



**FDA U.S. FOOD & DRUG
ADMINISTRATION**



WARNING LETTER

Date: May 26, 2020

TO: carefulcents@gmail.com – Carrie Lee Smith Nicholson, Careful Cents, LLC
6671 Bugle Drive
Colorado Springs, CO 80918

CC: regulatory-inquires@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 reviewed your website at the Internet address <https://abeginnersguidetoessentialoils.com> on May 6, 2020, and May 19, 2020, respectively. While reviewing your website, FDA observed that you participate in the Amazon Associates program. As an Amazon associate, you earn commissions by promoting the sale of essential 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 website 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 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, the President declared 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,

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 April 22, 2020), 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).

³ 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>). The declaration was renewed for another 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. April 21, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx>).

⁴ 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/>).

treat, diagnose, or cure COVID-19 in people. As described above, you promote and participate in the sale of products for use in mitigating, preventing, treating, diagnosing, or curing COVID-19 in people, as evidenced by the claims from your website quoted below. We request that you immediately cease promoting and participating in 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 website, abeginnersguidetoessentialoils.com/essential-oils-immune-system/, 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:

On a webpage with the heading “How to Boost Your Immune System Naturally With Essential Oils to Fight Coronavirus” you state:

- “Can you use essential oils to boost your immune system and fight coronavirus? Yes! Essential oils are one of the best tools to strengthen your immune system naturally . . .”
- “HOW TO BOOST YOUR IMMUNE SYSTEM NATURALLY”
 - “Use top antibacterial essential oils to kill germs”
 - “Diffuse essential oil blends for immune support”
 - “Try this essential oils immunity recipe blend”
- “Essential oils have many, many uses and a wide variety of treatments to help fight viruses. You can use them for preventative care before getting sick and on-going immune system support. Using the right blends of essential oils is an important part of making it through the coronavirus season healthy.”
- “Eucalyptus [Amazon associates link] essential oil . . . has antiseptic agents that help fight . . . viruses.”
- “Peppermint [Amazon associates link] essential oil . . . can be used to . . . clear chest congestion.”
- “Tea Tree [Amazon associates link] essential oil is considered to have potent antimicrobial properties. It aids in fighting against . . . viruses”
- “You already know that Citronella [Amazon associates link] . . . is also an . . . antiviral essential oil.”
- “DIFFUSE ESSENTIAL OIL BLENDS FOR IMMUNE SUPPORT”
 - “The quickest and easiest way to support your immune system with essential oils is by diffusing oils with . . . anti-viral properties.”
 - “Diffusing for 30-60 minute intervals a few times a week . . . is also the quickest way for the essential oils to enter your body and strengthen your immune system.”
 - You promote your Amazon associates products under “ANTIBACTERIAL BLEND,” “RESPIRATORY SUPPORT,” and “DISINFECTING CITRUS.”
- “TRY THIS ESSENTIAL OILS IMMUNITY RECIPE BLEND”
 - “If you have been exposed to someone who has a virus you can use essential oils to boost your immune system and help alleviate any symptoms.
You can mix up some essential oils in an ounce of carrier oil to use topically for preventive care or when you are feeling symptoms.
 - 5 drops Tea Tree [Amazon associates link]
 - 3 drops Citronella [Amazon associates link]
 - 3 drops Lemon [Amazon associates link]
 - 5 drops Cypress [Amazon associates link]
 - 4 drops Rosemary [Amazon associates link]”
 - “Apply this essential oils immunity recipe blend to your chest, neck, and wrists. And continue applying as often as needed.”
 - “Beware when using this immunity recipe blend with children under the age of six as it will need to be diluted further for safe use.”

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 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 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 promoting the sale of 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 Amazon associate products and activities are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

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 product identified above. Thus, any coronavirus-related prevention or treatment claims regarding such product 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,

Sincerely,

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

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