U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

Date: March 10, 2022

TO: ccombs@mockingbirdmeadows.com
dcombs@mockingbirdmeadows.com

Dawn Combs
Soda Pharm
16671 Burns Road
Marysville, Ohio 43040

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://sodapharmlife.com/ on February 7, 2022, and March 8, 2022, respectively. We also reviewed your social media websites at https://www.facebook.com/sodapharmlife/ and https://www.instagram.com/sodapharmlife/, where you direct consumers to your website, https://sodapharmlife.com/, to purchase your products. The FDA has observed that your website offers the "Cold/Flu/COVID Pack," "Cold and Congestion Loose Leaf Tea," "Goldenseal Extract," "Cool Down Loose Leaf Tea," "Resistance Extract," "Ache Ease Herbal Drink Syrup," "Pain Release Extract," "Headache Blend Extract," "Vapor Balm," and the "Mustard Plaster" products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] 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, there was a Presidential declaration of 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 any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

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[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, 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.
[3] 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/.

Some examples of the claims on your website and your social media 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:

- "**Practical Advice For Managing Covid-19 at Home**

  Over the past week, I've had a number of calls, emails and texts from people who are sick and need advice while managing covid at home. Some have tested positive for some form of COVID-19. It has come to a point that I have said or written some version of the same thing so many times that I thought I would just make a formal post. . . .

  Congestion . . .

  For congestion, you want an expectorant. This is why I created our Cold and Congestion Tea . . . it is filled with plants that aid the body in expelling mucus, but does so without being an irritant to the delicate mucous membranes in the lung. . . .

  Infection

  It is important to get ahead of infection if you are managing covid at home. My favorite remedy here is our Goldenseal Tincture. Goldenseal has a special affinity for our mucous membranes and is what I reach for when an antibiotic is needed. . . .

  Fever . . .

  If you are managing covid at home and have a threatening fever that is climbing into the danger zone or if you have a very high fever that is sustained for more than a day, it is good to interfere. This is where cold cloths on the forehead, lukewarm baths, or our Cool Down Tea can be of benefit. . . .

  This happens a lot in people who have compromised immune systems . . . particularly in those who as children were given OTC fever medicine. For these folks I have a tincture called Resistance, that is specific for people fighting off a flu-like illness with an unproductive fever mechanism. . . .

  Headache, Body Aches

  Anything that is anti-inflammatory is helpful here. We use our Ache Ease syrup for aches and pains and our Pain Release Tincture or our Headache Tincture to help those who are struggling with pain and/or headaches. Above all else, it is important to avoid over-the-counter remedies like Tylenol. . [*sic*] they will block your body's ability to clear the virus and contribute to a lengthening of your illness and symptoms. . [*sic*] or worse- contribute to an autoimmune disease." [from your webpage https://sodapharmlife.com/2021/08/31/my-recommendations-for-managing-covid-at-home/]

- "**Which Cough Do You Cough. . . and How Do You Make It Stop? . . .**

  WET UNPRODUCTIVE COUGH OR DRY BARKING/PAINFUL . . .

  With COVID, my observation is that the mucus produced is especially 'sticky.' . . . It is critical that you follow my recommendations in the Managing COVID at Home post until this cough is resolved. Get up and move! Hydrate like it's your job, steam, drink expectorant teas and get that mucus out of your lungs! . . .

  Useful Aides: . . .

- Cold and Congestion Tea . . .

General Recommendations . . .

2. A natural mentholated salve, like our Vapor Balm, can be applied at night. . . .
3. An old-fashioned mustard plaster. . . . This is by far one of my favorite weapons in my arsenal against an unproductive cough." [from your webpage https://sodapharmlife.com/2021/10/13/which-cough-do-you-cough-and-how-do-you-make-it-stop/]

- "**Mullein Leaves are Cryptonite [*sic*] to Congestion** . . .

  A Bit About The Healing Aspects of Mullein . . .

  I formulated my Cold and Congestion Tea with dried mullein leaf because it is so effective at moving out mucus while also being gentle to the lungs. This is especially important right now as so many are trying to recover from COVID. It's funny to me that I scheme to avoid touching the plant in its fresh or dried form. As irritating as it is on my hands and arms it is that soothing to my lungs." [from your webpage https://sodapharmlife.com/2021/08/31/mullein-leaves-are-cryptonite-to-congestion/]

- "Get your cold and flu pack - everything you need for cold/flu or COVID management at home in one click . . . https://sodapharmlife.com/product/cold-flu-covid-pack/ Don't just wait until you're bad enough to go to the ER!! Get better instead!" [from the November 8, 2021 posts on both your Instagram webpage at https://www.instagram.com/p/CWB7bIqrdbG/ and your Facebook webpage at https://www.facebook.com/sodapharmlife/]

Your website, https://sodapharmlife.com/, also includes various "Category" tags such as "Covid" that link to the "Cold/Flu/COVID Pack" and "Mustard Plaster" products and provide evidence of the products' intended uses.

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** 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 products 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.

FTC Cease and Desist Demand: 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. 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 $46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). 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 certifying that you have ceased making unsubstantiated claims for the product identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
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Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

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Date: 2022.03.08 16:16:46 -05'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission