



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



## **WARNING LETTER**

Date: May 19, 2020

TO: [david@spicetac.com](mailto:david@spicetac.com) – SpiceTac  
5000 US Highway 17  
Fleming Island, FL 32003

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.spicetac.com](http://www.spicetac.com) on May 11, 2020 and May 18, 2020, respectively. While reviewing your website, FDA observed that you participate in the Amazon Associates program. As an Amazon associate, you earn commissions by promoting the sale of a vitamin C product (hereinafter referred to as “Amazon associate product”)<sup>1</sup> with claims on your website representing or implying that the product can mitigate, prevent, treat, diagnose, or cure COVID-19<sup>2</sup> in people. Based on our review, these claims cause the Amazon associate product purchased through links on your website to be an unapproved new drug under 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. Causing 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). 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 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,

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<sup>1</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>2</sup> As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

<sup>3</sup> Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). The declaration was renewed for another 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. April 21, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.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/>).

treat, diagnose, or cure COVID-19 in people. As described above, you promote and participate in the sale of a product for use in mitigating, preventing, treating, diagnosing, or curing COVID-19 in people, as evidenced by the claims from your website quoted below. We request that you immediately cease promoting and participating in the sale of such an unapproved and unauthorized product for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

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

- “Your Coronavirus Secret Weapon – Vitamin C . . . Vitamin C can be your secret weapon against the Coronavirus! . . . The Surgeon General and other U.S. health officials have told us that masks are not very effective against the virus . . . [t]he secret weapon that is not being talked about is Vitamin C (chemically Ascorbic Acid), the good old fashioned cold fighter...I take Vitamin C daily and just reordered some to be sure I don’t run out before Coronavirus season does!. . . Consider it cheap insurance...[image of product/Amazon associate link].” [from your website [www.spicetac.com/blog/your-coronavirus-secret-weapon-vitamin-c/](http://www.spicetac.com/blog/your-coronavirus-secret-weapon-vitamin-c/)]
- “I take Vitamin C daily and just reordered some to be sure I don’t run out before Coronavirus season does! Consider it cheap insurance. . . [image of product/Amazon associate link]” [from your website [www.spicetac.com/blog/your-coronavirus-secret-weapon-vitamin-c/](http://www.spicetac.com/blog/your-coronavirus-secret-weapon-vitamin-c/)]
- “New SpiceTac blog post. Why you should think about Vitamin C! . . . Your Coronavirus Secret Weapon – Vitamin C” [from a March 14 post on your social media site [www.facebook.com/SpiceTac/about/?ref=page\\_internal](http://www.facebook.com/SpiceTac/about/?ref=page_internal)]

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 your activities as an Amazon associate do not violate the FD&C Act. We advise you to review your websites and other labeling and promotional materials to ensure that you are not misleadingly representing your Amazon associate product as safe and effective for a COVID-19-related use for which it has not been approved by FDA and that you do not make claims that misbrand the product 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 promoting the sale of 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 Amazon associate products and activities are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

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