WARNING LETTER

Date: May 8, 2020

TO: Ivysagarius@seanjaripreeti.com – Ivy Ruffin (Sagarius), Seanjari Preeti Womb Healing, L.L.C.
1000 North Pine Street, Spartanburg, SC 29303

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.seanjaripreeti.com on April 23, 2020 and May 5, 2020, respectively. We also reviewed your social media website the YouTube channel "Seanjari Preeti Womb Healing LLC", at https://www.youtube.com/channel/UCmi5nXusAmAL7DWGMGzwTJA/videos?disable_polymer=1, where you direct consumers to your website, www.seanjaripreeti.com, to purchase your products. The FDA has observed that your website offers a honey product for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. Based on our review, this product is an unapproved new drug 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, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product 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, the President declared 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 such unapproved and unauthorized

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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 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).

[3] 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/).

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

- (VIDEO 0:00 – 1:03) ". . . Developing a formula that's 100% Natural . . . OVER 150 impeccable ingredients . . . you have TO TRY an IMMUNE BOOSTER . . . HAVE PEACE OF FAMILY . . . & PEACE OF MIND . . . we can BEAT THIS with EDUCATION . . . covid19syrup" [From March 22, 2020 post to your social media website at https://www.youtube.com/watch?v=t-jOWyUKI0c]

- "COVID-19 COUGH Syrup . . . THIS IS VERY STRONG MOLASSES. . . A tablespoon to a cup of hot water. Drink this honey daily. Will cause frequent urination. Stay hydrated. Drink only water while detoxing with this honey . . . designed to remove waste from internal and external cells. [from your website www.seanjaripreeti.com/product-page/COVID19HONEY]

- "COVIDXIX SYRUP this is over 175 ingredients t [*sic*] requires three days of preparation . . . We added over 175 herbs to syrup . . . This is very strong. . . . Can pour directly into hot water and drink. May also add this syrup to Hot Apple Cider for Children. Safe for Elderly Men and Women." [from your website www.seanjaripreeti.com/product-page/COVID19HONEY]

- "With the Outbreaks and limited test, its only wise to protect yourself until more help is provided. YOUR HAVE A RIGHT TO TRY COVID-19 COUGH SYRUP. There may be no help till [*sic*] 2021 (vaccination)." [from your website www.seanjaripreeti.com/product-page/COVID19HONEY]

- "NJOY WITH ICE AND FRUIT JUICE – EASIER FOR CHILDREN TO ENJOY FOR LIMITED TIME, GET A BOTTLE OF UNICORN POO [fruity honey] WITH EACH PURCHASE OF COVIDXIX SYRUP****WHILE SUPPLIES LAST [from your website www.seanjaripreeti.com/product-page/COVID19HONEY]

- (VIDEO 0:00-3:09:52) titled "Covid19 Cough Syrup". Beginning around 44:25, "People who have a weakened immune system should be getting COVID syrup. If you have any type of virus in your body you should be drinking COVID [syrup]. . . . If you are living in a state where your numbers [of COVID-19 cases] are high or your numbers are starting to climb really really fast, do what's in your power to get you some COVID [syrup]. We put it on the website. . . . We made it so you could get the larger bottle. . . ." [From a March 29, 2020 post to your social media website at https://www.youtube.com/watch?v=5uxM-iWatXs&t]

- (VIDEO 0:00-1:15:38) titled "Covid19 Preparation Herbal Remedies for Helpless". Beginning around 48:50, ". . . save your whole . . . body from the corona virus, so we made that honey. We put up a promocode on the website so you can so you can go get 20 percent off. . ." [From a March 8, 2020 post to your social media website at https://www.youtube.com/watch?v=rwjCtibwL1M&feature=youtu.be&has_verified=1]

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 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 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 the sale of your 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 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) 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 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 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,

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002198907, cn=Donald D. Ashley -S
Date: 2020.05.08 07:57:12 -04'00'

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

Sincerely,

RICHARD QUARESIMA

Digitally signed by RICHARD QUARESIMA
Date: 2020.05.07 14:22:04 -04'00'

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