

Serena Viswanathan Associate Director Division of Advertising Practices United States of America FEDERAL TRADE COMMISSION Washington, D.C. 20580

November 4, 2021

CEASE AND DESIST DEMAND

VIA FEDEX TO

Mr. Timothy Pendry Sunshine Health Foods & Wellness Center 2916 South Washington Avenue Titusville, Florida 32780

Re: Unsubstantiated claims for Coronavirus prevention and treatment

Dear Mr. Pendry:

This is to advise you that in October 2021, FTC staff reviewed your social media website at <u>https://www.facebook.com/pages/category/Health-Food-Store/Sunshine-Health-Food-and-Wellness-Center-149086378451637/</u>, where you market various supplements including Quercetin, NAC, and Vitamin D. We have determined that you are unlawfully advertising that certain products treat or prevent Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or cure claims on your website include:

• In a September 10, 2021 Facebook post you state:

"Are you taking your vitamin D? If not, here is a good reason for making sure you are taking a healthy dose. In a recent meta-analysis which incorporated health data from almost 14,500 people who were hospitalized with COVID-19 infections, researchers found a significant correlation between lower serum concentrations of vitamin D and increased risk of becoming infected with the virus. Some practitioners suggest as much as 20,000 international units daily.

'While vaccination programs are widespread and the number of vaccinated patients grows, the underlying risk factors for the severe course of COVID-19 are still being investigated,' the authors of the study wrote. 'The common denominator for all of these

risk factors is the disturbed immunological response which may in fact be the underlying mechanism for the severe course of COVID-19. One of the most common and thoroughly examined causes of immunosuppression is vitamin D deficiency it comes as no surprise that in the era of COVID-19, vitamin D became an object of interest for much research worldwide in terms of preventing the severe course of the disease."

• In an August 30, 2021 Facebook post you state:

"Many are overwhelmed by opinions and protocols that span from sound science to the outer boundaries of conspiracy. It is a challenging time for Americans. Maintaining the right of choice is being challenged by practical concerns of the mandatory venue; and the press sends out its tentacles of fear and confusion fueling protest opposing views. The press has taken the sound articles of the government and manipulated them into a source of profound division. It is getting worse daily, and so it seems, is the pandemic. But there are alternative steps that one may take to protect themselves from the virus with or without vaccinations. It is encouraging to see that many of these alternative medical professionals are on the same page, although opinions about the dosing vary significantly. Most of the studies I have read tend to suggest heavier dosing. Here is a list of Nutraceuticals and Minerals that are currently recommended. They are Nano Colloidal Silver, Vitamin C (Pure Way), Vitamin D&K, Quercetin, N Acetylcysteine (NAC), and Zinc. Other recommendations include Olive Leaf Extract and Oregano Oil."

This post includes an image depicting a coronavirus with its spike proteins, with the text "TIM TALKS ABOUT COVID" superimposed.

In response to a comment on this post asking "How much ppm of colloidal silver should we get?," you state: "500 ppm would be good."

• In a July 26, 2021 Facebook post, you state:

"N-Acetylcysteine is generally identified as a nutraceutical that has been offered in the natural health care market for decades providing nutritional support to the respiratory tract. It is seen as a source of support for people struggling with asthma and COPD....

Why not enhance the immune system with NAC along with essential vitamins A, C, D, and the trace mineral zinc and selenium? It seems the pharmaceutical companies want to artificially intervene and introduce their patented antibody-provoking vaccines. There are three problems with that approach.

- 1. Mutation, just like influenza viruses.
- 2. Inadequate vaccine-induced antibodies in adults age 45-60 when compared to younger subjects. Neutralizing antibody drugs are under development and may

help those who don't respond to COVID-19 vaccines, but until they gain regulatory approval, NAC may fill this therapeutic gap.

3. T-cells, not antibodies, control COVID-19 infection long-term, NAC becomes more attractive because of its ability to raise T-cell counts via its ability to increase glutathione levels. Furthermore, NAC activates a type of white blood cell (natural killer cells that kills virally infected cells."

This post includes a link to an article titled "FDA Protects Covid-19 Vaccine Makers Seeks Withdrawal of Competing Dietary Supplement" available at https://www.lewrockwell.com/2021/05/no_author/fda-protects-covid-19-vaccine-makers-seeks-withdrawal-of-competing-dietary-supplement/.

• In a May 25, 2021 Facebook post you state:

"Tim Talks about NAC (N-Acetylcysteine):

With the help from NCBI, I have copied the protocol for the use of NAC in the treatment of COVID. Therefore the FDA is threatening to list NAC as a 'therapeutic agent' [a drug rather than a supplement], and thus remove it from our shelves. The thinking maybe that NAC will then be compared substandard (even though it works) to the vaccines and control NAC out of the market completely. Thankfully, we have plenty of NAC in stock from Health Comes First & Bluebonnet! Want to stock up? Don't forget we offer a 10% discount when you buy 3 like supplements!"

This post includes a graphic detailing different dosages of NAC dosages during various stages of COVID-19 development.

• In a March 12, 2021 Facebook post at you state:

"...But miracles do happen as Congressman Glenn Grothman (R-WI) has introduced a House Resolution to 'recognize the significant role Vitamin D might play in the fight against COVID 19'. Finally, reliable scientific data provided by medical professionals supporting the daily recommended intake of Vitamin D at 4,000 IUs, up from 400 IUs, to reduce the severity of Covid-19 is available. Yet both the FDA and the FTC have apparently attacked Doctors for simply sharing the good news (because Vitamin D is not approved for Covid-18 [sic]) that a natural preventative agent is on hand, along with other nutritionally based initiatives. We have Vitamin D under numerous labels, strengths, and forms. Ask for Health Comes First Vitamin D. If you have liver issues, general fat digestion problems or your Gallbladder removed, use the DRY FORM by Soloray instead."

• In a November 6, 2020 Facebook post you state:

> "I have been approached by twenty plus research-oriented individuals, some of which are medical professionals including MDs and DOs and other smart guys, with nutritional and pharmaceutical interventions for the SARS-CoV. The most compelling information I came across is from the Virology Journal published on line 2005 Aug 22. CHLOROQUINE IS A POTENT INHIBITOR OF SARS CORONOVIRUS [sic] INFECTION AND SPREAD. Match that with the information found in Dr. Seheult's MedCram mini lectures on YouTube (#35) regarding the potency of quercetin as an ionophore option to Chloroquine or Hydroxychloriquine [sic] with track record of success in treating the Ebola and Zika virus, and you have a readily available and comparably inexpensive nutritional supplement for support against viral attacks. Use Quercetin by Health Comes First!"

This post includes an image depicting a bottle of Solaray Mega Quercetin supplement and a bottle of Health Comes First Quercetin 500 Plus supplement, with the text "TIM TALKS ABOUT GETTING BACK TO CHLOROQUINE (QUERCETIN)" superimposed.

• In an October 5, 2020 Facebook post you state:

"The President's protocol is surprisingly simple except for the drug(s) that had been released for his treatment. I have found enough information about Hydroxychloroquine and its off the shelf relative Quercetin, that suggest they may help the body protect itself from RNA based viruses like COVID. Though it still remains an option, not currently recommended by Trump's physicians due to a large amount of push back from big Pharma.

Hence, I am still using it with Zinc, about 50 mg daily. No need to consider Zinc a mega nutrient. The important thing is to not become deficient. Then, there is Vitamin D. I take up to 10,000 IUs for immunity and protection from the sun. I've seen larger doses recommended by alternative care physicians. Next is Melatonin, an indigenous hormone in the serotonergic cascade that evidently provides some ancillary benefits of which I am not aware. Melatonin is well known as a natural sleep aid used mostly for sleep habit adjustments due to jet lag. Melatonin's apparent antioxidant behavior has benefits in the treatment of breast cancer in very large doses according to Dr. Eric Braverman, MD. Finally, an anti-histamine was mentioned. Since I have minor Methylation (MTHFR) defect causing an elevation of histamines in my body and a subsequent increase inflammatory response, I use the expensive [but naturally safe] Diamine Oxidase Enzyme – an enzyme that specifically reduces histamines.

Therefore, this is my preventative scheme for COVID19. So far, so good! I am surprised that the President is not on Vitamin C. Remember, he is on an IV Cocktail that has recently made available drugs in it as well as the older steroid Dexamethasone; perhaps for a more aggressive approach in reducing inflammation."

This post includes an image of the White House with the text "TIM TALKS ABOUT THE PRESIDENT'S PROTOCOL FOR COVID19" superimposed.

• In an August 15, 2020 Facebook post you state:

"School is about to be back in session... immune support is even more important this year with COVID-19... keep those kiddos safe with these preventative measures!"

In this post you share an August 8, 2018 post from your social media account in which you state:

"The kids are about to start school. For many students school is not only a challenge mentally, it is a challenge to their immune system.... Use these top 5 immune system supporting supplements to keep your kids, teenagers, grandparents, & yourself health from the start of the school year to the end!" The August 8, 2018 post includes an image depicting five bottles of Health Comes First supplements: Zinc Lozenges; Olive Leaf; PureWayC; Vitamin A and Vitamin D; and Garlic.

• In an April 11, 2020 Facebook post you state:

"We've talked about quercetin's benefits before, but now we are focusing on it's [sic] capacity to function as a biochemical relative of both chloroquine and hydroxychloroquine in terms of their common antiviral properties specific to the corona virus. For your additional education in the matter I can refer you to a brief lecture by Dr. Sheheult, who mentions the benefits of all three before Trump broke the news of their efficacy almost a month ago. So type in 'corona virus update 35' for great information on all three of these therapeutic agents.

Back to quercetin. Along with its possible benefits as a anti-coronal viral agent, quercetin has a bevy of benefits that make it a safe choice with many benefits. These biological properties provide elements contributing to overall health and disease prevention, including... ANTIVIRAL activities....

So I suggest you can't lose using this as a preventative. Over the counter, inexpensive (\$28 for 50 500 mg tablets) and possibly as effective as hydrochoroquine in protecting you from the Coronavirus! –Tim"

This post includes an image depicting a bottle of Health Comes First Quercetin 500 Plus with the text "Tim Talks About Quercetin For Prevention...Again" superimposed.

• In a March 19, 2020 Facebook post you state:

"There is no shortage of statistics during this pandemic crisis and if you read the fine print you'll see that the data group with the greatest numbers is the recovery group running at 90% today.... Probably the most significant question is the frequency of cases that practiced prevention... And, how simple it is to practice prevention enough to avoid what may be a very serious challenge to your health.

In my home and office I have aleast [sic] one bottle of oregano oil, a bottle of silver, and a bottle of olive leaf extract with in [sic] reach and use one or the other 2-3 times daily at least, and more if there are any symptoms at all, regardless of how mild. That's prevention.... The point is that there are significant steps we all can take to protect our immunity and maintain a superior state of health...

One other bit of Positive news. There is a drug used for malaria called plaquenil, hydroxychloroquine and chloroquine. These are related to the OTC supplement Quercetin. These seems [sic] to block the invasive properties of the Corona Virus. I first read about this on the Coronavirus Pandemic Update 35 under Medcram- Medical lectures. Now today I understand the President mentioned Hydroxychloroquine and related studies as a possible treatment option. The Chloroquine biochemical is simular [sic] to Quercetin, and subsequent studies show Quercetin to inhibit other influensa [sic] like Viruses. Quercetin therefore maybe [sic] an effective tool to supplement the immune system against viruses like Covid 19. Quercetin is regularly available at the store. We are here to help! Stay healthy! - Tim"

This post includes an image depicting a bottle of Health Comes First Quercetin 500 Plus supplement, with the text "TIM TALKS PREVENTION IN DANGEROUS TIMES" superimposed.

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 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 and services are not supported by competent and reliable scientific evidence.

You are also advised to review all other claims for your products and immediately cease and desist from making claims that are not supported by competent and reliable scientific evidence. You must immediately cease and desist making all such claims.

Violations of the FTC Act may result in legal action seeking a Federal District Court injunction. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to

a civil penalty of up to \$43,792 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b).

Within 48 hours, please send a message to Richard Cleland, Assistant Director via electronic mail at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Richard Cleland at 202-326-3088.

Very truly yours,

Serena Viswanathan Associate Director Division of Advertising Practices

cc: Facebook via email to consumerpolicy@fb.com