



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: May 19, 2020

TO: larry@lifeunlearned.com – Life Unlearned, LLC
2468 Fruited Plains Ct.
Colorado Springs, CO 80915

CC: regulatory-inquires@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.lifeunlearned.com on May 12, 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 vitamin D 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 website 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 consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent,

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](https://affiliate-program.amazon.com/help/operating/policies/#Associates%20Program%20Fee%20Statement)), 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 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>).

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/>).

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 website 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 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:

- “New Study Reveals Vitamin D May Be the Key to COVID-19”
 - “In previous posts, I’ve written that there may be a connection between a person’s vitamin D status and COVID-19 outcomes. At the time of those posts, even though research had not yet been done specifically on COVID and vitamin D, I continued to emphasize the importance of optimal vitamin D levels, as it has been shown to be a crucial part of a strong immune system.
Incredible news: Now there’s research to support this claim.
A recent analysis has shown that the severity of coronavirus patient outcomes is directly tied to the patient’s vitamin D status.”
 - In an infographic that states: “VITAMIN D HAS NEVER BEEN MORE IMPORTANT”
 - “Coronavirus Study Results:
In COVID patients with normal vitamin D status (>30 ng/ml)
85.5% has mild symptoms
In COVID patients with lower than normal vitamin D status (<30 ng/ml)
98.7% had pneumonia and worse conditions
63.7% had severe to critical outcomes
lifeunlearned.com”
 - “LIFE UNLEARNED’S TRUSTED VITAMIN D PRODUCTS”
 - NOW Supplements, Vitamin D-3 5,000 IU, High Potency . . . [Amazon associates link]
 - Swanson Vitamin D-3 5000 IU Bone Health Immune Support . . . [Amazon associates link]
 - “For most people, COVID-19 is not serious, while for others it can be fatal. The data from this study along with decades of research on the immune-supportive effect of healthy vitamin D levels should be enough to convince everyone to make this a priority.”
 - “The bottom line? In order to give yourself the best defense against the coronavirus, begin with optimizing your vitamin D status to at least 30 ng/ml starting today.”

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 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 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