VIA ELECTRONIC MAIL
READ/DELIVERY RECEIPT REQUESTED

June 18, 2025

Stuart Hinchen, CEO
QuVa Pharma, Inc.
3 Sugar Creek Center Blvd.
Suite 250
Sugar Land, TX 77478

Dear Mr. Hinchen:

You registered your facility with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b][1] on September 10, 2015, and most recently on December 9, 2024. From September 24, 2024 to October 28, 2024, an FDA investigator inspected your facility, QuVa Pharma, Inc., located at 1075 W. Park One Drive, Suite 100, Sugar Land, TX 77478. During the inspection, the investigator noted deficiencies in your practices for producing drug products, which puts patients at risk.

FDA issued a Form FDA 483 to your facility on October 28, 2024. FDA acknowledges receipt of your facility's responses, dated November 19, 2024, and February 3, 2025. FDA acknowledges that on March 6, 2025, your firm initiated a voluntary recall of the following products, within expiry, due to lack of sterility assurance: (1) Fentanyl Citrate PF 200 mcg/100 mL (2 mcg/mL) /0.1% Bupivacaine HCl 100 mg/100 mL (1 mg/mL), 100 mL in NS Yellow CADD FSFF, Injection for Epidural Use; (2) Fentanyl Citrate PF 200 mcg/100 mL (2 mcg/mL) /0.125% Bupivacaine HCl 125 mg/100 mL (1.25 mg/mL), 100 mL in NS Yellow CADD FSFF, Injection for Epidural Use; and (3) Fentanyl Citrate PF 200 mcg/100 mL (2 mcg/mL) /0.2% Ropivacaine HCl 200 mg/100 mL (2 mg/mL), 100 mL in NS Yellow CADD FSFF, Injection for Epidural Use. Based on this inspection, it appears you produced drugs that violate the FDCA.

A. Compounded Drug Products under the FDCA

Under section 503B(b) of the FDCA, a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate directions for use and the Drug Supply Chain

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

Security Act requirements in section 582 of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met.[2]

An outsourcing facility, which is defined in section 503B(d)(4) of the FDCA [21 U.S.C. § 353b(d)(4)], is a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section. Outsourcing facilities must comply with other applicable provisions of the FDCA, including section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], regarding current good manufacturing practice (CGMP), and section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)], regarding insanitary conditions. Generally, CGMP requirements for the preparation of drug products are established in Title 21 of the Code of Federal Regulations (CFR) parts 210 and 211.

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that:

1. Your firm did not perform adequate product evaluation and take appropriate corrective action after microbial contamination was recovered within the ISO 5 aseptic processing area.

The FDA investigator also noted CGMP violations at your facility, that caused your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a revised draft guidance, *Current Good Manufacturing Practice — Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act*. This draft guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21

[2] We remind you that there are conditions, other than those discussed in this letter, that must be satisfied to qualify for the exemptions in section 503B of the FDCA.

CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

C. Corrective Actions

We have reviewed your facility's responses to the Form FDA 483. FDA acknowledges that on March 6, 2025, your firm initiated a voluntary recall of the following products, within expiry, due to lack sterility assurance: (1) Fentanyl Citrate PF 200 mcg/100 mL (2 mcg/mL) /0.1% Bupivacaine HCl 100 mg/100 mL (1 mg/mL), 100 mL in NS Yellow CADD FSFF, Injection for Epidural Use; (2) Fentanyl Citrate PF 200 mcg/100 mL (2 mcg/mL) /0.125% Bupivacaine HCl 125 mg/100 mL (1.25 mg/mL), 100 mL in NS Yellow CADD FSFF, Injection for Epidural Use; and (3) Fentanyl Citrate PF 200 mcg/100 mL (2 mcg/mL) /0.2% Ropivacaine HCl 200 mg/100 mL (2 mg/mL), 100 mL in NS Yellow CADD FSFF, Injection for Epidural Use.

Some of your corrective actions appear deficient:

1. Regarding your response to deficiencies in your environmental monitoring (EM) reports related to gloved fingertip excursions within the ISO 5 laminar airflow hoods (LAFHs)/Biosafety Cabinets (BSCs), you did not thoroughly investigate and evaluate trending data to determine a root cause and take appropriate corrective actions and preventative actions (CAPA). It is unclear from your response as to what actions will be taken when an investigation related to EM/personnel monitoring (PM) excursions determines the root cause to be "personnel error." For example, you stated a potential cause for each gloved fingertip out of specification (OOS) was potentially due to "glove sanitization technique of the compounder." Your corrective/preventative actions state, "Based upon the data reviewed the event was an isolated incident and, as such, no CAPA is necessary." However, the investigator observed other investigations with similar statements without further evaluation in determining a root cause to take appropriate corrective and preventative actions.

   We acknowledge your firm's response in stating your enhancement to EM/PM investigation procedures; however, you did not provide additional information to support this statement or the specifics to the modifications. In addition, you submitted signatures of employees who participated in the training presentations provided by your third-party consultant. However, you did not provide supporting documentation ensuring your aseptic operators are qualified in performing appropriate gloving and gowning practices following this training.

In addition to reviewing the training adequacy of personnel practices, it is critical for personnel to maintain contamination-free gloves and gowns throughout aseptic operations. Conducting thorough investigations and evaluating EM/PM data can provide important information to a possible route of contamination.

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. *See* section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. [*See* 21 CFR 210.1(b), 21 CFR 200.10(b).]

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time within which you will do so.

All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. If you have questions regarding the contents of this letter, please contact compoundinginspections@fda.hhs.gov.

Sincerely,

Frances G. Bormel -S

Digitally signed by Frances G. Bormel -S
Date: 2025.06.18 09:55:17 -04'00'

F. Gail Bormel, JD, RPh
Director
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research