



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: June 30, 2020

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

Tom Yarema, M.D.
Center for Wellness and Integrative Medicine
3121 Park Avenue, Suite D
Soquel, California 95073

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 <https://drtommyarema.com> 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-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 website 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 webpage titled “COVID Household Value Pack,” you represent the following: “I recommend each and every family purchase the ‘4 Horsemen’ to outrun the tide of COVID. . . . Three (3) of

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>). The declaration was renewed for another 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. April 21, 2020.

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/>).

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 Coronaviruses."
 - "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'."
- "Thymosin-Alpha has been shown to have a multiple mechanisms of actions upon immune cells. . . . Studies have demonstrated benefit for a range of diseases which harbor age- or disease-related immune senescence/weakness. . . . I'm recommending individuals which [sic] chronic immune debility use this for 3-4 months during the oncoming tide of COVID infections."
- From a March 22, 2020 post: "#1 Easiest way to prevent Coronavirus exposure from developing into severe COVID infection: Vitamin C."

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 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:

- On the webpage titled “Supplies,” you state, “Currently, IV Vitamin C is under clinical trials in Shanghai for COVID hospitalized patients.... If you find yourself ‘behind the 8-ball’, click here to schedule an IV Vitamin C infusion in the Center.”
- In a May 16, 2020 blog post titled “Is there ‘HARD’ science supporting Nutritional Medicine against COVID?,” you state, “While news and many doctors proclaim ‘there is NO SCIENCE to support nutritional medicine against THIS novel Corona virus,’ the exhausting work of responsible nutritional medicine marches forward. For those of you wanting to BE INFORMED on PEER-REVIEWED SCIENCE ... not spin ... not internet marketing ... I’ve done the HARD work for you already.... If COVID is going to be around for a while, or if it becomes worse this Fall, or if it becomes a way of life for years to come ... only time will tell. No matter how this plays out ... your Foundational Nutrition is paramount. That’s why we are open every M – F, 9am – 5:30pm Pacific, to support your body’s regenerative and immune processes with:
 - IV nutrient therapies
 - Ozone immune & metabolic stimulation
 - B-12 injection kits for home use”
- In a March 24, 2020 blog post titled “Wouldn’t it be great to have a MILD rather than SEVERE infection? Boost your Immunity now,” you state, “With our community harboring COVID, there are many uncertainties about how sick one might become. The CDC expects more than half of the US will become infected. ***Rather than just wait and be a victim of the epidemic, wouldn’t you like to be doing something proactive?...*** Our ‘**Weekly Immune Booster Injection**’ is a scientifically-validated, time-tested method of immune stimulation. This is done by a weekly injection of a small amount of your own blood, mixed with saline and ozone. It takes about 10 minutes, and doesn’t hurt.... If we are going to be eventually exposed, let’s **ALL** have a **MILD CASE** and get on with life.”

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
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