WARNING LETTER

Date March 6, 2020

TO: jennifer@purevitalsilver.com – Jennifer Hickman, Colloidal Vitality LLC
3183 Forest Creek Dr.
Melbourne, FL 32901

RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the internet address www.purevitalsilver.com in February 2020. We have also reviewed your Facebook website at www.facebook.com/purevitalsilver where you direct consumers to your website www.purevitalsilver.com to purchase your products. The FDA has determined that your website offers essential oil products for sale in the United States and that these products are intended to mitigate, prevent, treat, cure or diagnose COVID-19[1] in people. FDA has determined that these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

The Secretary of Health and Human Services, under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, has determined that a public health emergency exists nationwide as a result of confirmed cases of COVID-19. Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose or cure COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your websites that establish the intended use of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- "So it's actually widely acknowledged in both science and the medical industry that ionic silver kills coronaviruses. And it's now known that the Chinese are employing ionic silver in their fight against the spread of the coronavirus." [from a February 17, 2020 post on your Facebook website http://www.facebook.com/purevitalsilver]

[1] COVID-19 is the official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China.

- "It is always good to go on the offense – taking a tsp or two twice daily of Structured Silver Advanced Formula helps fight the pathogens we are exposed to on a daily basis. The structured silver circulating in your blood attaches to bacteria, yeast, and viruses rendering them ineffective and boosting your immune system . . . It's important to note that although there are increasing numbers of cases being reported of corona virus, most of the fatalities are from older and younger folks with compromised immune systems." [from February 6, 2020 comments that you made on a post on your Facebook website http://www.facebook.com/purevitalsilver]
- "Wellness!! Vital Silver!!! Simple!!! Go on the offense this year against viruses including the Coronavirus – it's simple!" [from a February 6, 2020 post on your Facebook website http://www.facebook.com/purevitalsilver]
- "The Silver is flying off the shelves as folks stock up due to the increased awareness of the coronavirus." [from a February 4, 2020 post on your Facebook website http://www.facebook.com/purevitalsilver]
- "Structured Silver allows a silver particle-cluster of silver to kill multiple bacteria, viruses, and yeast/candida pathogens throughout the body until it is safely excreted." [from your website www.purevitalsilver.com]

You should take immediate action to correct the violations cited in this letter. The violations cited in this letter are not meant to be an all-inclusive list. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not representing your products for a COVID-19 related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov** describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products. Once you have taken corrective actions and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs are subject to detention and refusal of admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) listed above to be unapproved and misbranded products that cannot be legally sold to consumers in the

United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov.

In addition, it is unlawful under the FTC Act, 15 U.S.C. 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. To make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act.

There currently are no vaccines, pills, potions, lotions, lozenges or other prescription or over-the-counter products available to treat or cure coronavirus disease 2019 (COVID-19). Thus, the claims cited above are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. In addition, you are advised to review all claims for your products and immediately cease making claims that are not supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

RICHARD QUARESIMA
Digitally signed by RICHARD QUARESIMA
Date: 2020.03.06 09:00:22 -05'00'

Richard A. Quaresima
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission