



WARNING LETTER

RE: 648077

Date: January 10, 2023

TO: Info@purecraftcbd.com – Jason Navarrete
PureCraft LLC
237 A St., PMB 70555
San Diego, CA 92101-4003

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://purecraftcbd.com/> on December 14, 2022 and January 6, 2023, respectively. We also reviewed your social media websites at <https://www.facebook.com/purecraftcbd> and <https://www.instagram.com/purecraftcbd/>, where you direct consumers to your website, <https://purecraftcbd.com/>, to purchase your products. The FDA has observed that your website offers cannabidiol (CBD) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ 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.² In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.³ 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

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, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

³ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your website 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:

- From the July 1, 2022 blog post titled “CBD & COVID-19: NEW RESEARCH, NEW FINDINGS [JUNE 2022]” on your webpage <https://purecraftcbd.com/blogs/news/cbd-and-covid-new-research-and-findings>:

“* *This post covers research that was published since our July 6, 2021 post* Reviewing [sic] Research on CBD for COVID-19 Therapy (which we suggest reading if you need an overview of how COVID-19 works in the body). To the best of our knowledge, the studies referenced in this article all used therapeutic-grade CBD that was purer or contained higher concentrations of cannabidiol than what’s on the market for public consumption. . . .

COVID Prevention & CBD . . .

Early results show that therapeutic doses of CBD do have a protective effect against COVID. . . . According to the National Institute of Health’s COVID-19 Research initiative:(1)

- CBD is the only cannabinoid that exhibited a protective quality. When paired with THC, the preventive effect diminished.
- People who take CBD-based medications (like Epidiolex) reported fewer COVID diagnosis than other populations.
- More research in humans is needed but CBD be [sic] part of the COVID prevention protocol — along with (not in place of) vaccination, masking, and social distancing.

CBD vs SARS-CoV-2 . . .

[T]he CBD does start to attach the virus very soon after the virus is introduced into your system.

This anti-SARS-CoV-2 assault makes it so that the virus can’t spread or further develop. Basically, the CBD inhibits the virus’s capacity to replicate itself or change host cells in your body. CBD blocks the viral reproduction by activating the infected cell’s stress response, which makes it create virus-killing proteins. . . .

CBD For COVID Symptoms

According to a March 2022 article in *Frontiers in Immunology*, CBD has been shown to decrease the severity of COVID. It’s primarily doing this by counteracting the body’s inflammatory response to the SARS-CoV-2 virus. . . .

Will cannabis or cannabinoids protect you from COVID?

Current research indicates that therapeutic doses of CBD may provide some protection from the SARS-CoV-2 virus. The purer or higher concentration the CBD, the more effective this intervention seems to be.”

- From the July 6, 2021 blog post titled “REVIEWING RESEARCH ON CBD FOR COVID-19 THERAPY” on your webpage <https://purecraftcbd.com/blogs/news/reviewing-research-on-cbd-for-covid-19-therapy>:

“Interest from the medical community about the usefulness of CBD in battling the COVID-19 virus isn’t completely out of left field...

[S]everal studies have emerged that are expected to progress our understanding of CBD's therapeutic potential for COVID patients. . . .

Hypothesis #1: CBD May Be An Option For COVID-19 Prevention

Since contracting COVID-19 puts some at a higher risk of death and long-term effects, one study is focusing on the use of CBD for infection prevention. . . . They cultivated 800 new strains of Cannabis sativa L. Of these, 13 high-CBD strains were selected, which decreased the presence of ACE2 in 3D models of human respiratory and intestinal tissues. . . .

Hypothesis #2: CBD May Reduce Inflammation Related To COVID-19

Can CBD help combat inflammation from a cytokine storm caused by COVID-19?

Two studies using in vitro lung cell cultures have completed early stages of answering this question.(5, 6)

In the first study, the lung cultures were infected with the SARS-CoV-2 virus. . . . The high-CBD formula reduced inflammation considerably, whereas the high-THC formula had little anti-inflammatory effect. The high-CBD formula reduced the specific cytokines responsible for the COVID-19-induced cytokine storm. . . .

In the second study, CBD was found to halt viral replication. The researchers also concluded that CBD was more effective than THC. In fact, of the cannabinoids that were tested, CBD was found to be the only cannabinoid that produced this outcome. This study has not yet been peer reviewed, but is a promising line of investigation.

Hypothesis #3: CBD May Be Helpful In The Treatment Of COVID-19 . . .

In another study performed on mice experiencing respiratory distress due to an artificially-induced cytokine storm, CBD reversed the negative effects and restored homeostasis.(8) This suggests that CBD may support recovery from the virus.

Current Findings Spark More Questions

With the facts on the known relationship between CBD and COVID-19 laid out, it's clear that further research and incoming results will reveal CBD's role and effectiveness as a therapeutic tool. For now, the medical community and the world have earmarked these findings as a pivotal and encouraging chapter amidst the rollercoaster plot of the COVID-19 pandemic."

- From a July 10, 2022 post on your Instagram webpage <https://www.instagram.com/p/Cf2HNUtJLtQ/>, and a July 8, 2022 post on your Facebook webpage <https://www.facebook.com/purecraftcbd>, which links to your July 1, 2022 blog post:

"CBD & COVID-19: NEW RESEARCH, NEW FINDINGS [JUNE 2022] . . .

So, keep reading for the latest coronavirus-CBD research on:

- Whether preventing COVID with CBD is possible
- How CBD interacts with the SARS-CoV-2 (the virus that causes COVID)
- The COVID and cannabinoid receptors link
- Potential CBD benefits for COVID symptoms
- If CBD can curb COVID vaccination side effects"

- From a July 6, 2021 post on your Facebook webpage <https://www.facebook.com/purecraftcbd>, which links to your July 6, 2021 blog post:

“REVIEWING RESEARCH ON CBD FOR COVID-19 THERAPY. . . CBD is being examined as a possible therapy for COVID-19”

You should take immediate action to address this matter. 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** describing the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations 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 actions to address the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. 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 may be detained or refused 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.

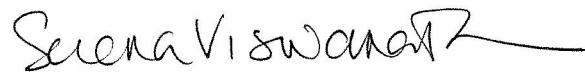
FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, 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 products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease and desist 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. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to \$50,120 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Serena Viswanathan, Associate Director of the FTC's Division of Advertising Practices, at sviswanathan@ftc.gov certifying that

you have ceased making unsubstantiated claims for the product identified above. If you have any questions regarding compliance with the FTC Act, please contact Ms. Viswanathan at 202-326-3244.

Sincerely,

CAPT Tina Smith
Acting Director
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

A handwritten signature in black ink that reads "Serena Viswanathan" followed by a stylized flourish.

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission