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The Golden Road Kratom - Warning Letter - 05/15/2020

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Product: Drugs

Recipient:

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Issuing Office:

Center for Drug Evaluation and Research | CDER
United States

WARNING LETTER

Date: May 15, 2020

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 website at the Internet address www.thegoldenroadkratom.com on May 1, 2020. The FDA observed that your website offered kratom products for sale in the United States and that these products were intended to mitigate, prevent, treat, diagnose, or cure COVID-19^[1] in people. Based on our review, these products were 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. SS 355(a). Furthermore, these products were misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. SS 352. The introduction or delivery for introduction of these products into interstate commerce violated sections 301(a) and (d) of the FD&C Act, 21 U.S.C. SS 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 sold products that were intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.

Some examples of the claims on your website that established the intended use of your products and misleadingly represented them as safe and/or effective for the treatment or prevention of COVID-19 include:

- "Can Kratom Stave Off the Coronavirus - Covid-19"
- "Dr. Usman makes it clear that kratom (*Mitragyna Speciosa*) contains a good amount of compounds that can strengthen the immune system and keep the coronavirus at bay."
- "Kratom contains a special compound known as chloroquine or Cq, that research shows is powerfully combative against the coronavirus. There are many viruses that can be harmful to humans and Cq could be a type of master key that protects against all of them." "In addition, he said it was reported from researchers in Wuhan that Chloroquine (Cq) can be used for the treatment of patients with Covid 19."
- "In conclusion, It's [*sic*] amazing that this plant so many of us believe in. . . can be the key to one of the worst viruses of our lifetime. We are still unlocking the true power of Kratom."
- "#Covid_19. . . #coronavirus. . . #CoronavirusOutbreak. . . #kratom. . . #kratomsaves"

We note that, as of the date of this letter, the claims cited above appear to have been removed. Due to the serious public health concerns related to the marketing and sale of unapproved drugs for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, it is essential that these violations do not recur.

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 prevent the recurrence of future violations.

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, with a notation that, as of the date of this letter, your firm's listed products are no longer sold for the prevention, treatment, mitigation, diagnosis or cure of COVID-19. This list can be found at <http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products>.

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-CDER@fda.hhs.gov.

Sincerely,

/S/

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
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 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 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/>).