U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

Date: December 10, 2020

TO: zzxblaze@att.net – Steve Crear, Indigenous Products
Dallas, TX 75232

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 Facebook page[1] at the Internet address https://www.facebook.com/Indigenous-Products-106070747498475/ on December 02, 2020, and December 4, 2020, respectively. The FDA has observed that your Facebook page offers mineral products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[2] 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.[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 such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

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[1] We observed that you direct consumers to your website, www.indigenousproduct.com, via your Facebook page and other media. As of December 02, 2020, the website, www.indigenousproduct.com, redirects to your Facebook page where you offer mineral products for sale.

[2] As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

[3] 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). The declaration has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible athttps://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx).

[4] 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/).

Some examples of the claims on your Facebook page 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:

- On a March 17, 2020 post: "Coronavirus Alert! Let indigenous product show you how a superior immune system can protect you and your family * . Learn how, video coming soon or call me now!"
    - You replied to this post with "Indigenous Products" and a YouTube video link at https://youtu.be/c-YjUd6siF8, which states:
        - At 04:15: "the corona virus basically is a living organism, it is a virus, it is a virus that is looking for a host to where it can live . . . but there's a way that you can change the genetics of your body where a virus can't live . . . and we're going to talk about it today"
        - At 07:45: "the electromagnetic Nano particles inside of indigenous product . . . will eradicate the infection inside of the body and you can call the infection coronavirus . . . it doesn't matter, it destroys it."
        - At 11:09: "The coronavirus, everybody seems to be talking about that. And one of the most deadliest things that it does C O V I D-19 is it attacks the respiratory system. Well let's talk about something, I hear a lot of talk about how do we fight this invisible enemy, how do we fight this invisible enemy? It's an invisible enemy. Well let's take the invisible and fight the invisible with the invisible. How about that. Let's talk about physics. Let's talk about this what I'm holding in my hand [while pulling out and holding a bottle of your product] . . . I'm not telling you that this cures the virus, I'm telling you it kills viruses." [while holding a bottle of your product].
        - At 50:53: "As far as it comes down to price . . . the Ionic Plus is 36.50 for one bottle . . . Yup, now this is the 50p [while holding one of your products], it goes with the nebulizer . . . you're just dealing with something that they call C O V dash I D 19. Put this in the nebulizer and you will sleep good at night . . . this is the nebulizer . . . once you put the 50p, the one that I showed you here in this little container and you close this off and you're having breathing problems you suck on this here for about 30 minutes . . . it destroys the viruses . . . It regenerates the tissue inside of the cell structure of the respiratory system. . .[while a chyron displays Indigenousproduct.com]"
        - At 55:10: "what do we do to make sure that we're not exposing ourselves to Covid-19, what we can do to counteract those things by taking these indigenous products as designed to strengthen our immune system"

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 product identified above. 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. 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
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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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Date: 2020.12.10 08:55:15 -05'00'

Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission