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	11/28/2016-12/8/2016* FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. David C. Short , Vice President of Quality

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S General Bruce Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY Temple, TX 76502-5804	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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 WE OBSERVED:

OBSERVATION 1

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

Specifically, your firm has not performed effectiveness testing for disinfectants such as (b) (4) and (b) (4) which are routinely used in the ISO 5 (b) (4)

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm failed to record continuous pressure differentials between the ISO 5 (b) (4) and ISO 7 Clean Rooms during aseptic drug production.

In addition, the pressure gauges measuring the pressure differential from the (b) (4) to the (b) (4) are not equipped with an alarm system as required in Section 4.2 of your firm's Standard Operating Procedure (SOP), QuVa Pharma Facility Standard, Document COR-SOP-TO-0002, Version 01, Effective date 7/8/2016.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephen D Brown, Investigator Lisa R Jennings, Investigator	X Stephen D Brown Stephen D Brown Investigator Signed by: Stephen D. Brown -5 (12/8/2016)	12/8/2016

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Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, your "(b) (4) Certification Report" dated (b) (4) for each (b) (4) includes an "Air Flow Smoke Pattern Test". In each case, there was no documentation to show that the test was performed under dynamic conditions.

OBSERVATION 4

The labels of your outsourcing facility's drug products are deficient.

Specifically, your labels do not include the address and phone number of the site under inspection. For example,

- Norepinephrine 8 mg added to 5% Dextrose 500ml Bag
- Promethazine HCl 25mg added to 0.9% Sodium Chloride
- Ephedrine Sulfate 5mg/ml in 0.9% Sodium Chloride

*DATES OF INSPECTION

11/28/2016(Mon),11/29/2016(Tue),11/30/2016(Wed),12/01/2016(Thu),12/02/2016(Fri),12/05/2016(Mon),12/06/2016(Tue),12/07/2016(Wed),12/08/2016(Thu)

12/8/2016

X Lisa R Jennings
Lisa R Jennings
Investigator
Signed by: Lisa R. Jennings -5

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