



WARNING LETTER

RE: 647390

Date: January 5, 2023

TO: info@pharmacanna.us Johnny H. Meier
PharmaCanna
2615 State Road 7 Suite B530
Wellington, FL 33414

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://www.pharmacanna.com> on November 30, 2022, and January 3, 2023, respectively. We also reviewed your Facebook and YouTube social media websites at <https://www.facebook.com/pharmacanna> and <https://www.youtube.com/@pharmacannacbdbypharmacist543>, where you direct consumers to your website, <https://www.pharmacanna.com> to purchase your cannabinoid products, including the CBDDefense 2000 product. The FDA has observed that your website offers the CBDDefense 2000 product for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. Based on our review, this product is an unapproved new drug 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, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product 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,

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/>.

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 a product that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take 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 and social media 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:

- “CBDefense 2000 - Virus Protective Formula . . . This revolutionary virus fighting product contains the two cannabinoids, CBDA & CBGA, that has been shown through a published study to keep covid from infecting human cells. These two acidic hemp molecules assist in blocking the ability of the virus to attach to human cells.” [From your product webpage <https://www.pharmacanna.com/products/cbdefense-2000>]
- “COVID prevention with CBD? Canada study shows it's possible. Might be time to start a daily dose of PharmaCanna's all-natural pharmaceutical grade CBD products.... USE CODE: COV19” [from a May 15, 2020, post on your Facebook social media webpage <https://www.facebook.com/pharmacanna>]
- “ATTN: PHARMACY OWNERS RE: COVID
If you are dealing with patients looking for covid vaccines, covid tests, and anything related to anti-covid, then PharmaCanna may have the revolutionary product for your patients. We introduce CBDefense 2000 with 1000mg of CBD/CBDA and 1000mg of CBG/CBGA. . . . From the recently published study. . . : ‘Two cannabinoids with the highest affinities for the spike protein, cannabidiolic acid (CBDA) and cannabigerolic acid (CBGA), were confirmed to block infection of human epithelial cells by a pseudovirus expressing the spike protein. More importantly, both CBDA and CBGA block infection of the original live SARS-CoV-2 virus and variants of concern, including the B.1.1.7 and B.1.351.’” [from a February 3, 2022, post on your Facebook social media webpage <https://www.facebook.com/pharmacanna>]
- “Our CBDefense 2000, anti-covid formula, is Now Available. . . Use Code: DEFENSE” [from a March 9, 2022, post on your Facebook social media webpage <https://www.facebook.com/pharmacanna>]
- “[S]o we’ve announced recently about our CBDefense which is the that [sic] contains the two active ingredients that’s in that product is the acidic version of cbd and cbg which would be cbda and cbga and those are two ingredients according to a published study that came out of Oregon state university that has shown that those two cannabinoids are attaching to the protein spikes or I should say the spike proteins of covid so basically not allowing covid to infect human cells so we’re super excited.” [From a March 10, 2022, video titled “PharmaCanna Phamily Update #3 - FREE CBD for a Year,” posted on your YouTube social media website <https://www.youtube.com/watch?v=UPMOp8zlljU>]
- “[F]or those of you out there that are interested in uh just boosting your covid fighting uh properties in your body uh we’ll be doing CBDefense at 30 percent off using the code defense so [it will] be DEFENSE.” [From a March 10, 2022, video titled “PharmaCanna Phamily Update #3 - FREE CBD for a Year,” posted on your YouTube social media website <https://www.youtube.com/watch?v=UPMOp8zlljU>]

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.

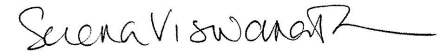
FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, 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 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 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 \$46,517 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,



Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission