

WARNING LETTER**Mercola.com, LLC****MARCS-CMS 607133 – FEBRUARY 18, 2021****Product:**Food & Beverages

Recipient:

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Center for Food Safety and Applied Nutrition (CFSAN)
United States

WARNING LETTER

Date: February 18, 2021

Cc: TAHarrison@Venable.com
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Venable LLP

Attn: Todd A. Harrison

Attn: Leonard Gordon

600 Massachusetts Ave., NW

Washington, DC 20001

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) reviewed your websites at the Internet addresses <https://www.mercola.com> and <https://www.mercolamarket.com> on February 8, 2021. We also reviewed your social media site at <https://www.twitter.com/mercola>, where you direct consumers to your website <https://www.mercolamarket.com> to purchase your products. The FDA has observed that your website offers “Liposomal Vitamin C,” “Liposomal Vitamin D3,” and “Quercetin and Pterostilbene Advanced” 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 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 products, based on statements about the purported effects of their ingredients, and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “Vitamins C and D are finally being adopted in the conventional treatment of novel coronavirus, SARS-CoV2. This fortunate turn of events is likely to save thousands of lives” [from an April 7, 2020 post on your Twitter page, <https://twitter.com/mercola/status/1247540121919827970>]

From your article titled “Vitamin C and D Finally Adopted as Coronavirus Treatment” (<https://articles.mercola.com/sites/articles/archive/2020/04/07/coronavirus-treatment.aspx>):

- “Vitamins C and D are finally being adopted in the conventional treatment of novel coronavirus, SARS-CoV-2.”
- “Vitamin C at extremely high doses acts as an antiviral drug, actually killing viruses.”
- “Vitamin C Is a Vastly Underutilized Antiviral ‘Drug’”
- “Another powerful component in the prevention and treatment of influenza is vitamin D. Although vitamin D does not appear to have a direct effect on the virus itself, it does strengthen immune function, thus allowing the host body to combat the virus more effectively. It also suppresses inflammatory processes. Taken together, this might make vitamin D useful against SARS-CoV-2 infection.”
- “In my view, optimizing your vitamin D levels is one of the absolute best strategies available to prevent respiratory illness of all kinds.”
- “Based on the available scientific evidence, there's no reason to ignore vitamins C and D for the prevention and treatment of COVID-19 and other respiratory infections.”
- “Vitamin C is also a crucial aid, both for the prevention and treatment of viral illnesses. You can find pertinent reports and research about vitamin C against COVID-19 on the Orthomolecular Medicine News Service website. I recommend using liposomal vitamin C, as it allows you to take far higher dosages than regular vitamin C”

From your article titled “Nutrition and Natural Strategies Offer Hope Against COVID-19” (<https://articles.mercola.com/sites/articles/archive/2020/03/29/andrew-saul-vitamin-c.aspx>):

- “Vitamin C . . . kills pathogens, including viruses, when taken in high doses.”
- “[T]he government of Shanghai has issued official recommendations that vitamin C should be used for treating COVID-19.”
- “High-Dose Vitamin C Kills Viruses”

From your article titled “Quercetin and Vitamin C: Synergistic Therapy for COVID-19” (<https://articles.mercola.com/sites/articles/archive/2020/08/24/quercetin-and-vitamin-csynergistic-effect.aspx>):

- “Vitamin C and quercetin have synergistic effects that make them useful in the prevention and early at-home treatment of COVID-19.”
- “[V]itamin C at extremely high doses acts as an antiviral drug, effectively inactivating viruses.”
- “While high-dose vitamin C is new for COVID-19 treatment, it’s been used as a treatment for sepsis since about 2017. The vitamin C-based sepsis treatment was developed by Dr. Paul Marik In the interview above, Marik explains how the COVID-19 critical care protocol grew out of his sepsis treatment, as he and other doctors noticed there were many similarities between sepsis and severe COVID-19 infection”
- “Quercetin was initially found to provide protection against SARS coronavirus in the aftermath of the SARS epidemic ... Now, some doctors are advocating its use against SARS-CoV-2, in combination with vitamin C, noting that the two have synergistic effects.”
- “There is evidence that vitamin C and quercetin co-administration exerts a synergistic antiviral action due to overlapping antiviral and immunomodulatory properties and the capacity of ascorbate to recycle quercetin, increasing its efficacy.”

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 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> (<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 products 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.

Sincerely,
/S/

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

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> (<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/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/> (<https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

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