WARNING LETTER

Date: November 17, 2020

TO: caspar.szulc@innovativemedicine.com info@innovativemedicine.com

Caspar Szulc, Innovative Medicine LLC
37-18 Northern Boulevard
Suite 202
Long Island City, NY 11101

CC: regulatory-inquiries@amazon.com

Amazon Associates on September 8-15, 2020 and November 2, 2

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-19[1] 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.

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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-

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, o 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, whe 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