WARNING LETTER

Date: June 30, 2020

TO: DrTom@DrTomYarema.com – FrontDeskStaff@DrTomYarema.com

Tom Yarema, M.D.

on June 17, 2020, and June 25, 2020, respectively. The FDA has observed that your website offers a "COVID Supplement Protection Pack" (also referred to as the "COVID Household Value Pack"), Thymosin-Alpha, and Methylene Blue Capsules 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.SU. e productmc.9.(e p)10.5E4DfiSU.SU(r)-6 (oduc)8[(ve)1(i)9.7(li)22t6TC/s.2e m Cted Sü&ˆˆ&

named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the

these are for PREVENTION, and one (1) is for EARLY TREATMENT of symptoms. . . . COVID's greatest hallmark, and it's [sic] greatest danger is it's [sic] RAPID PROGRESION in severe cases. . . . The 4th Horseman, SILVER FLOWER caps, are designed to 'buy time' during a RAPID ONSET of symptoms, especially if one feels 'short of breath' or 'winded with minor exertion.'"

- On a webpage titled "Supplies" which includes the products in the COVID Supplement Protection Pack, Thymosin-Alpha, and Methylene Blue Capsules:
    - "During the COVID pandemic, we will be sourcing, stocking, and shipping for your home-use products personally vetted by Dr Tom for their Immuno-Supportive effects."
    - "These products are tiered according to usage:
        - improving immunity of the tissues most susceptible to COVID viral attack
        - improving immune response once the virus has entered the body
        - improving immune response after one experiences respiratory symptoms or fatigue
        - improving immune response for those whom are at high risk for moderate-to-severe COVID disease"
- In the description of your "Covid Supplement Protection Pack":
    - "'Ascorbic Acid' is a fancy name for Vitamin C. . . . it has long been known in OrthoMolecular Medicine to be a valuable anti-viral agent both orally and intra-venously. . . Currently, IV Vitamin C is under clinical trials in Shanghai for COVID hospitalized patients."
    - "Vitamin D3 . . . Cell culture experiments demonstrate Vit D's direct anti-viral effect, especially in 'enveloped' viruses like Cornaviruses."
    - "Golden Flower Tea . . . inhibit[s] pathologic micro-organisms such as bacteria, fungi and respiratory viruses. The tea improves lung & GI immunity – the portal of attach of the Coronavirus. . . . [I]t assists in the exteriorization (or 'shedding') of respiratory viruses."
    - "Silver Flower capsules are a US version of 'Qingfei Paidu Decoction' developed and clinically tested in Wuhan, Hubei and 3 surrounding providences in Jan-March 2020. . . . 'Qingfei Paidu Decoction' was used to treat 214 confirmed Coronavirus cases. . . . Silver Flower formula is made from the same herbal ingredients as the original 'Qingfei Paidu Decoction'."

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 or service 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. Additional examples of claims for products or services that are not supported by competent and reliable scientific evidence include:

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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

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