WARNING LETTER

Date: August 3, 2020

TO: info@mmstabs.com – Terance Winson, MMSTabs.com
terancewinson.capetown@gmail.com

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.mmstabs.com on July 20, 2020, and July 30, 2020, respectively. We also reviewed your social media website at www.facebook.com/mmstabs, where you direct consumers to your website, www.mmstabs.com, to purchase your products. The FDA has observed that your website offers MMS products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-191 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, 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 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:

- “The Coronavirus [sic] (COVID-19) has brought the world to its knees. A highly infectious disease that originates from the animal kingdom . . . BE PROACTIVE, READY YOURSELF WITH

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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).
PREVENTATIVE AS WELL AS PROTECTIVE MEASURES. Our product has been tested in China for the past month and as we all know, Chlorine Dioxide (CLO2) destroys a virus naturally. The world's [sic] most natural gas, CLO2 oxidises the outer layers of a virus and exposes it to oxygen (O2).

- “From many resources on the ground we have established a COVID-19 PROTOCOL and have added additional safety measures to protect you from the virus.”

- “If you want to be precautionary (preventative) or if you have flu like symptoms or confirmed to have COVID-19 - please follow the below protocol.
  o Dissolve ONE TABLET in 2L (67 USA Oz) of water and drink use one glass (125ml) every two hours. Repeat this for eight to ten times a day. Repeat again second day. When symptoms subside you can pull back the dose to one glass (125ml) every two hours for two days. FOR PREVENTATIVE MEASURES: Use one glass every three hours a day while you are in containment and do not make contact with anyone from the outside. For children under the age of 16 - please dilute the 125ml glass of the solution by half and repeat the protocol. IMPORTANT: Please keep your solution in an air tight container and away from the light. Inside a fridge is best.
  o NASAL & MOUTH SPARY [sic]: Dissolve ONE TABLET in 1.5L (50 USA Oz) of water and keep your solution in an air tight container and away from the light. Inside a fridge is best. Pour your solution into the nasal or mouth dispenser provided and dispense the liquid inside your nose and deep into your throat with three squirts per application. Because the virus resides in the upper regions of the body, this application shows BEST results. Spray deep into your nostrils and mouth every hour - allowing the mixture to run down the back of your throat. If the solution is too [sic] strong for your throat or nose, then please dilute the solution with some water until you happy with strength. IMPORTANT: Keep your nasal or mouth spray in the fridge and in the dark at all times” [from your website, https://www.mmstabs.com/index.php?route=product/product&path=85&product_id=125].

  Our protocol has been tested in China for the past two months and is been used around the world. Chlorine Dioxide (CLO2) destroys all viruses naturally. FACT! The world’s [sic] most natural gas, CLO2 oxidises the outer layers of the virus and exposes it to oxygen – destroying it. FACT! From many resources on the ground we have established a COVID-19 PROTOCOL and have added additional safety measures to protect you from the virus . . . All these products are loaded with COVID-19 virus killing MMS . . . https://www.mmstabs.com” [from an April 4, 2020 post on your Facebook page, www.facebook.com/mmstabs].


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](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 for products that you advertise, market, sell, or otherwise promote or make available in the United States. 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
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission