



**FDA U.S. FOOD & DRUG
ADMINISTRATION**



WARNING LETTER

Date: November 17, 2020

TO: caspar.szulc@innovativemedicine.com – Caspar Szulc, Innovative Medicine LLC
info@innovativemedicine.com 37-18 Northern Boulevard
Suite 202
Long Island City, NY 11101

CC: regulatory-inquiries@amazon.com – Amazon Associates Program

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 websites at the Internet addresses <https://innovativemedicine.com> and <https://nadovim.com> on September 15, 2020 and November 2, 2020, respectively. We also reviewed your social media website at <http://www.instagram.com/nadovim/>, where you direct consumers to your website <https://nadovim.com> to purchase your product “Nadovim.” The FDA has observed that your website offers “Nadovim” for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. Based on our review, this product is an unapproved new drug 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, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

While reviewing your website <https://innovativemedicine.com>, FDA observed that you also participate in the Amazon Associates program. As an Amazon associate, you earn commissions by promoting the sale of certain products offered for sale on Amazon.com (identified in the quoted claims and Amazon associate links below, and hereinafter referred to as “Amazon associate products”)² with claims on your website representing or implying that the products can mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Based on our review, these claims cause the Amazon associate products purchased through links on your website to be unapproved new drugs under 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. Causing 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). In addition, it is a prohibited act under section 301(k) of the FD&C Act, 21 U.S.C. § 331(k), to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

¹ As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

² Specifically, your website contains links that direct consumers to the Amazon.com website to purchase the Amazon products you promote. As described in the Amazon Associates Program Fee Statement (<https://affiliate-program.amazon.com/help/operating/policies/#Associates Program Fee Statement>), accessed April 22, 2020), Amazon calculates your commission or “fee” by using your website’s Amazon associate ID to track sales to consumers who are redirected to Amazon.com by clicking one of the links on your website.

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.³ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.⁴ 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 a product that is 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 websites that establish the intended use of your product “Nadovim” and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

- Under the heading “Why Science Suggests NAD+ Might Give Us A Fighting Chance Against the Coronavirus (COVID-19)”:
 - “Scientists have known for years that NAD+ is the only direct activator of SIRT1, and now innovative research on the coronavirus has shown a new benefit: a chance to fight back against your body’s own response to the infection.”
 - “[I]f you’re looking to take the fight to the next level, increasing your SIRT1 activity might just slow down the infection enough to give your body a better chance of recovery.”
 - “. . . [W]ith the added benefits of SIRT1 activation – there is no better time to reap the benefits of NAD+ by adding in 3 pills a day of Nadovim to better arm your cells against viral infections.”

[from your website <https://nadovim.com/why-science-suggests-nad-might-give-us-a-fighting-chance-against-the-coronavirus-covid-19/>]

- “The Coronavirus hijacks the mTOR cellular pathway to initiate it’s [*sic*] viral replication. The Sirt1 protein blocks the mTOR pathway. NAD+ activates Sirt1.” [from a May 12, 2020 post on your Instagram account at www.instagram.com/nadovim/]

In addition, as an Amazon associate, you promote and participate in the sale of products for use in mitigating, preventing, treating, diagnosing, or curing COVID-19 in people, as evidenced by the claims from your website quoted below. We request that you immediately cease promoting and participating in the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

³ 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 has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx>).

⁴ 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/>).

Some examples of the claims on your websites that establish the intended use of your Amazon associate products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- Under the heading “Coronavirus Preparedness: Our Top Immune Boosting Supplements” on your webpage <https://innovativemedicine.com/coronavirus-preparedness-our-top-immune-boosting-supplements/>:

“Even with the most cautious habits, sometimes the virus prevails. IM has taken the time to list researched supplements that strengthen our already sophisticated immune system and help fight pathogenic invaders. Each supplement recommendation comes straight from the medical minds at NYCIM, and most of the staff here at IM takes them too.

...

9 Immune Boosters Sure to Keep You Healthy:

1. Mushrooms – Chaga (Maine Chunks) [links to <https://www.amazon.com/Mushroom-Premium-Sourced-Harvested-Servings/dp/B00GI6W83W/>] ...

2. RM-10 – Garden of Life Organic Fermented Mushroom Complex – Immune System Supplement with Selenium [links to <https://www.amazon.com/Garden-Life-Organic-Fermented-Mushroom/dp/B000GWLGHI/>] ...

...

4. Probiotics – Genestra Brands – HMF Forte – Four Strains of Probiotics to Promote GI Health [links to <https://www.amazon.com/Genestra-Brands-Strains-Probiotics-Capsules/dp/B003IG7PHY/>] ...

5. Vitamin C – Sunflower Formula Liposomal Vitamin C 1000 [links to <https://www.amazon.com/Optimized-Liposomal-SUNFLOWER-Quali®-C-Absorption/dp/B00YM8JRZU/>] ...

...

7. Elderberry – Dr. Dünner Sambu Guard Black Elderberry Syrup with Elderflower, Echinacea & Vitamin C [links to <https://www.amazon.com/Dr-Dünner-Organic-Elderberry-Elderflower-Echinacea/dp/B0763YL9HY/>] ...

8. Vrl-Gen (Genestra) – Genestra Brands Vrl-gen [links to <https://www.amazon.com/Genestra-Brands-Vrl-gen-Buckthorn-Supplement/dp/B00CFU0QKW/>] ...

9. Sea Buckthorn – Sea Buckthorn Seed Oil, Made with Organic Sea Buckthorn” [links to <https://www.amazon.com/gp/product/B004BKLHFW/>]

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 and your activities as an Amazon associate 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 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 selling and promoting the sale of 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 and your activities as an Amazon associate 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-CFSAN@fda.hhs.gov.

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. 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,

William A. Correll
Jr -S

Digitally signed by William A.
Correll Jr -S
Date: 2020.11.16 18:44:46 -05'00'

William A. Correll
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA
VISWANATHAN

Digitally signed by SERENA
VISWANATHAN
Date: 2020.11.05 09:15:15 -05'00'

Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission