

WARNING LETTER

Date: October 16, 2020

TO: Info@patriotsupreme.com – Justin Elenburg, For Our Vets LLC dba Patriot Supreme
1910 S. Stapley Dr.
#221
Mesa, AZ 85204

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

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:

“CBD AND COVID-19 – CAN CBD HELP COVID-19 LUNG INFLAMMATION?”

- “[t]here has been an increased interest in CBD and Covid-19 to treat lung problems and symptoms (mental or physical) associated with the coronavirus.”
- “CBD May Play a Role in Helping Lung Symptoms”
“Cannabis contains several cannabinoids that have anti-inflammatory properties. Specifically, CBD is the most likely possibility for treating COVID-19 related lung inflammation.”
- “Using CBD to Alleviate Inflammation ”
“CBD is available without a prescription. It is already being used to treat serious medical problems . . . where *pain and/or inflammation are a major factor*. This is why CBD has piqued the interest of the medical world as a significant aid to reduce inflammation for the COVID-19 lung inflammation.
Acute respiratory distress syndrome (ARDS) is a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs, rapid breathing and the inability to sustain adequate oxygen levels to the body and brain. Shortness of breath or difficulty breathing are some of the early signs of COVID-19 . . .”
- “CBD and Covid-19 / Why Do Researchers Believe CBD Can Help?”
“Firstly, the research performed to date has shown that CBD can reduce a number of pro-inflammatory cytokines (numerous different types of substances, such as interferon, interleukin, and growth factors, which are secreted by certain cells of the immune system and have an effect on other cells) including IL-6, the one reduced by other drugs being studied for COVID-19. CBD was also shown to reduce interleukin (IL)-2, IL-1 and , interferon gamma, inducible protein-10, monocyte chemoattractant protein-1, macrophage inflammatory protein-1 , and tumor necrosis factor- – all of which are associated with the pathology of severe cases of COVID-19. In addition to reducms ghe eltot-inflamunory cytoin t, CBit

- “Less need for ventilators”
 - “With control over cytokine storms, lungs may heal at an exceptional rate and the number of people going into ventilators may also reduce significantly.”
- “Final Thoughts”
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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) referenced 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. For COVID-19, no such study is currently known to exist for the product identified above. Thus, any coronavirus-related prevention or treatment claims regarding such product are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. 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,

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