



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: July 13, 2020

TO: ceo@keganwellness.com – Kegan Wellness
602, Aarohi Verve, Besides One World West Building
Ambli Bopal Cross Road
Sardar Patel Ring Road
Ahmedabad - 380058, Gujarat, India

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://www.keganwellness.com> on June 30, 2020 and July 9, 2020, respectively. We also reviewed your social media websites at <https://twitter.com/WellnessKegan> and <https://www.facebook.com/keganwellness>, where you direct consumers to your website, <https://www.keganwellness.com>, to purchase your products. The FDA has observed that your website offers “She Vitamin C Tablets,” “She+ Tablets,” and “Giloe+ Tablets” 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 website and your social media websites that establish the intended

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, 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 was renewed for another 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. April 21, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.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/>).

use of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “She+ - Boost Your Immunity . . . May help to prevent COVID 19 symptoms by supporting to [sic] increase immunity.” [from your website <https://keganwellness.com/shop/nutraceuticals/she-boost-your-immunity>]
- “She – Vitamin C Tablets . . . May help to prevent COVID 19 symptoms by supporting to [sic] increase immunity.” [from your website <https://keganwellness.com/shop/nutraceuticals/she/>]
- “Giloe+ . . . May help to prevent COVID 19 symptoms by supporting to [sic] increase immunity.” [from your website <https://keganwellness.com/shop/nutraceuticals/giloe/>]
- “Improve your body defence mechanism with #keganwellness SHE+ #supplements -a unique combination of #VitaminC, #VitaminD, #VitaminE and #ZINC that may help build your #Immunity in the fight against #CORONA[,] . . . #covid19 #coronavirus #Multivitamin” accompanied by a graphic including the statements “May Help Fight Disease[,] Helps to strengthen Immune system during Corona Outbreak[,] She+” [from a May 7, 2020 post on your Twitter social media website <https://twitter.com/WellnessKegan>]⁴
- “#immunity is the key today in the #pandemic #covid19 #keganwellness SHE #VitaminC #supplements may help you to strengthen your immune system[,] . . . #covid19 #coronavirus #vitamindeficiency . . . #immunitybooster” accompanied by a graphic including the statement “Boosts Immunity During Corona Outbreak” and an image of “She Vitamin C Tablets” [from a May 7, 2020 post on your Twitter social media website <https://twitter.com/WellnessKegan>]⁵
- “Fight the battle against the pandemic with our range of products that focuses completely on building immunity . . . #immunity #immunesystem #buildimmunity . . . #covid19” accompanied by a graphic including the statement “Shield yourself by Boosting Your Immunity with GILOE+” and an image of “Giloe+ Tablets” [from a June 23, 2020 post on your Facebook social media website <https://www.facebook.com/keganwellness/>]
- “GILOE+ & She+ are the best alternate options for those who are looking for natural immunity booster. Our products help in boosting immunity level and fights with Vitamin deficiencies. As a result you cover yourself with a shield in the current pandemic situation. #covid19 #coronavirus” accompanied by a graphic including the statement “Helps in improving Immunity System” and images of “Giloe+ Tablets” and “She+ Tablets” [from a June 30, 2020 post on your Facebook social media website <https://www.facebook.com/keganwellness/>]

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-CDER@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

⁴ A similarly worded post also appeared on your Facebook social media website <https://www.facebook.com/keganwellness/> on May 7, 2020.

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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 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-CDER@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 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,

Sincerely,

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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