DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	6/7/2022-6/16/2022* FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Travis A. Leeah, VP of Clinical Development & PIC

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S General Bruce Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Temple, TX 76502-5804	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 in that floors are not smooth and/or hard surfaces that are easily cleanable.

Specifically, on 6/7/2022, while performing visual observations of the firm's production of drugproducts intended to be sterile, in Cleanroom (b) (4) we observed the floor in the ISO 7 Cleanroom, which contains the ISO 5 BSC was found to have propagating cracks from a hole (approximately 1" height x approximately 2.5" length) in the epoxy flooring exposing the floor base material resulting in potential causing difficult to adequately clean and disinfect floor along with potentially harboring microbial contamination. Your firm's PIC was unaware of the ISO 7 Floor condition.

OBSERVATION 2

Input to and output from the computer and records or data are not checked for accuracy.

Specifically, during a review of your firm's batch record, your firm was found to be use an unvalidated online software, "(b) (4) " to determine your firm's documented BUD found on your firm's bulk drug finish product labeling. For example, while reviewing your firm's batch record for non-sterile bulk concentrate, Ephedrine Sulfate (b) (4) Bulk Bag, 50 mg/mL 3000 mL Bag Preservative Free, Date Compounded 6/3/2022, Exp: 6/30/2022, Lot #(b) (4) and (b) (4) sterile bulk Ephedrine Sulfate (b) (4) Bulk Bag, 5 mg/mL 3000 mL Bag Preservative Free, Date Compounded 6/8/2022, Exp: 7/5/2022, Lot # (b) (4) , was found to contain a print-out from the online software, (b) (4) ". Your firm Quality Manager stated your firm had not verified the accuracy of the online software used to determine drug product BUDs. Your firm management state the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator Damaris Y Hernandez, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 06-16-2022 17:28:37	6/16/2022

software use had been in place since the acquisition.

OBSERVATION 3

The master production and control records are deficient in that they do not include complete manufacturing and instructions.

Specifically,

A. During a review of selected bulk batch record for the non-sterile bulk drug concentrates, Ephedrine Sulfate (b) (4) concentrate, (b) (4) Bulk Bag 50mg/mL 3000 mL Bag, Lot # (b) (4), Compound date 6/3/2022, Exp. 6/30/2022 (b) (4) to compound the bulk finished drug batch, Ephedrine Sulfate PF 5mg/mL in NaCl 3L Bulk Bag, Lot # (b) (4), Compound Date 6/8/2022, Expiry 7/5/2022, failed to include instruction and documentation for placing non-sterile bulk concentrate bag into an (b) (4) bag to prevent light penetration resulting in the potential degradation of the product. Your firm's quality manager stated the (b) (4) requirement for concentrate bulk solutions was an oversight in the master batch record.

B. Your firm's procedure, Labeling Preparations, TEM-WI-PO-009, Labeling Preparations, which includes a section referencing (b) (4) bag requirements for produced drug products, Sub-section 3.4.2, fail to adequately document bulk drug concentrate packing and labeling of bulk (b) (4) concentrate non-sterile bulk drug products (b) (4) bag requirement to protect from light. This section includes requirements for only, "(b) (4)" and "(b) (4) Bulk Bag Label" in use of the (b) (4) bag.

OBSERVATION 4

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

A. The established name of the drug; Examples of your drug product labels that do not

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contain this information:

1. L.E.T. Solution 3 ml in 5 ml TS
2. L.E.T. Gel 1.5 ml in 3 ml Top Syr.
3. L.E.T. Gel 3 ml in 5 ml TS

***DATES OF INSPECTION**

6/07/2022(Tue), 6/08/2022(Wed), 6/09/2022(Thu), 6/10/2022(Fri), 6/13/2022(Mon), 6/14/2022(Tue), 6/15/2022(Wed), 6/16/2022(Thu)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."