DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314 Industry Information: www.fda.gov/oc/industry	03/20/2017-03/31/2017*
	FEI NUMBER 3007003644

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Phillip R. Pylant, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Village Compounding Pharmacy	975 Corbindale Road, Suite 100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Houston, TX 77024-2810	Producer to 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.

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

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

On 03/20/2017, I observed your firm utilizing non-sterile wipes to disinfect your firm's laminar airflow hood # (b) (4) Manufacturer (b) (4) Model # (b) (4) , Serial # (b) (4), (b) (4) the production of your firm's sterile injectable drug product, Prostaglandin 500 MCG/ML, 60 ML, Lot # 03202017@4, Manufacture Date 03/20/2017, Beyond Use Date 07/18/2017.

OBSERVATION 2

There is a (b) (4) in the cleanroom where the ISO 5 area is located which is a source of potential microbial contamination.

Specifically,

On 03/20/2017, I observed the presence of a (b) (4) in your firm's Cleanroom # (b) (4) located approximately five feet from your firm's (b) (4) hood # (b) (4) Manufacturer (b) (4) Model # (b) (4), Serial # (b) (4) . The firm's (b) (4) hood is utilized to aseptically process sterile drug products.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jason R. Caballero -A	Jason R. Caballero, Investigator	03/31/2017

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CITY, STATE AND ZIP CODE Houston, TX 77024-2810	TYPE OF ESTABLISHMENT INSPECTED Producer to Sterile and Non-Sterile Drug Products

*DATES OF INSPECTION
3/20/2017(Mon),3/21/2017(Tue),3/22/2017(Wed),3/23/2017(Thu),3/24/2017(Fri),3/27/2017(Mon),3/28/2017 (Tue), 03/29/2017(Wed),03/30/2017(Thu),03/31/2017(Fri)

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		Jason R. Caballero, Investigator	03/31/2017