



WARNING LETTER

Date: December 10, 2020

TO: rio.zavarce@ithrive.health – Alirio Zavarce, iThrive.Health

CC: 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 <https://ithrive.health/> on December 2, 2020, and December 3, 2020, respectively. We also reviewed your social media website at <https://www.facebook.com/iTHRIVE.health/>. While reviewing your websites, FDA observed that you participate in the Amazon Associates program. As an Amazon associate, you earn commissions by promoting the sale of vitamins, quercetin, zinc and omega-3 products (hereinafter referred to as “Amazon associate products”)¹ with claims on your website representing or implying that the products can mitigate, prevent, treat, diagnose, or cure COVID-19² in people. Based on our review, these claims cause the Amazon associate products purchased through links on your websites to be unapproved new drugs under 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. 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.³ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.⁴ Therefore, FDA is taking urgent measures to protect

¹ 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.

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

³ 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 has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

⁴ 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/>).

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 above, you promote and participate in the sale of products for use in mitigating, preventing, treating, diagnosing, or curing COVID-19 in people, as evidenced by the claims from your websites quoted below. We request that you immediately cease promoting and participating in 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 websites 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:

- A blog entitled “How To Boost Your Immune System Naturally Against COVID-19?” in which the title is superimposed over an image of a woman kicking a giant coronavirus.
 - “In this post, you will learn how to strengthen your immune system during the COVID-19 pandemic. . . And lastly, we’ll go over what nutrients you need to support a strong and rapidly reacting immune system that can fight CODIV-19 [sic] . . .
 - Vitamin A
 - Vitamin C
 - Vitamin D
 - Quercetin + Zinc
 - Omega-3”
 - **“How to Strengthen Your Immune System Naturally During the COVID-19 Pandemic?”** which is presented above an image of individuals fighting in which one person is labeled “[y]our [i]mmune [s]ystem” and the other is labeled “COVID-19.”
 - “**Vitamin A . . . My Favorite Amazon Pick** [followed by an Amazon associates link]”
 - “**Vitamin C . . .** It is well-known that vitamin C has effective antiviral properties . . . in the presence of an infection, more vitamin C is needed to support the function of your immune response! . . . Oral vitamin C should be taken daily for a strong immune system and increased amounts should be taken during an infection. **My Favorite Amazon Picks** [followed by Amazon associates links]”
 - “**Vitamin D . . .** Vitamin D supports production of antimicrobial peptides (short chains of amino acids) in the lungs, thus making infection with the virus and development of COVID-19 symptoms less likely. Vitamin D might help to reduce the inflammatory response (cytokine storm) to infection with SARS-CoV-2. . . The potential benefit of vitamin D in COVID-19 has been reviewed, and authors recommend a multi-day loading of 10,000 IUs a day and a steady dose of 5,000 IUs a day. **My Favorite Amazon Picks** [followed by Amazon associates links]”
 - “**Quercetin + Zinc . . .** Remember that when the SARS-CoV-2 virus attaches to an ACE2 receptor, it injects it [sic] genetic material (RNA) into the cell. This RNA provides the instructions to make replicase, an enzyme that involved in the replication of this viral RNA. Zinc is an essential mineral that’s known to inhibit replicase inside the cell. That’s right. Isn’t that wonderful? You also need to help your body drive the zinc ion into the cell. How do you do what? *Like hydroxychloroquine, QUERCETIN is also known as an ionophore, meaning that it can transport zinc ions across the cell membrane.* In other words, **quercetin helps drive zinc into the cells and inhibit viral replication!** Wonderful! **My Favorite Amazon Picks** [followed by Amazon associates links]”
 - “**Omega-3 . . .** Here’s the deal, EPA and DHA present at the site of inflammation are converted to specialized chemicals that function together to orchestrate the resolution of inflammation and to support healing, including in the respiratory tract. In other words, nutritional deficiencies in essential fatty acids can result in delayed resolution of inflammation, which could be very important in the context of severe COVID-19 which manifests as uncontrolled inflammation, also known as cytokine

- storm, linked with acute respiratory distress syndrome (ARDS). **My Favorite Amazon Picks** [followed by Amazon associates links]" [from your website at <https://ithrive.health/how-to-boost-your-immune-system-naturally-against-covid-19>].
- You included a link to this blog in a July 14, 2020 post on your social media website at <https://www.facebook.com/iTHRIVE.health>.

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 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 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.

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. 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 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,

Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission