WARNING LETTER

RE: 647603

Date: January 10, 2023

TO: hello@medicalmikes.com Mike Vanacoro
Medical Mikes, Inc.
3393 Nutly Circle
Yorktown Heights, NY 10598

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://medicalmikes.com/ on December 7, 2022, and January 6, 2023, respectively. The FDA has observed that your website offers cannabidiol (CBD) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] 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, there was a Presidential declaration of 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 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 products and

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[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, 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.
[3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- "Health Benefits of CBD Oil

  The science behind CBD and health continues to grow every day, and emerging studies have linked CBD to a number of medicinal and health benefits. The application of CBD is broad and can help alleviate symptoms of many common ailments. . . .

  - Boosts Immune System: This 2020 review of existing research concluded that CBD could control immune responses to cytokines, chemokines, and regulatory cell induction, creating a potential use case for Covid treatment by preventing Cytokine Storms–the condition that transforms standard cases into life-threatening scenarios." [From your September 2021 blog post titled "CBD FOR SENIORS: BEST PRODUCTS, BENEFITS, SAFETY, AND USES" https://medicalmikes.com/blogs/medical-mikes-blog/cbd-for-seniors-best-products-benefits-safety-and-uses]

- "Researchers Recommend CBD-Based Clinical Trials for Covid-19 Prevention

  Marsha Rosner of the University of Chicago and her team, who recently published a study in Science Advances, want to see CBD at the forefront of Covid-19 prevention studies. Why? Their widely circulated research indicated that highly potent oral CBD inhibits Covid infection in human lung cells and mice. According to their findings, CBD may work by inhibiting viral gene expression while boosting the body's stress and immune responses." [From your February 2022 blog post titled "COVID-19 AND CBD RESEARCH: THE LATEST FINDINGS AND TAKEAWAYS" https://medicalmikes.com/blogs/medical-mikes-blog/covid-19-and-cbd-research-the-latest-findings-and-takeaways]

- "Lab Research Says CBDa and CBGa Can Stop Covid-19

  We've talked a lot about the potential of concentrated, oral CBD formulas for Covid-19. But what about other hemp compounds? . . .

  Study investigators found that, of hemp's hundreds of cannabinoids, CBDa and CBGa exhibited the most powerful ability to inhibit the Covid protein from seizing human cells. Even more profound, these minor cannabinoids reduced viral infection loads (still, in a petri dish) by an astounding 50%." [From your February 2022 blog post titled "COVID-19 AND CBD RESEARCH: THE LATEST FINDINGS AND TAKEAWAYS" https://medicalmikes.com/blogs/medical-mikes-blog/covid-19-and-cbd-research-the-latest-findings-and-takeaways]

You should take immediate action to address this matter. 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 address any violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations 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 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.

This letter notifies you of our concerns and provides you with an opportunity to address them. 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. 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 may be detained or refused 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) 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.

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 and desist 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 $50,120 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 Serena Viswanathan, Associate Director of the FTC's Division of Advertising Practices, at sviswanathan@ftc.gov certifying that you have ceased making unsubstantiated claims for the product identified above. If you have any questions regarding compliance with the FTC Act, please contact Ms. Viswanathan at 202-326-3244.

Sincerely,

Tina R. Smith -S

Digitally signed by Tina R. Smith -S
Date: 2023.01.10 09:03:01 -05'00'

CAPT Tina Smith
Acting Director
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

Serena Viswanathan

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission