WARNING LETTER

Date: April 1, 2021

TO: info@mynaturaladventure.com – Jennifer Orejobi, Natural Adventure, LLC
13765 SW 32nd Street, Miramar, FL 33027

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 websites at the Internet addresses www.mynaturaladventure.com and on February 26, 2021, and March 12, 2021, respectively. We also reviewed your social media websites at https://www.facebook.com/MyNatAdventure and https://www.instagram.com/mynatadventure/, where you direct consumers to your website, www.mynaturaladventure.com, to purchase your products. The FDA has observed that your website offers Purity Sanitizer with 70% Alcohol and Purity Essential Oil Blend 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).[2]

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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] Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(3), drugs that were classified as Category III for safety or effectiveness in a tentative final monograph (TFM) that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements.

One of the active ingredients in your "Purity Sanitizer with 70% Alcohol" product is ethyl alcohol (ethanol), which is one of the three active ingredients that were classified as Category III for use in consumer antiseptic rub drug products (also known as hand sanitizers) in the most recently applicable proposal, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule).

Your Purity Sanitizer with 70% Alcohol product, however, does not conform to the 1994 TFM, as further amended by the Consumer Antiseptic Rubs Proposed Rule. For example, the labeling for your Purity Sanitizer with 70% Alcohol on the www.mynaturaladventure.com website represents that the product contains "anti-bacterial" essential oils, which were not classified as Category III for use as active ingredients in consumer antiseptic rub drug products

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, 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 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:

- "CORONAVIRUS, CORVID [*sic*] 19, ESSENTAIL [*sic*] OIL, HAND SANITIZER, RAVINTSARA. . . 6 Reasons to Use Ravintsara Essential Oil During the Coronavirus Outbreak and Beyond. . . During the spread of Coronavirus (Covid-19) and even beyond, there are many reasons why you should incorporate Ravintsara into you [*sic*] day to day activities. . . . 1. Ravintsara possesses excellent antibacterial, antiseptic and antiviral properties. 2. This essential oil gem is said to work on viral illnesses relating to the respiratory system and also the immune system. . . So in what products can you find Ravintsara? Products such as essential oils, hand sanitizers. Natural Adventure incorporates Ravintsara into our Purity Hand Sanitizer and Purity Essential Oil Blend." [from your webpage https://mynaturaladventure.com/blogs/blogs/six-reasons-to-use-ravintsara-essential-oil-during-the-spread-of-coronavirus-covid-19-and-beyond]
- "6 Reasons to Use Ravintsara Essential Oil During the Coronavirus Outbreak and Beyond" [from a March 27, 2020 post on your social media webpage https://www.instagram.com/mynatadventure/].
- "During the spread of the Coronavirus (COVID-19), and even beyond, there are many reasons why you should incorporate Ravintsara into you [sic] day to day activities. . . Natural Adventure incorporates Ravintsara into our Purity Hand Sanitizer and Purity Essential Oil Blend." [from a March 27, 2020 post on your social media webpage https://www.facebook.com/MyNatAdventure].
- "#essentialoils101 #corvid19 [*sic*] #quarantine" [from March 27, 2020 posts on your social media webpages https://www.instagram.com/mynatadventure/ and https://www.facebook.com/MyNatAdventure].

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in the 1994 TFM, as further amended. Nor does the product conform to any other TFM, proposed rule, or final rule, and it does not meet the conditions under section 505G(a) of the FD&C Act for marketing without an approved application under section 505. In addition, the formulation of this product is not consistent with the formulations described in the guidance setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency. *See Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* Guidance for Industry, *available at* https://www.fda.gov/media/136289/download.

[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), *available at* https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

You should take immediate action to address 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 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 these 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 your 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.

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 Purity Essential Oil Blend. 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. 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 $43,792 per violation. 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,

Jill P. Furman -S

Digitally signed by Jill P. Furman -S
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Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

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Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission