



WARNING LETTER

Date: July 28, 2021

TO: thomaspolucki@gmail.com – Thomas Polucki
Dr. Thomas Polucki Upper Cervical Chiropractic
25050 Peachland Ave #105
Newhall, CA 91321

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://getbetterxshop.com> on June 2, 2021 and June 9, 2021, respectively. The FDA has observed that your website offers your Nitric Oxide Support and Melatonin 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, there was a Presidential declaration of 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 any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

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, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

³ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

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:

Nitric Oxide Support product

- “Nitric Oxide Inhibits the Replication Cycle of Severe Acute Respiratory Syndrome Coronavirus

This significant study (1) demonstrated that:

- An organic NO donor significantly inhibited the replication cycle of coronavirus.
- NO inhibits viral protein and RNA synthesis.
- Furthermore, NO inhibits the SARS CoV replication cycle.”

[from your website <https://getbetterxshop.com/?product=nitric-oxide-support>]

- You also tag your Nitric Oxide Support product pages with “coronavirus” and “COVID19”.
[<https://getbetterxshop.com/?product=nitric-oxide-support>]

Melatonin product

Under the heading “Coronavirus”:

- “The COVID-19 crisis creates prolonged stress, anxiety and sleep deprivation. The not so obvious effects of uncertainty, and sustained isolation creates severe negative effects on the immune system and the ability to resist coronavirus....
... [L]ong term stress depletes the body’s ability to fight off infection. While so much attention focuses on costly and potentially dangerous treatment options, Melatonin remains inexpensive, with a long shelf life, self-administered orally. With no severe side effects reported in the case of occasional overdose.”
[from your website <https://getbetterxshop.com/product/melatonin/>]
- You also tag your Melatonin product page with “coronavirus” and “COVID19”.
[<https://getbetterxshop.com/product/melatonin/>]

You should take immediate action to address 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-CFSAN@fda.hhs.gov** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations 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 actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. 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 may be detained or refused 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-CFSAN@fda.hhs.gov.

FTC Cease and Desist Demand: 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. We also reviewed your website <https://santaclaritachiropractor.com/>, and additional examples of claims for products or services that are not supported by competent and reliable scientific evidence include:

- “Sometimes we could all use an immune boost. Jeri was on the diamond princess when they all got quarantined with COVID-19. And everyone in her party tested positive for the coronavirus. But she never did. First, this baffled researchers from around the world as they studied her blood for months. Because at the time they needed as much help on creating the vaccine as possible. But they could never figure out why she never even tested positive for the virus antibodies. While many people exposed to coronavirus don’t get sick nearly all of them will test positive for exposure ... So what is so different about Jeri? .. [I]f you act more like her you too could have the same immune boost that kept her Covid proof. And that immune boost is not as hard as you might think.... So what’s Jeri’s secret? Even though Jeri promotes her relationship with upper cervical chiropractic care... And the immune-boosting supplements she takes... None of that ever made any news story. Jeri found a way to create an amazing defense against viruses long before the pandemic. .. Both upper cervical chiropractic care and functional medicine when done properly focus on restoring balance and function. And for Jeri, that’s exactly what she needed. Because to this day she tests negative for Covid antibodies. ”

[from your website <https://santaclaritachiropractor.com/blog/post/immune-boost>]

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 an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, 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 Mr. Cleland at 202-326-3088.

Sincerely,

**Michael W.
Roosevelt -S**

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W. Roosevelt -S
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Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

**SERENA
VISWANATHAN**

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Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission