes has not been substantiated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Brown, Investigator	05/09/2019