



## **WARNING LETTER**

Date: February 18, 2021

TO: [b4bcorpUSA@gmail.com](mailto:b4bcorpUSA@gmail.com) – B4B Corp.  
40 Remsen Ave, Brooklyn, NY 11212

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.b4bcorp.com> on January 25, 2021 and January 29, 2021, respectively. We also reviewed your social media website at <https://www.twitter.com/b4bcorpUSA>, where you direct consumers to your website, <https://www.b4bcorp.com>, to purchase your products. The FDA has observed that your website <https://www.b4bcorp.com> offers the product Earth Tea Extra Strength for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>1</sup> 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.<sup>2</sup> In addition, on March 13, 2020, the President declared 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 a

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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 Alex M Azar, Determination that a Public Health Emergency Exists. January 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). The declaration has been renewed for an additional 90 days several times. The most recent renewal went into effect on January 21, 2021. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. January 7, 2021. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-07Jan2021.aspx>).

<sup>3</sup> President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Mar. 13, 2020. (Accessible at <https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak>).

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 that establish the intended use of your product and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

- “Earth Tea works fast so it can eliminate quarantine time. With those simple steps we can move to end the Pandemic fast. While vaccines gets distributed we are clearing the sick and needy.” [from a December 18, 2020 post titled “Covid19 Pandemic Plan” on your website <https://www.b4bcorp.com/covid19-pandemic-plan>]
- “You do not need to take this treatments continuously for Virus Issues . . . Earth Tea Extra Strength natural antibiotics will works on virus . . . You’ll be back to normal within 24-48hrs. Loss of taste and smell will resume there after or immediately.” [from your website <https://www.b4bcorp.com/product/earth-tea-extra-strength>]
- “Health Benefits . . . 3. COVID19 . . . So Far we have seen other benefits of Earth Tea. Even though it was specifically developed to fight Covid19 . . . Earth Tea is confirmed to stop coughing from Covid-19 100% . . .” [from your website <https://www.b4bcorp.com/health-benefits>]
- “SO basically Earth Tea came to life from our manager trying to cure himself back in march when there was no treatments available, he cured himself successfully then realized if it helped him it can help others. As someone who is considered a patient not a doctor or scientist he had no idea what to expect from the medical world. As he self checked himself min by min he tweaked Earth Tea to a set formula that worked against COVID19.” [from your websites <https://www.b4bcorp.com/earth-tea-extra-strength> and <https://www.b4bcorp.com/how-earth-tea-started-and-lessons-learned>]
- “We know Earth Tea LOVES your #lungs which is why its so powerfull against #COVID19 so as this volunteer makes progress we are planning to uplift Earth Tea to be #1 choice to get people off the #ventilator not only for covid19 but in general.” [from a December 13, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpusa/>]
- In a November 27, 2020 post on your Twitter website at <http://www.twitter.com/b4bcorpusa>, you Quote Tweet another user’s post that says: “Covid19 Stopper How it came to Life and lessons learned #COVID19 #coronavirus #naturaltreatment . . .” This post contains an image of your Earth Tea Extra Strength product label, which says, “100% Natural COVID-19 SMOKING COUGH STOPPER.”
- “We would suggest to anyone out there facing #Covid19 issues. #TryEarthTea you do not have to be a #longhaulers Earth Tea can fight for you.” [from a November 5, 2020 post on your Twitter website at <https://twitter.com/b4bcorpusa/>]
- In a November 3, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpusa/>, you post an image of your Earth Tea Extra Strength product label, which says, “100% Natural COVID-19 SMOKING COUGH STOPPER,” and you state, “Got #Covid19 Call the Stopper Hotline . . .”

- “Well we are sitting on the greatest weapon of all against SARS-Cov-2 waiting and waiting and waiting and waiting for the Gov to say Attack!!!! The Mr Furious (Earth Tea) can go to work...” [from an October 30, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpUSA/>]
- “When it comes to #COVID19 Earth Tea stops the prolong issues. Loss of taste and smell etc comes back fast.” [from an October 30, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpUSA/>]
- “Earth Tea the #1 #Covid19 fighter!!!!” [from an October 29, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpUSA/>]
- “Covid19... Has met its match.. Earth Tea.. Our official formula now 100% guarantee to get rid of #Covid19.. If you would love to try Earth Tea for Free as prevention send us a text . . .” [from an October 19, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpUSA/>]
- “To this day.. Earth Tea is the most effective Treatment against#COVID19 as Treatment and Prevention.. All Natural.. #TRYEARTHTEA Get well in 24-48 Hours..72 Hours MAX..” [from an October 9, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpUSA/>]
- “EARTH TEA PROVEN NATURAL TREATMENT FOR COVID-19.. BY B4B CORP WORK IN MINUTES GET U FEELING NORMAL WITHIN 24 HRS.. EARTHTEA.US #COVID19 #CORONAVIRUS.” [from an August 4, 2020 post on your Twitter website at <https://www.twitter.com/b4bcorpUSA/>]

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-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@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 immediately address this matter 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 such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

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-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@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. 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 \$43,792 per violation. 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) 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,

**William A.  
Correll Jr -S**

Digitally signed by William A.  
Correll Jr -S  
Date: 2021.02.17 17:28:42  
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William A. Correll  
Director  
Office of Compliance  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

Sincerely,

**SERENA  
VISWANATHAN**

Digitally signed by SERENA  
VISWANATHAN  
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Serena Viswanathan  
Associate Director  
Division of Advertising Practices  
Federal Trade Commission