



WARNING LETTER

Date: November 10, 2020

TO: valerie@sagewomanherbs.com, Valerie Blankenship

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:

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Buhner Bundle⁴. . .

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 lcanuss[ic] 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!”]

- x “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>
- x “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>]
- x “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 (

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