



WARNING LETTER

RE: 641241

Date: November 1, 2022

TO: sales@ahdist.com –Lee Vantine, III
Alternative Health Distribution LLC (d/b/a CannaAid)
106 N. Commercial Dr.
Ste. B
 Mooresville, NC 28115

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.cannaaidshop.com> on October 5, 2022, and October 7, 2022, respectively. The FDA has observed that your website offers cannabinoid products, including 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

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/>.

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 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 your webpage <https://www.cannaaidshop.com/how-does-cbd-help-to-fight-against-covid-19/>:

- **“HOW DOES CBD HELP TO FIGHT AGAINST COVID-19? . . .**

Recent analyses from numerous preliminary in vitro and animal studies have shown that cannabinoids in hemp, specifically **CBD**, can significantly reduce COVID-19’s ability to infect new cells – limiting inflammation in the lungs and possibly improving a patients’ quality of life during severe COVID-19 infection.”

- **“Cannabis Compounds Prevent Coronavirus – Study of Oregon State University . . .**

The research, led by Richard van Breeman, confirmed that CBGa and **CBDa** cannabinoids needed to be ingested in edible forms to perform the desired effect and that cannabinoids effectively blocked COVID-19 infection even in normal cells, not just immune system cells. . . .”

- **“CBD Blocks the Replication of Sars-CoV2 in the Lungs . . .**

Research out of medical and dental colleges in Georgia has shown that the cannabinoid compound CBD, and possibly a few of its variants, are effective at blocking and even reversing the replication of COVID-19 in cells deep within the respiratory tract. . . .”

- **“CBD in the Fight Against COVID-19 – More Research . . .**

Here at **CannaAid**, we provide the best in what’s wellness. If you’re interested in trying CBD to mitigate the flu-like symptoms, check our online selection to find what best fits your needs — our **Immune Plus tincture** is a 4,200 mg. proprietary wellness blend made with CBGa and CBDa that just may do the trick!”

- From your webpage <https://www.cannaaidshop.com/product-category/cbda/>:

- **“Can CBDa Fight Against Covid Variants?**

Preliminary research performed by Oregon State University and medical research colleges in Georgia has found that CBDa may be highly effective in fighting against COVID variants. Studies would suggest that raw, unheated CBDa compounds effectively block COVID spike proteins and keep the virus from entering healthy cells.

The Georgia study concluded that the use of CBD, the result of heating CBDa, may also be effective at increasing oxygen levels and reducing the adverse respiratory symptoms of acute COVID infections. It does so by affecting apelin and ACE2 receptor function responsible for regulating and stabilizing blood pressure and promoting healthy blood flow.

Both studies suggest that CBDa would be beneficial as a treatment or even a deterrent to COVID infections only in its raw forms. Smoking CBDa or CBD products would not produce the same results as taking sublingual oil drops or consuming edibles that have been made using CBDa.

Although more research and human trials are needed to conclusively conclude the benefits of CBDa oil on COVID, consumers should monitor new research as it becomes available.”

Your website <https://www.cannaaidshop.com/blog/> also includes various “Category” tags, including “COVID-19,” that link to the blog post “How Does CBD Help to Fight Against COVID-19?.” The blog post has links to CannaAid products available for purchase. The “Category” tags and links in the blog post further establish your products’ intended uses.

You should take immediate action to 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.

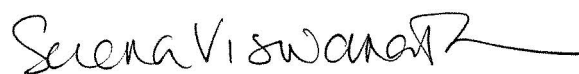
Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov

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 \$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 Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Carolyn Becker
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