



WARNING LETTER

Date: February 22, 2022

TO: <u>contact@mynaturaltreatment.com</u> – Andreea Laza, MyNaturalTreatment.com

CC: regulatory-inquiries@amazon.com – Amazon Associates Program

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://www.mynaturaltreatment.com on January 18, 2022, and February 11, 2022, respectively. We also reviewed your social media website at https://www.facebook.com/mynaturaltreatment/, where you direct consumers to your website, at https://www.mynaturaltreatment.com to purchase your products. While reviewing your websites, FDA observed that you participate in the Amazon Associates program. As an Amazon associate, you earn commissions by promoting the sale of thyme, black seed, eucalyptus, rosemary and peppermint oil products (hereinafter referred to as "Amazon associate products")1 with claims on your website representing or implying that the products can mitigate, prevent, treat, diagnose, or cure COVID-19² in people. Based on our review, these claims cause the Amazon associate products purchased through links on your websites to be unapproved new drugs under 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. Causing 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). In addition, it is a prohibited act under section 301(k) of the FD&C Act, 21 U.S.C. § 331(k), to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

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

¹ Specifically, your website contains links that direct consumers to the Amazon.com website to purchase the Amazon products you promote. As described in the Amazon Associates Program Fee Statement (https://affiliate-program.amazon.com/help/operating/policies/#Associates Program Fee Statement), accessed January 18, 2022, Amazon calculates your commission or "fee" by using your website's Amazon associate ID to track sales to consumers who are redirected to Amazon.com by clicking one of the links on your website.

² As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

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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.³ In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.⁴ 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.

Some examples of the claims on your website that establish the intended use of your Amazon associate products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

"How to Make Your Own Natural Antiviral for COVID-19 . . .

In This Article You Will Find: Natural Antiviral for Covid-19 with Essential Oils The 5 Best Essential Oils for Covid-19

- 1. Thyme Oil
- 2. Black Seed Oil
- 3. Eucalyptus Oil
- 4. Rosemary Oil
- 5. Peppermint Oil

How to Make The Natural Antiviral for Covid-19 Other Natural Antivirals for Covid-19 . . .

The most potent essential oils that you can use to make your own natural antiviral for Covid-19 have a large number of monoterpenes, a class of terpenes widely studied for their antiviral property. They also have powerful antimicrobial, antiviral, and anti-inflammatory properties, and you can use them independently or, even better, together in a powerful natural antiviral for Covid-19.

These Essential Oils Are

Thyme oil Black seed oil Eucalyptus oil Rosemary oil Peppermint oil

³ 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.

⁴ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Mar. 13, 2020, 85 FR 15337, available at https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak.

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Before we move on to the simple natural antiviral recipe, here is a little info on each of these essential oils and why they make the best combo for mild symptoms of Covid-19 and prevention. . .

- 1. **Thyme Oil** . . . To top everything off, this amazing oil contains another powerful active compound called isoborneol, which is also a notable antiviral agent with important neuroprotective and anticoagulant properties. All these make thyme oil a solid potential natural antiviral for Covid-19.
- 2. **Black Seed Oil** . . . Recent studies indicate that this natural compound has potential benefits for Covid-19. . . .
- 3. **Eucalyptus Oil** . . . Eucalyptus oil has bronchodilating and anti-inflammatory properties and is one of the top herbal medicines to add to your natural antiviral for Covid-19 blend. . . .
- 4. **Rosemary Oil** . . . Rosemary oil also contains camphene, a terpene that possesses anti-inflammatory, antibiotic, analgesic, and antioxidant properties, especially when mixed with vitamin C. Even more, borneol has proven efficacy in bronchial symptoms. This makes rosemary oil a top natural antiviral for Covid-19.
- 5. **Peppermint Oil** . . . Needless to say, peppermint oil makes it to the shortlist as a potential natural antiviral for Covid-19. . . .

How to Use

You can take 3-5 drops three times a day for 7-14 days. . . . For children between 7-14 years of age, the dosage is 1-2 drops three times a day with honey. . . .

Where to Find These Essential Oils?

Zongle USDA Certified Organic Thyme... Buy it here [followed by an Amazon Associate link]

Organic Black Seed Oil 4oz - USDA... Buy it here [followed by an Amazon Associate link]

LorAnn Eucalyptus Oil (100% Pure... Buy it here [followed by an Amazon Associate link] Zongle USDA Certified Organic [product label states in part "Organic Rosemary"] . . . Buy it here [followed by an Amazon Associate link]

Zongle Peppermint Oil, Safe to... Buy it here [followed by an Amazon Associate link]"

[from your webpage https://www.mynaturaltreatment.com/make-natural-antiviral-for-covid-19/.] You also included a link to this page in a January 3, 2022 post, a December 27, 2021 post, a November 21, 2021 post, on your social media page at https://www.facebook.com/mynaturaltreatment/.

You should take immediate action to address the deficiencies cited in this letter. This letter is not meant to be an all-inclusive list of violations that may exist in connection with your products or operations. It is your responsibility to ensure that your activities as an Amazon associate do not violate the FD&C Act. We advise you to review your websites and other labeling and promotional materials to ensure that you are not misleadingly representing your Amazon associate products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you are not distributing misbranded 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 any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related

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documentation. Failure to adequately address this matter may result in legal action, including, without limitation, seizure and injunction.

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. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your Amazon associate products and activities are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration within 48 hours.

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 any 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.

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 products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Sincerely,

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

Serena Viswanathan Associate Director Division of Advertising Practices Federal Trade Commission