



## **WARNING LETTER**

Date: April 7, 2021

TO: [info@allureimports.com](mailto:info@allureimports.com) – Cory Chiarello, Allure Imports  
405 E Easterday Ave., Unit 2  
Sault Sainte Marie, MI 49783

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 websites at the Internet addresses: [www.facedoctor.ca](http://www.facedoctor.ca), [www.vitalityc60.com](http://www.vitalityc60.com), and [www.allureimports.com](http://www.allureimports.com) on 02/25/21 and 03/31/21, respectively. We also reviewed your social media websites at [www.facebook.com/facedoctorca/](https://www.facebook.com/facedoctorca/), [www.facebook.com/vitalityc60](https://www.facebook.com/vitalityc60), [www.instagram.com/facedoctor.ca/](https://www.instagram.com/facedoctor.ca/), and [www.twitter.com/FaceDoctorRx/](https://www.twitter.com/FaceDoctorRx/), where you direct consumers to your website, [www.facedoctor.ca](http://www.facedoctor.ca), to purchase your products. The FDA has observed that your websites offer Silver Soul Immune Support, Silver Soul Body Spray and Vitality C60 for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>1</sup> 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. FDA also observed that the product, Vitality C60, is intended for use in the mitigation, treatment, or prevention of COVID-19 in animals, which makes it a drug under section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B). The product is not the subject of an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act, 21 U.S.C. §§ 360b, 360ccc, and 360ccc-1. Therefore, the product is unsafe within the meaning of section 512(a) of the FD&C Act, 21 U.S.C. § 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. § 351(a)(5). 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.<sup>2</sup> In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.<sup>3</sup> Therefore, FDA is taking urgent measures

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

<sup>2</sup> Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>3</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

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 and animals. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people and animals. We request that you take immediate action to cease the sale of any 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 and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- A graphic of your product, “Silver Soul Body Spray,” which includes “Colloidal Silver” on the label, followed by:

**“Myths and Facts About Colloidal Silver for Coronavirus**

Coronavirus is quickly becoming a worldwide health issue due to the rapid way in which it spreads and the absence of a medical cure or vaccine for the virus. Unfortunately, disreputable vendors are taking advantage of panicked citizens and selling products that are not only ineffective but also harmful. Others are spreading misinformation that prevents people from using potentially helpful natural remedies to protect themselves against the virus: one such remedy that has come under fire is colloidal silver. We are here to clarify the myths and facts about colloidal silver and coronavirus. . . .

**Fact: Colloidal Silver is Used for Variety of Health Applications**

People are exposed to minute amounts of silver every day through the air and drinking water. Currently, the health industry uses colloidal silver products in the construction of medical instruments, wound dressings and prosthetics due to the . . . antiviral properties it possesses. . . .

**Fact: Research Supports the Benefits of Silver**

Research has shown that colloidal silver eliminates a variety of organisms in a test tube environment. This suggests that colloidal silver used topically could prevent the spread of coronavirus by disinfecting the skin and preventing the internal transmission of the virus. [From your webpage, [www.facedoctor.ca/myths-and-facts-about-colloidal-silver-for-coronavirus](http://www.facedoctor.ca/myths-and-facts-about-colloidal-silver-for-coronavirus). You also link to this page from your Facebook page, [www.facebook.com/facedoctorca/](https://www.facebook.com/facedoctorca/), posted on March 19, 2020 and your Twitter page, [www.twitter.com/FaceDoctorRx/](https://www.twitter.com/FaceDoctorRx/) posted March 19, 2020.]
- “C60 packs a host of benefits for people and pets. Leveraging C60 for the health benefits is especially helpful for keeping you and your furry friends mentally and physically sound during a global pandemic. C60 benefits people and pets in many of the same ways because it interacts with the compounds in your pet’s body in the same way that it does in yours.

**Boosts Dogs’ Immune Systems . . .**

C60 can also stimulate white blood cell production in your dog’s bone marrow. These immune cells play an important role in helping pets exposed to the coronavirus stay healthy, especially now that it’s clear dogs can contract Covid-19 from people.” [From your webpage [www.vitalityc60.com/how-c60-boosts-pets-immune-systems/](http://www.vitalityc60.com/how-c60-boosts-pets-immune-systems/).]
- “Health enthusiasts are continually looking for new ways to protect their bodies against new, harmful pathogens. It’s widely known that immune-compromised people are more susceptible to feeling the adverse effects of Covid-19, but it’s less well known how people can help get their immune systems up to the task of fighting off this novel pathogen. . . .

**How Viruses Work**

To understand how C60 can help your immune system fight viruses, it’s important to have an idea of how viruses infect your body. Viruses contain nucleic acid, either DNA or RNA, and cannot reproduce outside of a host organism. Viruses are tiny parasites that work their way through the cell membrane to the cell body. They hijack the cell’s reproductive mechanisms and begin rapid proliferation. . . .

**Strengthening Skin**

C60 can help your body stop viruses before they can even get into your cells. The skin is the

body's first line of defense against harmful pathogens, so promoting healthy skin can help you fight off viruses. . . .

### **Strengthen the Source of Immune Cells**

C60 stimulates the production of white blood cells in your bone marrow. White blood cells are central to the functioning of your immune system; these cells are responsible for consuming and destroying hijacked cells so you can get rid of the harmful effects of a viral infection.

### **Final Thoughts**

C60 may be able to help you strengthen your immune system . . . To learn more about C60 and how it might be able to help you weather the current pandemic." [From your website [www.vitalityc60.com/how-carbon-60-boosts-your-immune-system/](http://www.vitalityc60.com/how-carbon-60-boosts-your-immune-system/).]

- “. . . **[C]OVID-19? How C60 Can Help Ease Your Symptoms?**

C60 is a potent antioxidant that can help alleviate the symptoms of viral infections . . . This naturally-occurring compound works in various ways to support and strengthen your immune system, helping you get over viruses' effects more efficiently. Research also shows that strengthening your immune system can make you more able to fight off the effects of coronavirus. Here, you'll find several ways in which taking C60 regularly can help you to bolster your immune system and ease the physical effects of viral infections. . . .

### **The Take-home Message**

When it comes to easing the effects of viral illnesses like COVID-19 . . . , one of the best solutions is to improve and invigorate your immune system. Regularly taking C60 helps encourage weight loss, better sleep patterns, and higher energy levels, boosting your immune system and ability to fight off harmful diseases. [From your website [www.vitalityc60.com/cold-flu-or-covid-19-how-c60-can-help-ease-your-symptoms/](http://www.vitalityc60.com/cold-flu-or-covid-19-how-c60-can-help-ease-your-symptoms/). You also link to this website from your Facebook page [www.facebook.com/vitalityc60/](http://www.facebook.com/vitalityc60/) posted 11/01/20.]

You should take immediate action to address 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-CDER@fda.hhs.gov](mailto:COVID-19-Task-Force-CDER@fda.hhs.gov)** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations 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 actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. 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 may be detained or refused 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-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 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. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to \$43,792 per violation. 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,

Eric M. Nelson  
Director  
Division of Compliance  
Center for Veterinary Medicine  
Food and Drug Administration

Sincerely,

Serena Viswanathan  
Associate Director  
Division of Advertising Practices  
Federal Trade Commission