



**WARNING LETTER**

**RE: 627042**

Date: March 28, 2022

TO: support@tanasi.com – David B. Laroche  
GreenWay Herbal Products, LLC (d/b/a Tanasi)  
509 W. College Street  
Murfreesboro, TN 37130

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://tanasi.com/> on February 18, 2022, and March 22, 2022, respectively. We also reviewed your social media website at <https://www.facebook.com/tanasibotanicals/>, where you direct consumers to your website, <https://tanasi.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-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, there was a Presidential declaration of 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 any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

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

<sup>2</sup> 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>.

<sup>3</sup> 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/>.

Some examples of the claims on your website and social media 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:

- **“Does CBD Defend Against COVID? . . .**

At the University Of Chicago, a team led by Marsha Rosner discovered that CBD curbs COVID-19 cell infections in lab experiments. By using small doses of CBD (approximately what patients would receive in an oral drug), the team discovered that CBD didn’t stop the spread of COVID-19 in test tubes. Rather, it started acting as soon as the virus entered healthy cells, blocking it from making copies of itself, thanks to interferon (an inflammatory protein).

### **CBD, COVID and Epilepsy**

When the team studied adults with severe epilepsy, they realized that individuals on Epidiolex, a CBD-based medication, showed lower COVID-19 infection rates. . . . Another team from Oregon State University, led by Richard van Breeman, recently shared a report in the Journal of Natural Products. It stated that high doses of CBDA and CBG actually prevent coronavirus from breaking into cells.” [from the January 30, 2022 blog post on your webpage <https://tanasi.com/blog/does-cbd-defend-against-covid/>]

- **“3 CBDA Studies To Know Right Now . . .**

### **3. COVID**

A lab study in the Journal of Nature Products shows that cannabis compounds inhibit the COVID 19 virus from easily penetrating healthy human cells. Specifically, CBDA, and CBGA possess the ability to combat coronavirus. . . .

Even better? Researchers examined the compounds’ impact against the COVID’s alpha and beta variants in a laboratory. And they proved effective. . . . lead researcher Richard van Breemen said that these compounds could prevent and even treat SARS-CoV-2 infections. And he suggested taking them orally, thanks to their extended history of safe application in humans. . . .

You can enjoy the better-together benefits of CBDa and CBD in Tanasi’s range of full-spectrum hemp extracts.” [from the January 27, 2022 blog post on your webpage <https://tanasi.com/blog/3-cbda-studies-to-know-right-now/>]

- **“Cannabis and Covid: New Hope For Preventing Infections and Speeding Recovery . . .**

### **Cannabis and COVID: Preventing Infection**

In the new study, author Richard van Breemen reveals that cannabinoids can help prevent a Sars-Cov-2 infection., [sic] How does that work? It seems that they block Covid-19 from entering your healthy cells. And, while all cannabinoids may be useful, two offer the most protection: CBGA and CBDA. (Also known as cannabigerolic acid and cannabidiolic acid.)

Now, if you’re familiar with our Tanasi products, you probably know that these two compounds have many potential therapeutic properties. But now, with this study, we’ve learned that they may fight COVID by binding to the virus’ spike proteins. In turn, this makes it harder for Covid to force its way into your body’s healthy cells, possibly preventing infection.

Already, that’s pretty exciting news. And it keeps getting better, because the cannabinoids seem to

work against several Covid variants.” . . .

### **Cannabis and COVID: How Cannabinoids Fuel Recovery from Infection**

After announcing his new findings, van Breemen also said that cannabinoids ‘have the potential to prevent as well as treat infection by SARS-CoV-2.’ [from the January 14, 2022 blog post on your webpage <https://tanasi.com/blog/cannabis-and-covid-how-cannabinoids-could-prevent-infection/>]

- **“The Latest Information On CBD Covid Implications**

As the COVID-19 outbreak affects countries across the globe, we’re all hoping and waiting for new disease treatments. Thankfully, the latest studies and research shows cannabis’ potential to treat coronavirus-related symptoms. . . .

#### **2. CBD May Prevent a Cytokine Storm, and stop the Havoc it Wreaks in the Body**

Early results of an ongoing study published in HealthEuropa suggest that a specific combination of cannabinoids and terpenes appears to be twice as effective as the corticosteroid dexamethasone at lowering COVID-19 inflammation. . . .

#### **3. Ongoing Research Is Examining The Full Effects Of The Virus And How CBD Can Mitigate Long-Term Damage**

Research from the Rabin Medical Center holds another clue. Their findings suggest that 8 out of the 11 patients receiving cannabis treatments program saw improvements in virus-related infections.

#### **CBD Covid Treatment: Can Cannabis Help?**

Many researchers believe that CBD might help fight COVID-19. It’s classified as a contagious respiratory illness that causes fatigue, breathing problems, and fever. For some people, it’s proven to be fatal. So could CBD and cannabis offer assistance in the ongoing fight against Covid-19? . . .

CBD shows significant potential in the fight against Covid-19, mainly due to its significant anti-inflammatory properties. The latest research shows that cannabis and CBD might drastically improve Covid-19 symptoms. It could do so by lowering cytokine storms and protecting lung tissue from inflammation.” [from the October 3, 2021 blog post on your webpage <https://tanasi.com/blog/cbd-covid-treatment-option/>]

- **“5 Things You Need to Know About THCV . . .**

#### **Anti-Inflammatory Effects . . .**

More recently, THCV was highlighted in connection with cannabinoids’ anti-inflammatory impact on Covid-19- lung inflammation. The research, published in the Nature journal Scientific Reports, suggests that cannabigerol (CBG) and low-dose THCV reduces inflammation in Covid patients’ lung cells. But at this time, there are no approved cannabinoid COVID treatments. . . .

3. Most cannabis plants produce low concentrations of THCV. Certain strains can offer higher concentrations. . . . your best bet may be from the entourage effect associated with our full-spectrum CBD products.” [from the June 4, 2021 blog post on your webpage <https://tanasi.com/blog/5-things-you-need-to-know-about-thcv/>]

- “The Effects of Hemp on Inflammation . . .

The Medical College of Georgia and Dental College of Georgia recently conducted a relevant study. It showed that CBD could help reduce cytokine storms . . . and unrestricted lung inflammation in patients with Covid-19.” [from the November 17, 2020 blog post on your webpage <https://tanasi.com/blog/effects-of-hemp-on-inflammation/>]

- “What Is Dexamethasone?

Dexamethasone has recently emerged as the best drug to treat severe life-threatening cases of Coronavirus Disease 2019 (COVID-19). . . . Dexamethasone is a synthetic corticosteroid that is used as an anti-inflammatory or immunosuppressant agent. . . .

### What Are the Anti-Inflammatory Effects of Cannabinoids? . . .

GreenWay Tanasi, LLC, and its brand, Tanasi, a subsidiary of GreenWay Herbal Products, LLC, sells a number of cannabidiol (CBD) products that feature a unique patent-pending blend of cannabinoids (CBD and Cannabidiolic-acid (CBDA)) extracted from *Cannabis Sativa L.* hemp plants. GreenWay Herbal Products, LLC developed this patent-pending technology with a university partner, which has demonstrated that cannabinoids are natural anti-inflammatory agents that can suppress cytokine storms. In direct comparison studies, the unique formulation of cannabinoids used in the Tanasi CBD product line was as effective as dexamethasone in reducing cytokine storms. Thus [sic] it is not surprising that customers using the Tanasi CBD/CBDA products report that they are very effective at reducing a number of inflammatory conditions. See the customer reviews at [www.tanasi.com](http://www.tanasi.com). Tanasi is not recommending using its CBD/CBDA patent-pending formula as a treatment for COVID-19.” [from the July 2, 2020 blog post on your webpage <https://tanasi.com/blog/what-is-dexamethasone/>]

- “In the new study, author Richard van Breemen reveals that cannabinoids can help prevent a Sars-Cov-2 infection.

It seems that they block Covid-19 from entering your healthy cells. And, while all cannabinoids may be useful, two offer the most protection: CBGA and CBDA. . . .

Cannabis and Covid | CBDa prevents Covid-19 infection | Tanasi CBD with CBDa” [from the January 18, 2022 post on your Facebook webpage at <https://www.facebook.com/tanasibotanicals/>]

- “It does matter to know. . . TANASI.COM  
CBD Covid Relief | Cannabis Treatment for COVID 19 . . .” [from the October 8, 2021 post on your Facebook webpage at <https://www.facebook.com/tanasibotanicals/>]

You should take immediate action to address 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 address these 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 your 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 products 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)

**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 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, via electronic mail at [rcleland@ftc.gov](mailto: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,

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

Sincerely,

Serena Viswanathan  
Associate Director  
Division of Advertising Practices  
Federal Trade Commission