WARNING LETTER

MONQ, LLC

MARCS-CMS 613570 — JUNE 30, 2022

Delivery Method:

Via Email

Product:

Drugs

Recipient:

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Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Federal Trade Commission (Federal Trade Commission)

WARNING LETTER

June 30, 2022

RE: 613570

Dear Eric Fishman:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at https://monq.com/ in May 2022 and June 2022, respectively, and have determined that you take orders there for various inhalation essential oil products, including but not limited to “sleepy,” “zen,” “ocean,” “sexy,” “relieve,” “mountain,” “bright,” and “peace”[1] (hereinafter collectively referred to as “your essential oil products”). The claims on your website for your essential oil product ingredients, including lavender, ylang ylang, eucalyptus, cinnamon, ginger, peppermint, bergamot, lemon, and rosemary, establish that your essential oil products are unapproved new drugs sold in violation of sections

505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d). As explained further below, introducing or delivering these products for introduction into interstate commerce violates the FD&C Act.

The Department of Health and Human Services (HHS) has determined that a public health emergency exists nationwide involving the opioid crisis.[2] You market various inhalation essential oil products for the treatment or cure of opioid addiction and withdrawal symptoms. However, these products have not been determined by FDA to be safe and effective for these (or any other) uses. Further, the unproven treatments could cause patients to forego or delay FDA-approved treatments for opioid addiction or withdrawal. The marketing and sale of unapproved opioid addiction treatment products is a potentially significant threat to the public health. Therefore, FDA is taking measures to protect consumers from products that, without approval by FDA, claim to diagnose, mitigate, prevent, treat or cure opioid addiction.

Furthermore, the use of your essential oil products raises safety concerns for the agency because the ingredients and/or impurities in oral inhalation products may trigger laryngospasm or bronchospasm, may be toxic to the tissues in the upper or lower airways, or may be absorbed and exert undesirable systemic effects or organ toxicity.

Unapproved New Drugs

Your essential oil products are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body.

Examples of claims observed on your website, https://monq.com/, that establish the intended use of your products as drugs include, but may not be limited to, the following:

On your webpage https://monq.com/blogs/lifestyle/symptoms-addiction-withdrawal:

- **"Best Essential Oils for Symptoms of Addiction and Withdrawal"**

o "Recovering from addiction to anything from drugs and alcohol . . . can be a challenge. The initial discomfort and withdrawal symptoms are well worth it in the end, however, considering the benefits gained by overcoming addiction. Fortunately, there are several ways to help reduce these symptoms. One way of doing so is through aromatherapy."
o **"Aromatherapy for Recovery from Addiction"**
"OPIATE ADDICTION"
o "Best Essential Oils to Help With Opiate Withdrawal Symptoms"
"LAVENDER OIL . . . This multipurpose essential oil is derived from the steam distillation of lavender leaves and flowering tops and is utilized for its relaxing, calming effects. . . . Alternatively, use it through a vaporizer, a room diffuser, or a portable aromatherapy diffuser."
"YLANG YLANG OIL . . . use it aromatically in a room diffuser or personal aromatherapy diffuser."
"EUCALYPTUS OIL . . . The oil produces a stimulating effect on the body and mind. This aids in reducing the lethargy that may be experienced during opiate withdrawal."
"CINNAMON OIL . . . The essential oil can help boost the activity of adrenal glands, in addition to providing relief to confusion, stress, fear, or doubt."
"GINGER OIL . . . Ginger essential oil has a strong, aromatic fragrance, and can help to suppress opiate cravings. When used in a room diffuser, personal aromatherapy diffuser . . . ginger essential oil can relieve fatigue, muscle aches, and stress."

"PEPPERMINT OIL . . . The oil is also helpful in clearing a fuzzy brain, relieving nausea, tension, and headaches, all of which are symptoms of opiate withdrawal. The oil can be . . . used in aromatherapy in a vaporizer, room diffuser, or portable essential oil diffusers."

o **"Essential Oils for Substance Withdrawal Symptoms"**

"BERGAMOT OIL"

"LEMON OIL"

"PEPPERMINT OIL

This essential oil has the effect of relieving headaches and nausea, making it highly effective for aiding in managing the withdrawal symptoms of hard substance abuse"

"ROSEMARY OIL . . . It's also been shown to be effective at aiding in managing substance addiction withdrawal symptoms."

o **"Essential Oils for Alcohol Withdrawal Symptoms"**

"LAVENDER OIL

Lavender oil is one of the best choices for use in aromatherapy to manage the anxiety and psychological stresses related to recovering from alcoholism. Furthermore, the oil is great for aiding in relieving conditions such as hypersensitivity and insomnia related to alcohol withdrawal. The oil is also known to act as a stress-reliever and sedative with calming properties."

"LEMON OIL

Lemon is high in limonene which many studies have shown can have a positive effect on alleviating depression."

"GINGER OIL"

On your webpage https://monq.com/blogs/health-wellness/how-you-can-use-aromatherapybenefits-to-improve-your-overall-wellness:

- **"How You Can Use Aromatherapy Benefits to Improve Your Overall Wellness"**

o "Surprisingly, it seems that serotonin, endorphin, and noradrenaline are all signaled for release in the body with the use of calming essential oils. [] Serotonin and endorphin are two compounds that serve a similar function to that of certain opioids, thus explaining the calming effect that you could experience with regular use."

Your essential oil products are not generally recognized as safe and effective for their above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There are no FDA-approved applications in effect for any of the above mentioned products.

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA and FTC laws and regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of 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. 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 cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance, by email to **FDAADVISORY@fda.hhs.gov**.

FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. §§ 41–57, to advertise that a product can prevent, treat, or cure human disease, including addiction to alcohol, nicotine, or drugs, 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 addiction, no such study is currently known to exist for essential oil products. Thus, any addiction treatment claims regarding such products are not supported by competent and reliable scientific evidence. **You must immediately cease making all such claims** and staff strongly suggests that you review all health-related claims that you or any of your affiliates are making in any medium to ensure that they are properly substantiated and do not violate the FTC Act. **Violations of the FTC Act may result in legal action seeking a Federal District Court injunction. In addition, pursuant to Section 8023 of the Opioid Addiction Recovery Fraud Prevention Act of 2018, 15 U.S.C. § 45d, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of any substance use disorder, including addiction to alcohol, nicotine, or drugs, 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).**

With regard to the advertising claims discussed above, within fifteen (15) working days of receipt of this letter, please notify Rick Quaresima, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rquaresima@ftc.gov of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Quaresima at (202) 326-3130.

Sincerely,
/S/

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

Sincerely,
/S/

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

1 The products “sleepy,” “zen,” “ocean,” “sexy,” “relieve,” “mountain,” and “bright,” are examples of your essential oil products that are labeled to contain one or more of the essential oils lavender, ylang ylang, eucalyptus, cinnamon, ginger, peppermint, bergamot, lemon, and/or rosemary.

2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued October 26, 2017, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx (https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx).

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