



WARNING LETTER

Date: August 14, 2020

TO: adrian@silveryguy.com – SilveryGuy
1003 Toa Payoh Industrial Park
Singapore 31907

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 www.silveryguy.com on August 5, 2020, and August 12, 2020, respectively. We also reviewed your Facebook page at www.facebook.com/silveryguy/. 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 the product Colloidal Silver (hereinafter referred to as “Amazon associate product”)¹ with claims on your website representing or implying that the product can mitigate, prevent, treat, diagnose, or cure COVID-19² in people. Based on our review, these claims cause the Amazon associate product purchased through a link 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 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, 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 websites quoted below. We request that you immediately cease

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 twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.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/>).

promoting and participating in the sale of such unapproved and unauthorized product for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your website and your social media website 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:

- In the section of your website entitled “Protecting Yourself and Your Family From COVID-19 With Colloidal Silver ... So How Can Colloidal Silver Help Fight COVID-19?” you include the following statements:
 - “Colloidal Silver can be atomized by using an ultrasonic humidifier and the resulting atomized ‘fumes’ can be inhaled deep into the lungs, the action of silver colloids getting on the lining of your lungs may prove to inhibit the virus from replicating too quickly.”
 - “Silver particles may reduce your body’s overreaction to the virus. (excessive reaction by a body’s immune system in presence of COVID-19 can cause too much mucous to be created within the lung which basically starts to suffocate a person).” [from your website at www.silveryguy.com]
- In a section of your website entitled “Wuhan Coronavirus #nCov2019 And How Colloidal Silver Can Help” you include the following statements:
 - “Similar to a nebulizer, using colloidal silver in its atomized form may be the final defence [sic] against an unseen enemy such as the coronavirus. The virus as with any virus, is a RNA-based entity that infiltrate cells and transform healthy cells into virus replicators. . . . The idea behind atomizing colloidal silver solution and inhaling it, seeks to allow the silver particles and colloids to coat the internal lung tissue and form a defensive layer to the aggressive virus attack.”
 - “Good quality colloidal silver solutions contain high amounts of very small colloidal silver nano particles. Which as you’ve read earlier can bind with viruses and coronaviruses and disable them.” [from your website at www.silveryguy.com]
- On a January 31, 2020 post on your Facebook page you state “What’s your plan if the wuhan #Coronavirus fills up hospitals with patients and you can’t get a bed for treatment? #colloidalsilver may be your last option or your first. Check my latest blog entry to find out how you can save your life and keep your family safe.” [from your Facebook page at <http://www.facebook.com/silveryguy/>]

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 for products that are available for sale in the United States. 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