



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: October 23, 2020

TO: admin@predatornutrition.com
support@predatornutrition.com

Rajinder Singh Johal
Predator Nutrition
62 Broomfield Avenue
Halifax, West Yorkshire
Great Britain HX30JF

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, www.predatornutrition.com on September 16 and 29, 2020, and October 6, 2020, respectively. We also reviewed your social media at www.facebook.com/prednutrition/, where you direct consumers to your website, www.predatornutrition.com, to purchase your products. The FDA has observed that your website offers the products Elixir (labeled to contain oxymatrine, berberine, and ecklonia cava), Salidroside, Unbreakable (labeled to contain BPC-157), Vitamin C + Bioflavonoids & Rosehip, Vitamin D3, and Ashwagandha 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, the President declared 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:

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 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 twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx>).

³ 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/>).

- From your article titled, “SUPPLEMENTS FOR IMMUNE SUPPORT - CORONAVIRUS (COVID-19) 2020” at www.predatornutrition.com/articlesdetail?cid=supplements-for-immune-support:
 - “Natural Ingredients Used in Treating Covid-19. Doubtless, over time we will learn more about what works best for treating Covid-19 but for now, with widespread adoption in numerous countries of a combined pharmaceutical and nutraceutical approach, we think it best to focus on prevention and investing your efforts on those products with the strongest evidence base.”
 - “Berberine is a natural ingredient which has shown... broad antimicrobial action against viruses...”
 - “Oxymatrine – Antiviral. . .”
 - “Ecklonia Cava – Anti-Coronavirus and Antimicrobial Activity”
 - “Salidroside – Antiviral Properties. . . Its ability to... reduce inflammation is matched by its consistent antiviral activity with research showing it can combat. . . respiratory viral infections. [footnote omitted]”
 - “Finally, numerous studies have shown Salidroside’s potential in ameliorating sepsis induced lung injury [footnote omitted], and protection against pulmonary fibrosis. [footnotes omitted] Attacking the lungs and causing pulmonary fibrosis is one of the most common symptoms seen in those for whom Covid-19 turns severe or fatal. [footnote omitted]”
 - “Of particular interest in the context of potential damage to the lungs as seen in Covid-19, BPC-157 was shown to reverse even severe lung damage in at least two studies. [footnotes omitted]”
 - “Vitamin C plays a key role in the production of immune cells and is often used in hospital environments to help support patients’ immunity, including being used in China among coronavirus patients.”
 - “Vitamin D - Helps Prevent Respiratory Infections”
 - “As it happens, studies have shown just that with Ashwagandha being shown to have a ‘broad range of medicinal properties including anti-viral activity’ . . .”
- From your article titled, “RESEARCH REVIEW – WHAT TREATMENT WORKS BEST FOR COVID-19?” at www.predatornutrition.com/articlesdetail?cid=research-review-covid-19-treatment:
 - Under the heading “Bolster Immunity and Reduce the Risk of Contracting Covid-19”:
 - “With the wait for a vaccine that can be deployed en masse likely to take us into 2021 at the earliest, everyone should be focused on prevention and immune support such as: . . . Supplementing with evidence based nutrients shown to support immunity, or else those that show antiviral properties, such as oxymatrine, berberine and ecklonia cava (found in the product Elixir).”
 - Under the heading “A Review of Treatments Being Used for Coronavirus”:
 - “[T]he antiviral properties shown in the research for ingredients like berberine, oxymatrine and ecklonia cava. . . [F]or those interested in trialling these ingredients . . . , all three are found in the product Elixir.”
- “After 100’s of hours scouring journals you too can learn. . . Which ingredient was shown to INHIBIT SARS-COV VIRUSES via strong antiviral activity? Which ingredient helped REDUCE DURATION AND SYMPTOMS OF CORONAVIRUSES!* . . . Which ingredients have ANTI-VIRAL PROPERTIES?. . .” [from a March 24, 2020 post to your Facebook page at www.facebook.com/prednutrition, which directs consumers to your article titled, “SUPPLEMENTS FOR IMMUNE SUPPORT - CORONAVIRUS (COVID-19) 2020” at www.predatornutrition.com/articlesdetail?cid=supplements-for-immune-support, where you make statements about the purported effects of the ingredients in your products.]

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 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 the sale of your 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 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 product are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims for products that you advertise, market, sell, or otherwise promote or make available in the United States. 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: 2020.10.23
18:11:32 -04'00'

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

Sincerely,

SERENA

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VISWANATHAN

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