



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: April 6, 2020

TO: fcathay@cathaynatural.com – Ms. Cathay Fung, Cathay Natural, LLC
1810 Summit Street
Kansas City, MO 64108

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.cathayherbs.com on March 27, 2020 and April 3, 2020, respectively. The FDA has observed that your website offers herbal 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, 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 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:

- “Chinese Medicine treatments for Coronavirus Disease . . . How can we prepare for Coronavirus Disease 2019 (COVID-19)?” [from your website <http://cathayherbs.com/coronavirus-disease>]
- “Surprisingly, several hospitals designated for mild-moderate COVID-19 patients that are dominated by and fully implemented with Traditional Chinese Medicine (TCM) treatments reported zero medical worker infection and very low or zero conversion rate to severe cases. This was in vast contrast with significant medical worker infections and about 15-20% conversion to sever [sic]

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>).

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/>).

cases in certain hospitals that do not use the TCM treatments. Such a big contrast let [*sic*] many frontline doctors to call for mandatory implementation of Chinese herbal medicine treatments, which eventually become part of the CDC official guide for diagnosis and treatment of COVID-19 in China.” [from your website <http://cathayherbs.com/coronavirus-disease>]

- “[S]ome senior chief physicians in charge of many frontline doctors in multiple hospitals simultaneously . . . were surprised to see the great outcome with TCM. . . . [T]hose senior physicians . . . eventually became the ones who strongly called for implementation of TCM in the prevention and treatment of COVID-19 in China. This was how it became CDC’s treatment option in China.” [from your website <http://cathayherbs.com/coronavirus-disease>]
- “Chinese Herbal Solutions for Coronavirus Disease 2019 . . . See below for a selection of the Chinese herbal products that were reported with success in China for the prevention and treatment of the COVID-19.” [from your website <http://cathayherbs.com/coronavirus-disease>]
- “Chinese Herbal Sachet for COVID-19, portable version [hyperlink to “CoronaDefender Herbal Sachet-S” product page]: Similar product as above but filled with grinded Chinese herbal powder in smaller sachet so that one can carry it in a pocket or tie on belt.” [from your website <http://cathayherbs.com/coronavirus-disease>]
- “Chinese Herbal tea for preventing COVID-19 [hyperlink to “CoronaDefender Herbal Tea” product page]: Concentrated herbal extracts formulated for internal use to be better prepared for fighting with the Novel Coronavirus when necessary. Dissolve in hot drinking water to consume as herbal tea.” [from your website <http://cathayherbs.com/coronavirus-disease>]
- “CoronaDefender Herbal Sachet-S . . . Use:* Formulated for modifying your body surface so that the Novel Coronavirus stands less chance to survive on your body.” [from your website <https://cathayherbs.com/product/coronadefender-herbal-sachet-s/>]
- “Herba Agastachis Pill for Restoring Healthy Energy . . . Use:* Formulated for use with the symptoms of headache, faintness, chest, tightness, abdominal pain, vomiting, and diarrhea . . . regardless is infected with the coronavirus.” [from your website <https://cathayherbs.com/product/herba-agastachis-pill-for-restoring-healthy-energy/>]
- “CoronaDefender Herbal Tea . . . Use:* Formulated for internal use to better prepare yourself for fighting with the Novel Coronavirus when necessary.” [from your website <https://cathayherbs.com/product/coronadefender-herbal-tea/>]
- “Ginseng detoxication Pill . . . Use:* It is a classic Traditional Chinese Medicine remedy for flu or cold caused by weak immunity with symptoms of fever and chills, headache, muscle ache, fatigue, cough, and nasal congestion but no sweat nor thirst. Use it regardless if infected with the novel coronavirus.” [from your website <https://cathayherbs.com/product/ginseng-detoxication-pill/>]
- “Honeysuckle and Forsythia Formula . . . Use:* Formulated for use with symptoms of fever, headache, cough, dry mouth, and sore throat, regardless if infected with the novel coronavirus.” [from your website <https://cathayherbs.com/product/honeysuckle-and-forsythia-formula/>]

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 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-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. 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,

Richard A. Quaresima
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission