



## **WARNING LETTER**

Date: March 6, 2020

TO: [support@quinessence.com](mailto:support@quinessence.com) – Geoff Lyth, Quinessence Aromatherapy Ltd  
Unit 2, Forest Court, Linden Way  
Coalville  
Leicestershire LE67 3JY  
United Kingdom

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 [www.quinessence.com](http://www.quinessence.com) in February 2020. We have also reviewed your Twitter website at [www.twitter.com/quinessence\\_where](https://www.twitter.com/quinessence_where) you direct consumers to your website [www.quinessence.com](http://www.quinessence.com) to purchase your essential oil products. The FDA has determined that your website offers essential oil products for sale in the United States and that these products are intended to mitigate, prevent, treat, cure or diagnose COVID-19<sup>1</sup> in people. FDA has determined that 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 section 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

The Secretary of Health and Human Services, under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, has determined that a public health emergency exists nationwide as a result of confirmed cases of COVID-19. 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.

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:

- “Essential Oils to Protect Against Coronavirus . . . There are a wide range of essential oils that have been clinically proven to possess antiviral properties. Whilst these essential oils do not all offer the same level of defence (*sic*), many have been proven to

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<sup>1</sup> COVID-19 is the official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China.

have a measurable effect on a wide range of infective agents such as influenza A and B, parainfluenza strains 1,2 & 3, vaccinia, herpes simplex and polio.” [from your website [www.quinessence.com](http://www.quinessence.com)]

- “The most powerful anti-virus essential oils to provide defence (*sic*) against coronavirus include: • Basil • Bergamot • Cajuput • Cedarwood Virginian • Cinnamon • Clove Bud • Eucalyptus Globulus, Radiata and Smithii • Juniper Berry • Lavender Spike • Laurel leaf • Lemon • Manuka • Niaouli • Peppermint • Ravensara • Ravintsara • Rosemary • Sage • Tea Tree • Thyme Sweet and Thyme White.” [from your website [www.quinessence.com](http://www.quinessence.com)]
- “If you don’t want to make your own blends, Quinessence Anti-virus Synergy contains some of the most powerful, expertly blended anti-viral essential oils that can be used . . . to deliver you protection. Since this new strain of virus continues to be a very serious threat right now, it certainly can’t hurt to use the essential oils you already have to avoid infection until a cure has been developed . . . ” [from your website [www.quinessence.com](http://www.quinessence.com)]
- “Anti-Virus Synergy *Ravensara, Tea Tree, Basil and Cedarwood Virginian* This pure essential oil Synergy is ideal to use during a chill or the cold season because of the powerful anti-viral and antiseptic properties of these essential oils.” [from your website [www.quinessence.com](http://www.quinessence.com)]
- “Eucalyptus radiata . . . has a powerful antibacterial, antifungal and anti-infectious action, which makes it extremely useful for all types of infection.” [from your website [www.quinessence.com](http://www.quinessence.com)]
- “In my opinion, Eucalyptus radiata is better suited than *globulus* for chronic respiratory conditions and viral or bacterial infections, especially with young children.” [from your website [www.quinessence.com](http://www.quinessence.com)]
- “Niaouli essential oil has also been shown to be very effective against . . . most types of infectious respiratory ailments.” [from your website [www.quinessence.com](http://www.quinessence.com)]
- “White Thyme Essential Oil exhibits a powerful anti-infectious action, making it the perfect winter essential oil because its expectorant properties stimulate the expulsion of catarrh whilst an antispasmodic action soothes the strain of coughing, plus a powerful antiviral action helps kill off the infection.” [from your website [www.quinessence.com](http://www.quinessence.com)]
- “Essential Oils To Protect Against Coronavirus” [from a February 14, 2020 post on your Twitter website at [www.twitter.com/quinessence](https://www.twitter.com/quinessence)]

You should take immediate action to correct the violations cited in this letter. The violations cited in this letter are not meant to be an all-inclusive list. 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 representing your products 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](mailto: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 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 product(s) listed 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](mailto: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. To make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act.

There currently are no vaccines, pills, potions, lotions, lozenges or other prescription or over-the-counter products available to treat or cure coronavirus disease 2019 (COVID-19). Thus, the claims cited above are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. In addition, you are advised to review all claims for your products and immediately cease making claims that are not supported by competent and reliable scientific evidence. 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](mailto: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,

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

Sincerely,

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