



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



WARNING LETTER

Date: December 2, 2020

TO: heavenlynaturalproductsc60@gmail.com – Heavenly Natural Products
100 Monroe St #406
Centeron, AR 72719

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://heavenlynaturalproducts.com> on September 11, 2020, and November 10, 2020, respectively. We also reviewed your social media websites at <https://www.facebook.com/heavenlyc60>, <https://twitter.com/hnpC60>, and <https://www.pinterest.com/heavenlynaturalproductsc/>, where you direct consumers to your website <https://heavenlynaturalproducts.com/> to purchase your products. The FDA has observed that your website offers various C60 (Carbon 60) and colloidal silver products for sale in the United States, including “AVOCADO C60 ANTI-VIRAL COMBO – VIRUS PREVENTION” (which includes the products “C60 WITH AVOCADO” and “Heavenly Silver”), and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ 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).

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.² In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.³ 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

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

² 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.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx>).

³ 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/>).

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 websites that establish the intended use of your products, based on statements about the purported effects of their ingredients, and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

From your blog post titled “C60 and Coronavirus,”

<https://heavenlynaturalproducts.com/blogs/news/c60-and-coronavirus:>

- Under the heading “HOW C60 MAY HELP FIGHT AGAINST CORONA VIRUS”:
 - “Some of the common therapeutic potentials of C60 that may be useful to people suffering from COVID-19 have been summarized below . . .”
 - “Improved antioxidant activity:
C60 is an excellent antioxidant, 172 times higher strength than vitamin C. This means it has the capacity to produce a more visible effect than vitamin C. One of the reasons why Vitamin C was recommended as a treatment plan for COVID-19 is due to its antioxidant activities, and this can be improved by using C60 compounds.”
 - “C60 possess some antiviral characteristics”
 - “The potential antiviral activities of C60 have been reported against HIV, and possible interest is rising concerning how C60 may also play the same role in controlling COVID-19 even though HIV and COVID-19 belong to different families.”
 - “In Summary, as the burden of COVID-19 increases and spread to unaffected areas, there is a need to develop an antiviral therapy that will assist both infected and non-infected patients to stay healthy. These moves led to the endorsement of Vitamin C as one of the first lines of treatment for infected cases. It is believed that C60 can also play an active in . . . modulating immune responses in patients, and prevents exposure to the virus.”

From your blog post titled “The Benefits of Colloidal Silver (Anti-Viral),”

<https://heavenlynaturalproducts.com/blogs/news/the-benefits-of-colloidal-silver-anti-viral:>

- “Colloidal silver is an ancient remedy commonly utilized for its . . . anti-viral activities.”
- In a paragraph describing the antimicrobial properties of colloidal silver: “It’s also been widely used to help prevent other viruses like the coronavirus develop in otherwise healthy individuals.”
- “. . . Colloidal Silver serves as an excellent healing agent, limiting the spread of . . . viral infections. It is recommended to be used daily as a preventative measure against disease, as well as the prevention of viral infections common in our society.”

From your social media websites:

- “Concerned about the #Coronavirus? Read this article and get educated on how to best protect yourself” [from a March 10, 2020 post on your Facebook website, <https://www.facebook.com/heavenlyc60>, which links to your blog post titled “C60 and Coronavirus” at <https://heavenlynaturalproducts.com/blogs/news/c60-and-coronavirus>]

- “Learn about the benefits of Colloidal Silver as an #antiviral #antibacterial #immune support supplement... #coronavirus” [from a March 19, 2020 post on your Facebook website, <https://www.facebook.com/heavenlyc60>, which links to your blog post titled “The Benefits of Colloidal Silver (Anti-Viral)” at <https://heavenlynaturalproducts.com/blogs/news/the-benefits-of-colloidal-silver-anti-viral/>]
- “C60 AND CORONAVIRUS
Information from research has shown that C60 plays an important role in decreasing muscle fatigue while boosting the activity of the immune system.” [from a July 27, 2020 post on your Twitter website, <https://twitter.com/hnpC60>, which links to your blog post titled “C60 and Coronavirus” at <https://heavenlynaturalproducts.com/blogs/news/c60-and-coronavirus>]
- “COLLOIDAL SILVER . . . Fights Bacteria & Viruses” and “THE BENEFITS OF COLLOIDAL SILVER (ANTI-VIRAL) . . . It’s also been widely used to help prevent other viruses like the coronavirus develop in otherwise healthy individuals.” [from your pin on your Pinterest website, www.pinterest.com/pin/670051250798247048/, which links to your blog post titled “The Benefits of Colloidal Silver (Anti-Viral)” at www.heavenlynaturalproducts.com/blogs/news/the-benefits-of-colloidal-silver-anti-viral/]
- “C60 AND CORONAVIRUS . . . Since the antioxidant and immune-boosting activities of Vitamin C have been shown to play significant roles in the treatment and management of COVID-19, researchers are positive that Carbon-60 (C60) may play a better role at easing the COVID-19 burden. People who have used C60 products have reported a stronger immune system with less exposure to respiratory infections like flu, and there is presently a high demand for C60 in major parts of the world affected with the COVID-19.” [from your pin on your Pinterest website, <https://www.pinterest.com/pin/670051250798001380/>, which links to your blog post titled “C60 and Coronavirus” at <https://heavenlynaturalproducts.com/blogs/news/c60-and-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 are in compliance with the FD&C Act and FDA's implementing regulations. 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-CFSAN@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-CFSAN@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,

Michael W.
Roosevelt -S

Digitally signed by Michael W.
Roosevelt -S
Date: 2020.12.02 07:47:39 -05'00'

On behalf of William A. Correll, Jr.
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA
VISWANATHAN

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VISWANATHAN
Date: 2020.11.18 08:50:02 -05'00'

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