



WARNING LETTER

Date: January 4, 2021

TO: cocosholisticspecialties.etsy@gmail.com - Janine Havins
Coco's Holistic Specialties & Apothecary

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://cocosholisticspecialties.org/> on November 19th, 2020, and December 17, 2020, respectively. We also reviewed your social media websites at <https://www.facebook.com/KaliLengua/> and <https://twitter.com/CocoEtsy>, where you direct consumers to your website, <https://cocosholisticspecialties.org/> to purchase your products. The FDA has observed that your website offers 4-Thieves Florida Tea Concentrate and 4-Thieves Florida Tea Powder for sale in the United States and that this product is 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, 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 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.

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 three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.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/>).

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

- “[A]ntiviral, ongoing clinical research on effectiveness against COVID-19” [from your website, <https://cocosholisticspecialties.org/>]
- “January I decided to put aside her [sic] upwards of 20 different holistic plant-based product lines to focus on binge researching herbs from past pandemics, why they worked, what the similarities there are to CV-19 . . . In January this year when I 1st heard of what later transpired into the Novel Coronavirus Pandemic, had binge-researched pandemics of the past, and what had been used to remedy them at those times . . . there were enough similarities between the transhuman variations . . . that I was so intrinsically inclined to acquire the herbs I researched for the original Marseilles France 4-Thieves recipe . . . I next binge-researched what antiviral herbs I could augment in to make it effective against Covid-19 . . . I had taken out the 2 herbs that made the original for external use only, cause I intended to make tea pills to inoculate CV-19, exchanging those with 6 herbs that specifically kill viruses...!” [from your website, <https://cocosholisticspecialties.org/>].
- “4-Thieves Florida Tea Concentrate is an anti-COVID herbal inoculation, that is 100% plant-based.” [From your social media website in the “About” section, <https://www.facebook.com/KaliLengua/>].
- “[W]anted to share my COVID story . . . [t]here were 8 women that allowed me to treat them for covid-19(-like symptoms) as well as using on myself as a preventative . . . [t]he only thing I’ve been using this whole time, since I finished my 1st batch the 2nd week of February, my 4-Thieves Florida Tea Concentrate . . . The herbal prophylactic inoculation I made against Coronavirus is safe & effective for people of all ages & health conditions.” [From an August 12, 2020 post on your social media website <https://www.facebook.com/KaliLengua/>].
- “I had formulated in January of this year from my binge-researching pandemics of the past & found that 4-Thieves was the only thing effective against the Black Plague of the dark ages(14-1700s). It was found to be a bacterial infection, & 2 ingredients in the original recipe created in Marseilles England by the mother of one of the 4 thieves, made the recipe for external use only & not effective against viruses. So listening to my intuition & knowledge I further binge-researched what antiviral herb I could replace those 2 with to make it effective against COVID-19. After having run my own clinical trials resulting in proof of the efficacy of my anti-viral variation of this herbal inoculation, I aptly named it 4-Thieves Florida Tea, & I sell it as a concentrate.” [from a June 15, 2020 post on your social media website <https://www.facebook.com/KaliLengua/>].
- “This is me singing . . . because it waa [sic] the best way I could think of to show my health 10 days after the beginning of my exposure to COVID-19 that I still [am] healthy as a horse, due to my antiviral herbal inoculation.” [from a September 21, 2020 tweet from your social website <https://twitter.com/CocoEtsy>].

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-CDER@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 any violations, as well as copies of related documentation. Failure to immediately address this matter 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 actions to address 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 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 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.

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 product 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. 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,

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

Sincerely,

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