



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION



## **WARNING LETTER**

Date: May 7, 2020

TO: [patriothempco@gmail.com](mailto:patriothempco@gmail.com) – Mr. Doug Pineda, AgroTerra, Ltd. DBA Patriot Hemp Company  
209 McConnell Ct.  
Lyons, CO 80540

CC: [regulatory-inquiries@amazon.com](mailto:regulatory-inquiries@amazon.com) – Amazon Associates Program

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 [www.patriotcbd.org](http://www.patriotcbd.org) on May 1, 2020, and May 5, 2020, respectively. 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-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).

In addition, FDA observed that you participate in the Amazon Associates program. As an Amazon associate, you earn commissions by promoting the sale of the products silver, iodine, medicinal mushroom, vitamin C, selenium, zinc, vitamin D3, astragalus, and elderberry (hereinafter referred to as “Amazon associate products”)<sup>2</sup> with claims on your website representing or implying that the products can mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Based on our review, these claims cause the Amazon associate products purchased through links on your website to be unapproved new drugs under section 505(a) of the 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. Causing 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). In addition, it is a prohibited act under section 301(k) of the FD&C Act, 21 U.S.C. § 331(k), to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

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>3</sup> In addition, on March 13, 2020, the President declared a

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

<sup>2</sup> Specifically, your website contains links that direct consumers to the Amazon.com website to purchase the Amazon products you promote. As described in the Amazon Associates Program Fee Statement (<https://affiliate-program.amazon.com/help/operating/policies/#Associates Program Fee Statement>), accessed April 22, 2020), Amazon calculates your commission or “fee” by using your website’s Amazon associate ID to track sales to consumers who are redirected to Amazon.com by clicking one of the links on your website.

<sup>3</sup> Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. Jan.

national emergency in response to COVID-19.<sup>4</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 such 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 CBD products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “The best natural defence and treatment of Coronavirus (and viruses in general) is a strong immune system. . . Bolster your defences, so when and if Coronavirus strikes, your system is ready to fight it off. . . The Number ONE KILLER Of Your Immune System . . . that is stress. When your body is chronically stressed, your immune system suffers. With the spread of this potentially deadly Coronavirus, stress will be high . . . consider CBD Oil.”
- “Many people are finding relief from anxiety, sleeplessness, and general stress by dosing up on CBD.”

Some examples of the claims on your website that establish the intended use of your Amazon associate products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “Top 9 Natural Anti-Virals For Coronavirus (COVID-19) . . . natural antiviral therapies both for treatment and prevention of viruses and specifically the coronavirus (COVID-19). . . . we have created this post to provide you with a comprehensive list of antivirals for this corona virus pandemic. . . .”
- “Colloidal silver is a potent antiviral . . . Take this as a preventative, and as a treatment for Coronavirus. Double your dose if you start to feel seek [*sic*]. . . . Links to our trusted source of Colloidal Silver for Coronavirus: [amazon associate link]”
- “Iodine . . . a potent antiviral . . . Links to our trusted source of Nascent Iodine for Coronavirus: [amazon associate link]”
- “Medicinal Mushrooms . . . We suggest taking these 3 mushrooms alongside each other in tincture form for both prevention and treatment. . . . Double if symptoms of COVID-19 begin. Links to our trusted sources of medicinal mushrooms for Coronavirus: [amazon associate links]”
- “Vitamin C has been shown to have a wide variety of beneficial effects on immune function. These effects are most pronounced before infection, and during early signs of symptoms. . . . Links to our trusted sources of Vitamin C for Coronavirus: [amazon associate links]”
- “Selenium . . . Take as prevention and treatment of COVID-19. Links to our trusted source of selenium for Coronavirus: [amazon associate link]”

31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>).

<sup>4</sup> 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/>).

- “Zinc . . . Take 15mg per day for prevention. With onset of symptoms, take 15mg 5-6 times per day as long as needed, but for a maximum of 2 weeks. Links to our trusted source of Zinc for Coronavirus: [amazon associate link]”
- “Vitamin D3 . . . Links to our trusted source of Vitamin D3 for Coronavirus: [amazon associate link]”
- “Astragalus . . . has been used in TCM and folk medicine for thousands of years. . . . Take in tea, tincture or capsule. . . . Double suggest dose on bottle with onset of COVID-19 symptoms. Links to our trusted source of Astragalus for Coronavirus: [amazon associate links]”
- “Elderberry Syrup . . . Elderberries have been used for centuries as folk medicine for flus, colds . . . Links to our trusted source of Elderberry Syrup for Coronavirus: [amazon associate link]”
- “The above antivirals are the best natural therapies we have found for the COVID-19 coronavirus.”
- The URL “[https://patriotcbd.org/blog/top-9-natural-anti-virals-for coronavirus/](https://patriotcbd.org/blog/top-9-natural-anti-virals-for-coronavirus/)”

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 and your activities as an Amazon associate do not violate the FD&C Act. 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](mailto: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](mailto: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. 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](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,

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