



WARNING LETTER

Date: April 16, 2020

TO: support@canabd.com – Nova Botanix LTD DBA CanaBD
International House
24 Holborn Viaduct
London
EC1A 2BN,
United Kingdom

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 at <https://canabd.com> on April 10, 2020, and April 14, 2020, respectively. We also reviewed your social media websites at <https://twitter.com/ShopCanaBD>, where you direct consumers to your website, <https://canabd.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-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, the President declared 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,

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>).

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/>).

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 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-19⁴ include:

- “5 ways CBD can Boost Your Immune System during the virus” [from your website <https://canabd.com/blog/5-ways-cbd-can-boost-your-immune-system-during-the-coronavirus/>]
- “It’s never too late to start taking really good care of yourself during this unfortunate virus we are facing [*sic*] with. Whether or not you are choosing to self-quarantine so as to minimize the risk and spread of the virus, the time is now to start ramping up your immune system. Keeping your immune system in good working order is key to helping curb the stay healthy [*sic*]. [from your website <https://canabd.com/blog/5-ways-cbd-can-boost-your-immune-system-during-the-coronavirus/>]
- Especially those of us with autoimmune disease, taking CBD (in various forms) can be especially good during this time.” [from your website <https://canabd.com/blog/5-ways-cbd-can-boost-your-immune-system-during-the-coronavirus/>]
- “Here are several ways CBD can help you with your immune system in the current crisis . . . CBD Helps Fight Inflammation . . . In short, CBD can calm a hyperactive immune system, and strengthen a compromised one. And if you find yourself with a chronic cough, that’s your bronchial pathways being inflamed. Yes, CBD can help with that, too.” [from your website <https://canabd.com/blog/5-ways-cbd-can-boost-your-immune-system-during-the-coronavirus/>]
- “With the global virus, wreaking havoc across the globe, finding relief from an incurable virus is just within reach in the form of CBD oil.” [from your website <https://canabd.com/blog/how-to-handle-anxiety-and-stress-during-the-coronavirus-and-boost-your-immune-system/>]
- “CBD oil may help to prevent getting infected by strengthening your immune system. It has also been proven to offer relief to some of the symptoms.” [from your website <https://canabd.com/blog/how-to-handle-anxiety-and-stress-during-the-coronavirus-and-boost-your-immune-system/>]
- “By using CBD oil, you can keep inflammation at bay, retain a healthy or even higher than average white blood cell count, stay calm and relaxed (which is best for a strong immune system), and prevent catching a virus or infection beforehand.” [from your website <https://canabd.com/blog/how-to-handle-anxiety-and-stress-during-the-coronavirus-and-boost-your-immune-system/>]
- “In the wake of the current epidemic, it is now more important than ever to keep your immune system as healthy as can be . . . Here are 5 key ways to strengthen your immune system during the outbreak . . . Take supplements such as CBD . . .” [from your website <https://canabd.com/blog/5-ways-to-strengthen-your-immune-system-during-the-coronavirus-epidemic/>]

⁴ While your webpage does not currently specifically state “COVID-19” or “coronavirus,” we noticed that as of 3/31/2020, it had made direct reference to these terms. Further, your existing statements still clearly refer to COVID-19.

- “In the wake of the current #Coronavirus epidemic, known as #COVID19, it is now more important than ever to keep your immune system as healthy as it can be. #HealthyLiving” [from a March 16 post on social media website <https://twitter.com/ShopCanaBD>]

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** 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.

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 for products that you advertise, market,

sell, or otherwise promote or make available in the United States. 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 A. Quaresima
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission