

**WARNING LETTER**

**For Our Vets LLC dba Patriot Supreme**

**MARCS-CMS 611043 – OCTOBER 16, 2020**

**Product:**

Drugs

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**Issuing Office:**

Center for Drug Evaluation and Research | CDER

United States

🏛️ Federal Trade Commission (Federal Trade Commission)

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**WARNING LETTER**

Date: October 16, 2020

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 <https://patriotsupreme.com> on October 5, 2020, and October 8, 2020, respectively. We also reviewed your social media websites at <https://www.facebook.com/patriotsupreme/> and <https://www.instagram.com/patriotsupreme/>, where you direct consumers to your website, <https://patriotsupreme.com>, to purchase your products. The FDA has observed that your website offers CBD products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>[1]</sup> in people. Based on our review, 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 sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.<sup>[2]</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>[3]</sup> 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:

- **“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 $\alpha$  and  $\beta$ , interferon gamma, inducible protein-10, monocyte chemoattractant protein-1, macrophage inflammatory protein-1 $\alpha$ , and tumor necrosis factor- $\alpha$  – all of which are associated with the pathology of severe cases of COVID-19. In addition to reducing these pro-inflammatory cytokines, CBD has also been shown to increase the production of interferons, a type of signaling protein that activates immune cells and prevents viruses from replicating.”
- <https://patriotsupreme.com/cbd-covid-19-lung-inflammation>]

- **“CBD INFLAMMATION COVID / A PLAUSIBLE METHOD?”**

- **“CBD Inflammation Covid”**

- “It has been determined that CBD may be beneficial in curing inflammation of the lungs caused by covid-19 (CBD inflammation covid). In this article we shall discuss it in detail.”

- **“How is CBD inflammation Covid a plausible method?”**

- “ARDS, which is ‘Acute Respiratory Distress Syndrome’ is one of the severe symptoms of the covid-19. In this syndrome, the corona virus causes the inflammation of the lungs, which in turn may lead to severe difficulty in breathing, pain or perhaps even coughing.”
  - **“How is inflammation cured?”**
    - “Talking about CBD inflammation Covid, Coronavirus causes cytokine production in the body which is an active agent for inflammation. CBD may play a role in reducing the rate of cytokine production, which will give the lungs of a patient enough time to recover, from the damages. As a result, the oxygen levels in the body will spike up again to ideal levels and the lung condition will get back to normal.”
  - **“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”**
    - “So, if you are looking to get any help related to CBD inflammation Covid, you can visit PatriotSupreme.com to get all your queries answered.” [from your website <https://patriotsupreme.com/cbd-inflammation-covid-a-plausible-method/> and <https://patriotsupreme.com/tag/cbd-inflammation-covid/>]
- “Today we talk about Covid-19 and CBD!

#### CBD Inflammation Covid

With the corona virus outbreak, researchers have been testing various drugs and methods that can help us cope with the virus and cure its symptoms. One such method is CBD, that is one of the extracts from cannabis. It has been determined that CBD may be beneficial in curing inflammation of the lungs caused by covid-19 (CBD inflammation covid).” [Your post is followed or accompanied by a picture of your CBD product, from a September 10, 2020, post on your Facebook and Instagram pages <https://www.facebook.com/patriotsupreme/> and <https://www.instagram.com/patriotsupreme/>, respectively.]

- ““What we are seeing here is, what we feel, a direct effect from what’s happening with the coronavirus. Our customers are suggesting that using CBD is helping to ease the symptoms of COVID-19. We are seeing people literally flocking to purchase high quality CBD for

the potential relief it gives,' states Justin Elenburg, Patriot Supreme's CEO and Founder." [Your post is followed by a picture of your CBD product, from a July 23, 2020, post on your Facebook page <https://www.facebook.com/patriotsupreme/>]


You should take immediate action to correct the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. 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 misleadingly representing your products as safe and effective 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](mailto:COVID-19-Task-Force-CDER@fda.hhs.gov) (<mailto: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 to cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, 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) 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](mailto:COVID-19-Task-Force-CDER@fda.hhs.gov) (<mailto: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](mailto: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,

/S/

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

Sincerely,

/S/

Serena Viswanathan  
Acting Associate Director  
Division of Advertising Practices  
Federal Trade Commission

[1] As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

[2] Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (<https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>)). The declaration has been renewed for an additional 90 days twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx> (<https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx>)).

[3] President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/> (<https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>)).

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