DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	02/26-28/19, 03/01, 4-8, & 14/19
	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Alicia L. Ashford, Director of Manufacturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S. General Bruce Drive
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

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

OBSERVATION 1

Written procedures are lacking which describe in sufficient detail the receipt, identification, approval, and rejection of components.

Specifically, your firm is using non-pharmaceutical grade components in the formulation of sterile drug products. For example,

a) Your firm uses (b) (4) for adjusting the pH of sterile drug products. The (b) (4) (b) (4) is labeled "NOT FOR DRUG, FOOD, OR HOUSEHOLD USE".
b) Your firm uses (b) (4) for adjusting the pH of sterile drug products.

OBSERVATION 2

There are no established written methods of cleaning or methods of processing to remove pyrogenic properties.

Specifically, your firm has not validated the depyrogenation process for the (b) (4) used in compounding sterile drug products. Your firm has not demonstrated that the washing process you have implemented is adequate for endotoxin removal.

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Your firm had a confirmed endotoxin failure in January 2019 (Finished product lot #10019623 of Heparin PF 0.25 U/mL (b) (4) mL 0.5 NS – Bulk lot #(b) (4) .

OBSERVATION 3

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

Specifically,

a) In January 2019, your firm removed the(b) (4) in all (b) (4) ISO 7 Cleanrooms that were (b) (4) (b) (4) . As part of the change control, your firm did not perform an assessment to justify how you are bringing the materials into the cleanroom or if any changes were needed to the environmental monitoring program as a result of the change.

b) Your firm is not sampling sites that are frequently touched during production such as the surface of the (b) (4) Repeater Pump and the door handle from the ISO 7 Cleanroom into the ISO 8 Gowning/Ante Room.

OBSERVATION 4

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, rust and residue could be seen on the metal hinges of the totes used to hold and bring items into and out of the ISO 7 Cleanrooms and/or the ISO 8 Gowning/Ante Rooms, including empty sterile bags used for filling the sterilized product into; packages containing sterile tubing, (b) (4) and environmental monitoring plates; and bags with the (b) (4) drug product. Rust was also noted on the wheels of the trash cart in the ISO 7 Cleanroom (b) (4) and the inside of the lid on the trash can in the ISO 8 Gowning/Ante Room for Cleanroom (b) (4)

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OBSERVATION 5

Production personnel were not practicing good sanitation and health habits.

Specifically, your firm does not have handwashing facilities near the gowning areas for entry into compounding areas, including entry into ISO 7 Cleanrooms/ISO 5 (b) (4) . In addition, your written procedures regarding gowning do not require hand washing.

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has not validated the incubation temperature and time for growth promotion of media and the environmental and personnel monitoring plates. Your firm is incubating the plates at (b) (4) - (b) (4) degrees C (b) (4) (b) (4) .

OBSERVATION 7

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound 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; or b) are not identical or nearly identical to an approved drug, but 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.

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

- Neostigmine methylsulfate 1mg/1ml
- Glycopyrrolate 0.2mg/ml
- Midazolam PF 1mg/ml

OBSERVATION 8

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 statement "This is a compounded drug";

b) ~~The name, address, and phone number of the outsourcing facility;~~ MMA 3/14/19

c) The dosage form and ~~strength;~~ MMA 3/14/19

d) ~~The quantity or volume;~~ MMA 3/14/19

e) The National Drug Code number, if available;

f) The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only";

g) ~~A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.~~ MMA 3/14/19

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Examples of your drug product labels that do not contain this information include:

- Fentanyl 10mcg/mL Preservative Free (PF) 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

OBSERVATION 9

The containers of your outsourcing facility's drug products does not include information required by section 503B (a)(10)(B). Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088;

Examples of your container labels that do not contain this information include:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
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b) Route of administration.

Examples of drug product containers that do not contain this information:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
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