



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



WARNING LETTER

Date: November 18, 2020

TO: info@redmoonherbs.com Jeanette Dunn Acevedo
jeannie@redmoonherbs.com – New Red Moon, LLC dba Red Moon Herbs
433 Weaverville Hwy
Suite A
Asheville, NC 28804

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://redmoonherbs.com> on November 4, 2020 and November 5, 2020, respectively. We also reviewed your social media websites www.facebook.com/redmoonherbs/ and www.instagram.com/redmoonherbs, where you direct consumers to your website, <https://redmoonherbs.com>, to purchase your products. The FDA has observed that your website offers the products American Ginseng Elixir, Ashwagandha, Astragalus, Breathe Clear, Chickweed, Dandelion, Echinacea, Elderberry, Elderberry Elixir, Elecampane, Garlic Elixir, Ginkgo, Hyssop, Kudzu, Lobelia, Lung Support, Mushroom Elixir, Turmeric, Usnea, Violet, Viral Spiral, Wild Cherry Bark Syrup, and Yarrow 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, 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,

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 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>).

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/>).

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:

On your webpage titled “COVID-19 Herbal Resource Hub” (<https://redmoonherbs.com/pages/covid-19-herbal-resource-hub>):

- “These tweaks and substitutions are essential even simply to prevent one herb that could be the darling of COVID-19 treatment completely disappearing from commerce - kudzu, elderberry, or reishi for instance – because it’s sold out and even hoarded.... As much as there's not one single herb that treats any infection, it's likely that there are multiple routes to supporting the body's resistance to this new pathogen.”
- “As this virus continues to infiltrate among us, so does the backyard medicine that can be foraged in urban and rural spaces: dandelion root for optimal liver health, chickweed to keep the lymphatic system flowing nicely, and violet leaf and flower to soothe and moisten dry upper and lower respiratory tissues.”
- “Immunomodulating herbs - my top go-tos which are showing up again and again in the building literature surrounding this pandemic are astragalus, any and all medicinal mushrooms (reishi, turkey tail, chaga, lion's mane, and Mushroom Elixir are favorites), and adaptogens including ashwagandha and ginseng. Echinacea and usnea are both effective immune stimulants and usnea has an affinity for the lungs which may prove relevant here. Astragalus and reishi are particularly gentle and good for all ages and my three year old takes them daily.”
- “Antiviral herbs - many of these cross over categories and are also nervines or immune supporters. Viral Spiral combines three of these: St. John's wort, lemon balm, and calendula. Yarrow may play an important role here and is widely available. Elderberry belongs in this category, of course”
- “Herbs to support optimal regulation of the infected body Kudzu is very powerful but little-known in western herbalism for immune support Ginkgo is in the same camp.”
- “Respiratory herbs - a dry, inflamed lower respiratory system may be soothed and nourished by cooling, mucilaginous herbs. My top choices here are wild cherry bark (a well-known sedative for the lungs), elecampane, and hyssop.... Lobelia is a low-dose acute bronchial dilator which may be indicated for some. A general respiratory tonifying formula such as Lung Support or Breathe Clear is not a bad idea.”

On your social media websites www.facebook.com/redmoonherbs/ and www.instagram.com/redmoonherbs/:

- “Promising Coronavirus Research Looks at Elderberry. Chicago Daily Herald. May 5, 2020. In the search for effective therapies against COVID-19, emerging scientific research is identifying elderberry as holding promise for the preclusion of viral infection due to the presence of a compound known as caffeic acid.’ If you are looking for information on elderberry and cytokine storms, we have a number of links to the best research and well-considered thoughts on the topic in our COVID-19 Herbal Resource Hub.” [from a May 26, 2020 post on your social media website, www.facebook.com/redmoonherbs/]
- “Promising Coronavirus Research Looks at Elderberry. Chicago Daily Herald. May 5, 2020. In the search for effective therapies against COVID-19, emerging scientific research is identifying

elderberry as holding promise for the preclusion of viral infection due to the presence of a compound known as caffeic acid.' ... #covid19 ... #antiviralherbs #antiviral" [from a May 26, 2020 post on your social media website www.instagram.com/redmoonherbs]

- You have an Instagram story titled "COVID-19" that begins with your statement, "Going to share some excellent and thorough COVID-19 herbal strategies." This story includes images of:
 - Documents titled "HERBAL TREATMENT FOR CORONAVIRUS INFECTIONS" and "An Herbalist's Notes on the COVID-19 Virus"
 - The herbs astragalus, elderberry, garlic, yarrow, violet, and elecampane, which are sold on your website <https://redmoonherbs.com>
 - A repost of your March 19 Instagram post linking to your "COVID-19 Herbal Resource Hub" webpage (<https://redmoonherbs.com/pages/covid-19-herbal-resource-hub>)
 - A study titled "Revealing the Potency of Citrus and Galangal Constituents to Halt SARS-CoV-2-Infection," with your caption "Interesting study on citrus and curcumin (turmeric) versus COVID-19"
[from your Instagram story at www.instagram.com/stories/highlights/17870946031619238/]

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 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
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William A. Correll Jr -S
Date: 2020.11.17
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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
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VISWANATHAN
Date: 2020.11.16 08:16:49
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Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission