**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<br>Dallas, TX 75204<br>(214)253-5200 Fax:(214)253-5314 | 4/5/2019-4/23/2019*<br>FEI NUMBER<br>3012053582 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Travis M. McGrady, Senior Director Production Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| QuVa Pharma, Inc. | 1075 W Park One Dr Ste 100 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Sugar Land, TX 77478-2576 | 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 I OBSERVED:**

## OBSERVATION 1

Equipment for adequate control over air pressure, humidity and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, your firm failed to adequately implement procedure, QuVa Pharma Facility Standard, COR-SOP-FM-0002, Rev. 4, concerning measuring, recording, and monitoring of controlled space temperature, relative humidity and differential pressure. For example, your firm's (b) (4) system (b) (4) failed to electronically measure, record, and transfer environmental conditions data in Cleanrooms 1 – (b) (4) for the dates/times 3/3/2019 @ 8:00am – 3/5/2019 @8:00 am & 3/5/19@ 11:00 pm – 3/7/2019 @ 5:00 pm for Cleanrooms 1 – (b) (4) to a designated server. During these dates and times, your firm facilities management and quality unit was unaware of the condition and continued to aseptically process sterile drug products. Your firm's (b) (4) failed to send notifications to the Facilities Management Department regarding the issue of missing measurement data.

## OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

A) On 4/5/2019, while conducting observations of the firm's compounding technician aseptically processing Heparin 30,000 units added to 1000ml 0.9% Sodium Chloride solution bag, Item 7009128108, Lot 10023176, Expiry 7/4/2019, I observed processing supplies and drug components blocking the movement of first pass air during filling sterile to sterile product transfer, which potentially may result in cross-contamination in LAF hood (b) (4)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Camerson E Moore, Investigator | X Camerson E Moore Investigator Signed By: Camerson E. Moore -5 Date Signed: 04-23-2019 10:43:08 | 4/23/2019 |

B) On 4/8/2019, while observing environmental sampling of Cleanroom # (b) (4) environmental sampling technician fail to re-sanitize gloves following performing tasks in the ISO 7 area prior to placing air sampling unit in BSC #(b) (4) where the compounding technician was aseptically process Cefazolin PF 2 g added to 100mL NS Bag, Item 70092101803, Lot 10023328.

**OBSERVATION 3**

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A) Your firm's stools located in all ISO 7 Cleanrooms, used by your compounding technicians during aseptic processing, is covered with a material which cannot be adequately disinfected.

B) On 4/5/2019 during a walk-through of your firm's aseptic processing areas, I observed in LAF hood (b) (4) HEPA grate with white and black residue, while aseptic processing Morphine PF 1mg/ml 100 ml (1 mg/ml) in 0.9% Sodium Chloride solution (b) (4) , Item 70092151875, Lot 10023288, Expiry 7/4/2019, Qty. (b) (4) units. Your firm's Senior Director of Production Operations stated compounding technicians cleaned the HEPA filter grate. He continued in stating the firm believes it was caused by sterile drug product splash during aseptic processing. No laboratory analysis was performed on the foreign material to confirm its identity.

**OBSERVATION 4**

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product.

Specifically, during review of Recall # D-0295-2019, Norepinephrine 8 mg (32 mcg/mL) added to 0.9% Sodium Chloride Injection 250 mL Bag, your firm's investigation identified the issue to be a drug component picking issue. Your firm's compounding technician aseptically admixed 250mL 5% Dextrose Injection 250 mL Bag in error. Your firm's quality unit failed to investigate why your firm's

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 4040 North Central Expressway, Suite 300<br>Dallas, TX 75204<br>(214)253-5200 Fax:(214)253-5314 | 4/5/2019-4/23/2019*<br>FEI NUMBER<br>3012053582 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Travis M. McGrady, Senior Director Production Operations | |
| FIRM NAME<br>QuVa Pharma, Inc. | STREET ADDRESS<br>1075 W Park One Dr Ste 100 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Sugar Land, TX 77478-2576 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility |

(b) (4) Testing Laboratory failed to report an unusual peak found during potency testing. I requested the lot laboratory test data, which resulted in the firm finding the presence of an unknown peak of the finished sterile drug product sample. Your firm's director of quality reported the firm will be reopening the CAPA to further investigate this finding made during this inspection. Your firm failed to adequately investigate the unusual laboratory test results.

## OBSERVATION 5

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, during a walk-though of your firm's non-controlled sterile drug finished drug storage located at 1005 Industrial Blvd., Sugar Land TX, I found your firm's quality unit failed to review and approve (b) (4) refrigeration unit maintenance/monitoring logs since 10/2018 used for storage of sterile non-controlled finished drug products. Your firm's quality manager stated the logs should have been reviewed and approved by the quality unit.

## OBSERVATION 6

Your compounded drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503(a)(5) and 503B(d)(2).

Specifically, your compounded drug products that:

a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under Section 506E at the time of compounding, distribution, and dispensing; of
b) are not identical or nearly identical to an approved drug, but that contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Camerson E Moore, Investigator | X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 04-23-2019 10:43:06 | DATE ISSUED<br>4/23/2019 |
|---|---|---|---|

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 4040 North Central Expressway, Suite 300<br>Dallas, TX 75204<br>(214)253-5200 Fax:(214)253-5314 | 4/5/2019-4/23/2019* |
| | FEI NUMBER<br>3012053582 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Travis M. McGrady, Senior Director Production Operations | |
| FIRM NAME<br>QuVa Pharma, Inc. | STREET ADDRESS<br>1075 W Park One Dr Ste 100 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Sugar Land, TX 77478-2576 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility |

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

A. Phenylephrine HCL, 50mg added to 250ml 0.9% Sodium Chloride Solution Bag, Item 70092104505, Lot 10019552, Expiry 4/12/2019.

B. Neostigmine, 1mg/ml 5 ml Syringe, Item 70092118944, Lot 10022441, Expiry 6/16/2019.

***DATES OF INSPECTION**

4/05/2019(Fri), 4/08/2019(Mon), 4/09/2019(Tue), 4/10/2019(Wed), 4/11/2019(Thu), 4/12/2019(Fri), 4/15/2019(Mon), 4/16/2019(Tue), 4/23/2019(Tue)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Camerson E Moore, Investigator | X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 04-23-2019 10:43:08 | DATE ISSUED<br>4/23/2019 |
|---|---|---|---|