

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. D 304.804.8006 0s ad Sin pen pen pen pen pe5.9 Jjr

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 depl44.2 (u)22etroia(t=)19.9 (n)-44.2 (itr)32.7 (ADC d22.2 (Tf()TMC/P MCID 16 BT.7 (

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.

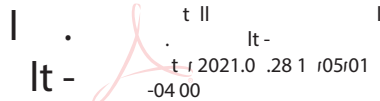
If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you 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 _____

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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,



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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
Digitally signed by SERENA VISWANATHAN
Date: 2021.07.21 12:56:46 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission