



WARNING LETTER

Date: November 10, 2020

TO: valerie@sagewomanherbs.com,
clinic@sagewomanherbs.com –

Valerie Blankenship
Sage Woman Herbs, Ltd. dba Sage Consulting & Apothecary
2727 North Tejon St.
Colorado Springs, CO 80907

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://www.sagewomanherbs.com> on September 9, 2020 and October 23, 2020, respectively. We also reviewed your social media website at <https://www.facebook.com/pg/sageconsultingandapothecary/>, where you direct consumers to your website, <https://www.sagewomanherbs.com>, to purchase your products. The FDA has observed that your website offers the products X-tra Strength CV Bundle, Golden Mushroom Blend, Golden Mushroom Blend Tincture, Moducare Chewables, Vitamin C with Bioflavonoids, Protocol for Life Balance K2 MK-7 & D3, Sovereign Silver Bio-Active Silver Hydrosol, Super Elderberry Syrup, Respiratory Tonic, Cistus Incanus Tea, Manuka Honey, Respiratory/Head Lungs, Shuang Huang Lian, Winter Rescue, and Winter Rescue Tincture for sale in the United States 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,

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/>).

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 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 and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “HOW YOU CAN PREPARE FOR THE CORONA VIRUS . . .

As you know, COVID-19, otherwise known as the Corona Virus, has taken our world by storm overnight. . . . We are doing everything we can to maintain a good stock of all of the herbs you may need to prevent and possibly to treat what may arise for you or your loved ones. . . . Many of you are waiting for the availability for the Buhner Bundles that we are making according to . . . author of several books on infectious diseases, Stephen Buhner.”

[from your newsletter entitled “Corona Virus Recommendations from Your Clinical Herbalist!” (<https://myemail.constantcontact.com/Corona-Virus-Recommendations-from-Your-Clinical-Herbalist--FREE-PDF--Herb-Lover-.html?soid=1103654869586&aid=jPsvegC3qlw>), available through a link in a March 20, 2020 post on your social media website <https://www.facebook.com/sageconsultingandapothecary/photos/a.279987735357058/2977757708913367/>]

- “How to Prepare for the Corona Virus from the herbalist”

- “Kids 3 and up should also get vitamin C in reduced doses for prevention. No kids have died from the Corona virus.”

- “FOR PREVENTION TAKE:

IMMUNE MODULATING SUPPLEMENTS

Golden Mushroom Blend . . .

Moducare . . . It works GREAT as a preventative. . . . I have seen it stop chronic annual colds and flus. . . .

Vitamin C . . .

Zinc . . .

D3 (I love our new Protocol for life – only 1 cap a day gives you 5,000 ius of D . . .)

. . . Sovereign Silver – 1 teaspoon a day for prevention or 2 x a day for treatment of opportunistic infections in folks with the virus.”

- “FOR TREATMENT TAKE (You’ll be fine. Take your herbs and stay home.)

. . .

Antivirals –

. . .

Buhner Bundles⁴ . . .

A good quality Elderberry syrup or tincture. With Super Elderberry, you will use 5-6 teaspoons per day. . . .

Winter Rescue or Respiratory Head and Lung formulas – contain many antimicrobial herbs that are very effective for viruses that affect the lungs as well as decongesting the lungs.

Take Respiratory Tonic if you have weakened lungs already.

Cistus Icanus [*sic*] tea . . . Helps keep the virus from entering the cellular envelope.

. . .

Manuka honey”

[from your “Herbal Immunity Guide”

(<https://files.constantcontact.com/25ad4f6f001/852e4bdb-96e1-4912-9f29-34bf89d5de57.pdf>), available through a link from your newsletter “Corona Virus Recommendations from Your Clinical Herbalist!”]

- “RESPIRATORY/HEAD & LUNGS . . . This formula is effective for . . . congested . . . chest & lungs. A soothing bronchial expectorant . . .” [from your website <https://www.sagewomanherbs.com/respiratory-head-lungs-150-caps.html?id=16739647>]
- “SHUANG HUANG LIAN . . . Dr. So Tsz-him, . . . registered Chinese medicine practitioner at the University of Hong Kong, told AFP . . . ‘They [Shuang Huang Lian] are most commonly used to treat various infections according to TCM theory, including respiratory tract infections’ In a February 4 press conference, Chinese National Health Commission expert committee member Zhang Boli said pharmacological experiments had found Shuang Huang Lian helpful in ‘controlling’ the new virus” [from your website <https://www.sagewomanherbs.com/shuang-huan-han-8-oz.html>]
- “WINTER RESCUE . . . This formula helps kill infections & viruses that cause illness.” [from your website <https://www.sagewomanherbs.com/sage-woman-herbs-winter-rescue-150-caps.html>]

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

⁴ Your website no longer offers the original Buhner Bundle but now offers an updated version called the “X-tra Strength CV Bundle,” which you describe as an update of the Buhner Bundle (<https://www.sagewomanherbs.com/x-tra-strength-cv-bundle.html>).

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 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,

**William A.
Correll Jr -S**

Digitally signed by
William A. Correll Jr -S
Date: 2020.11.10 14:35:54
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William A. Correll
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

Digitally signed by SERENA
VISWANATHAN
Date: 2020.10.27 07:51:13
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Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission