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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”
- €

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

In addition, it is unlawful under the FTC Act, 15 U.S.C. 41 et seq., to advertise that a product can prevent,