



WARNING LETTER

Date: February 18, 2021

TO: <u>b4bcorpusa@gmail.com</u> – 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-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.

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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]
- "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 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 . . ."

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.

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