



WARNING LETTER

Date: April 9, 2020

TO: customercare@earthley.com – Earthley Wellness (dba Modern Alternative Mama LLC)
240 Outerbelt Street, Suite #8
Columbus, Ohio 43213

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 websites at the Internet addresses <https://earthley.com> and <https://modernalternativemama.com> April 2, 2020 and on April 8, 2020, respectively. We also reviewed your social media website at Internet address www.facebook.com/pg/earthley, where you direct consumers to your website, <https://earthley.com>, to purchase your products. The FDA has observed that your website offers herbal tinctures and herbal remedy products 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

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>).

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/>).

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:

- “Immune Support Collection . . . Worried about your family coming down with colds, flu – coronavirus? Strengthen your immune systems to stay healthy naturally, with our Immune Support Collection! . . . Elderberry Elixir . . . Immune-Aid Vitamin C Powder . . . Good Night Lotion . . . Vitamin D Cream . . . Nourish Me Naturally.” [from your website <https://earthley.com>]
- “Respiratory Aid Kit . . . With concerns about coronavirus and the end of flu season, many people are worried about experiencing respiratory symptoms. Luckily, natural remedies can help! Herbal tinctures can support the immune system and the lungs to help you get through respiratory illnesses more quickly and more easily. This collection has our favorite natural remedies for respiratory concerns. . . . Learn more about prepping for coronavirus here: <https://modernalternativemama.com/202003/12/natural-remedies-for-coronavirus/> . . . Cough-B-Gone Herbal Extract . . . Anti-Inflammatory Herbal Extract . . . Breathe Well Salve . . . Immune-Biotic . . .” Next to these claims is an image stating “Natural Remedies for Coronavirus.” [from your website <https://earthley.com>]
- “Natural Remedies for Coronavirus . . . Right now (Mar. 12), there are about 1300 cases in the US, and have been around 40 deaths. . . . When it comes to *avoiding* coronavirus, there are some herbs that have shown promise. These herbs include: . . . Elderberry . . . Many have heard that elderberry isn’t the right remedy for CoVid-19. . . . Although for the majority, it is perfectly fine to use. . . . Elderberry is best used for daily support or at the very onset of symptoms. . . . What if you get coronavirus? . . . When it comes to natural remedies, they will be most effective at symptom onset . . . This is pretty universal, btw, not just for CoVid-19. Remedies get your body ready to fight effectively, but if it’s already overwhelmed, that’s a lot harder. . . . [Find some of these natural remedies as a kit HERE.](#)” The word “HERE” is a hyperlink to the page on your website <https://earthley.com> where you offer your “Respiratory Aid Kit” for sale. [from a March 12, 2020 posting on your website <https://modernalternativemama.com>]
- “Continuously supporting your immune system should be an ongoing habit to help prevent you or your family from getting sick. Strengthen your immune system naturally to help fight off the possibility of you or your family getting the coronavirus with our powerful Immune Support Collection!” Below this claim is a graphic displaying your “Vitamin D Cream,” “Nourish Me Naturally,” “Immune Aid,” “Good Night Lotion,” and “Elderberry Elixir” products. [from a March 31 posting on your social media website www.facebook.com/pg/earthley]
- “Worried about your fam [*sic*] coming down with colds, flu, or even worse – the coronavirus? Luckily, natural remedies can help! We’ve put together a Respiratory Aid Kit to help get through the respiratory illnesses more quickly and more easily. Click below to shop.” Below this claim is a graphic displaying your “Breathe Well” product. [from a March 18 posting on your social media website www.facebook.com/pg/earthley]
- “Don’t panic and assume the worst when it comes to the coronavirus -yet! . . . if you are worried, here are some coronavirus prevention tips . . . Take key supplements to boost your immune system naturally- our Immune Support Collection is a MUST-HAVE for

every family” [from a March 13 posting on your social media website www.facebook.com/pg/earthley]

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-CDER@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 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.

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,

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

Richard A. Quaresima
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission