



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: April 27, 2020

TO: info@HopewellOils.com – Hopewell Essential Oils

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://hopewelloils.com> on April 13, 2020 and April 23, 2020, respectively. The FDA has observed that your website offers essential oils and herbal 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 immediate action to cease the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

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/>).

Some examples of the claims on your website 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:

- “Hopewell Essential Oils is dedicated to using pure plant extracts. . . tested for their . . . therapeutic quality. . . View our more recent newsletter on the Coronavirus - What We Currently Know and How We Plan to be Prepared [hyperlink⁴]” [from your website www.hopewelloils.com]
- “Coronavirus . . . The following is something I prepared in early February 2020 due to numerous calls emails [sic] we started receiving about the new Coronavirus outbreak in China. . . the general approach to being prepared for this or any virus is the same.” [from your website <https://hopewelloils.com/coronavirus.php>]
- “Coronavirus. . . The new Coronavirus strain (COVID-19) is a respiratory virus with typical respiratory symptoms such as fever, shortness of breath and difficulty breathing. . . **If we become ill** [sic], we follow these tips: . . . Fresh ginger is less drying than dried ginger, and if available, can be used interchangeably with cardamom. . .” [from your website <https://hopewelloils.com/coronavirus.php>]
- “When our family is ‘at risk’ with the flu or a threatening virus that is affecting people nearby, we diffuse oils in our living/office space. . . If needed, I am prepared with Warrior [hyperlink⁵] and/or Cinnamon Bark [hyperlink⁶] essential oil to give orally (a diluted drop or two) every few hours while awake until the symptoms abate. Absolve [hyperlink⁷] blend is another one I’d consider taking orally . . . Absolve includes Cinnamon Bark and other oils that are noted to help support our immune response. There are a number of oils and blends that we feel support our immune response for virus issues, so basically use what you’ve found helpful.” [from your website <https://hopewelloils.com/coronavirus.php>]
- “The Coronavirus presents pneumonia-like symptoms, making it difficult to breathe. For respiratory issues, my favorite blends are Lung Support [hyperlink⁸] and Respiratory Relief [hyperlink⁹]. For children or pregnant women, I’d consider Breathe Easy [hyperlink¹⁰] and/or Breathe Happy [hyperlink¹¹]. If I became ill with a respiratory virus, I’d diffuse one of these, but if I didn’t have a diffuser, I’d get an inexpensive surgical or dust mask. . . and put a couple of drops of essential oil onto the mask. I’d wear it . . .to inhale

⁴ The words “Coronavirus - What We Currently Know and How We Plan to be Prepared” is a hyperlink to your website <https://hopewelloils.com/coronavirus.php>.

⁵ The word “Warrior” is a hyperlink to your website <https://hopewelloils.com/warrior.php> where you offer your “Warrior” product for sale.

⁶ The words “Cinnamon Bark” are a hyperlink to your website <https://hopewelloils.com/cinnamon-bark.php> where you offer your “Cinnamon Bark” product for sale.

⁷ The word “Absolve” is a hyperlink to your website <https://hopewelloils.com/absolve.php> where you offer your “Absolve” product for sale.

⁸ The words “Lung Support” are a hyperlink to your website <https://hopewelloils.com/lung-healing.php> where you offer your “Lung Support” product for sale.

⁹ The words “Respiratory Relief” are a hyperlink to your website <https://hopewelloils.com/respiratory-relief.php> where you offer your “Respiratory Relief” product for sale.

¹⁰ The words “Breathe Easy” are a hyperlink to your website <https://hopewelloils.com/breathe-easy.php> where you offer your “Breathe Easy” product for sale.

¹¹ The words “Breathe Happy” are a hyperlink to your website <https://hopewelloils.com/breathe-happy.php> where you offer your “Breathe Happy” product for sale.

the essential oils. . . Inhaling essential oils is an excellent way to get the oils into the bloodstream, thus I'd figure out some way for those ill to inhale them frequently. . . .

Hopewell Products to Consider:

- [Warrior](#) [hyperlink¹²] (for adults)/[Immune Support](#) [hyperlink¹³] (for children and the elderly)
- [Cinnamon Bark](#) [hyperlink¹⁴]
- [Lung Support](#) [hyperlink¹⁵] (for adults)/[Breathe Easy](#) [hyperlink¹⁶] (for children and the elderly)
- [Respiratory Relief](#) [hyperlink¹⁷] . . .

Popular Herbs for Respiratory Illness include: . . .

Ginger . . .

Sage

Turmeric” [from your website <https://hopewelloils.com/coronavirus.php>]

- “Warrior essential oil blend may support . . . Respiratory infection Just want to thank you for Warrior and [Top Gun](#) [hyperlink¹⁸]. . . I plan to continue to take these essential oils, especially during this time of the COVID-19 breakout.” [from your website <https://hopewelloils.com/warrior.php>]

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

¹² The word “Warrior” is a hyperlink to your website <https://hopewelloils.com/warrior.php> where you offer your “Warrior” product for sale.

¹³ The words “Immune Support” are a hyperlink to your website <https://hopewelloils.com/immune-support.php> where you offer your “Immune Support” product for sale.

¹⁴ The words “Cinnamon Bark” are a hyperlink to your website <https://hopewelloils.com/cinnamon-bark.php> where you offer your “Cinnamon Bark” product for sale.

¹⁵ The words “Lung Support” are a hyperlink to your website <https://hopewelloils.com/lung-healing.php> where you offer your “Lung Support” product for sale.

¹⁶ The words “Breathe Easy” are a hyperlink to your website <https://hopewelloils.com/breathe-easy.php> where you offer your “Breathe Easy” product for sale.

¹⁷ The words “Respiratory Relief” are a hyperlink to your website <https://hopewelloils.com/respiratory-relief.php> where you offer your “Respiratory Relief” product for sale.

¹⁸ The words “Top Gun” are a hyperlink to your website <https://hopewelloils.com/bacteria-top-gun.php> where you offer your “Top Gun” product for sale.

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