

March 24, 2017

Mr. Stuart Hinchen Chief Executive Officer QuVa Pharma, Inc. 14140 Southwest Freeway Sugar Land, TX 77478

Reference: Inspection Date(s): 01/20/2016 - 02/08/2016

FEI: 3012053582

Dear Mr. Hinchen:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

If there is any question about the released information, feel free to contact me at (214)253-5262 or jason.schilling@fda.hhs.gov.

Sincerely,

Jason H. Schilling, MBA Program Support Specialist, Compliance Branch, Dallas District

Food and Drug Administration Dallas District Office 4040 North Central Expressway Suite 300 Dallas, Texas 75204