WARNING LETTER

Date: July 6, 2020

TO: mohammad@sinotradition.com – sinotradition.com
marry@sinotradition.com
neil@sinotradition.com

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.sinotradition.com on June 12, 2020, and July 1, 2020, respectively. The FDA has observed that your website offers traditional Chinese medicine (TCM) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] 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:

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[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/).

- "How Wuhan People Defeat COVID? No vaccine, no special medicine from USA or Eurpope [*sic*], Wuhan people put COVID under control within 3 months, what role Chinese herbs played in Wuhan?" [from your webpage www.sinotradition.com]

- "**No.1 Hubei Presciption** [*sic*] Suitable for healthy people to prevent COVID, it restores body function and consolidated the constitution, enhance immunity and prevent viral pneumonia." [from your webpage www.sinotradition.com]

- "**Lung cleaning & detoxifying Pill** Suitable for COVID patients, On January 27, 2020, the State Administration of Traditional Chinese Medicine of China emergently launched the special project of 'Screening effective Chinese medicine prescription for prevention and treatment of COVID-19.' total effective rate of the formula reached more than 90%." [from your webpage www.sinotradition.com]

- "**Lianhua Qinwen Capsules** According to the drug administration law of China, the prescription manual of Lianhua Qingwen capsule was approved, to add the functional of 'the routine treatment of COVID pneumonia,' can be used for light, common type of fever, cough, fatigue.'" [from your webpage www.sinotradition.com]

- "**Preventing COVID Herbs--NO1. Hubai** . . . **Source:** Diagnosis and Treatment of Pneumonitis for New Coronavirus Infection of Hubei Province (Trial Version1), jointly issued by prevention and control headquarters and medical treatmernt [*sic*] specialists for new coronavirus infection of Hubei province and Hubei medical treatment experts. **Domestic application:** During February to March in 2020, it has been widely used in Wuhan, the epicenter of the outbreak of COVID-19 of China, which can help improve immunity. . ." [from your webpage www.sinotradition.com/products/preventing-covid-herbs-no1-hubai]

- "**Qing Fei Pai Du Tang(Anti-COVID Pill)** . . . It is indicated for mild, ordinary and serious COVID-19 patients. Also it can be used for the severely critical patients subject to the actual condition of patients . . . 'Qing Fei Pai Du Tang' was used to treat clinical COVID - 19 patients, which proved that the total effective rate of the formula reached more than 90%. This formula was released to the public for the first time on February 6, 2020. Later, after a large number of clinical applications, the efficacy of it was confirmed. So 'Qing Fei Pai Du Tang' is included in the Diagnosis and Treatment of Pneumonitis for a New Coronavirus Infection (Trial Version 6&7) of China, which has been playing a positive role in the prevention and control of COVID-19 pandemic." [from your website www.sinotradition.com/products/no-1-covid-killer-herbsno1-paidu-for-patients-only]

- "**Lianhua Qingwen Capsule(Lotus Help-Flighting COVID Capsule)** . . . **Help-Flighting COVID Herbs in the 'Health Parcels' to overseas students** . . . The results show that the disappearance rate of major clinical symptoms and the duration of clinical symptoms in the treatment group are better than the control group. The application of lianhua qingfen capsules (granules) can improve the clinical symptoms of fever, fatigue, cough and other symptoms of covid-19 patients, significantly improve the CT features of the lungs, shorten the duration and cure time of symptoms, improve the clinical cure rate. . ." [from your website www.sinotradition.com/products/lotus-coronavirus-killerlianghua-qinwen]

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 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 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 -S

Digitally signed by Donald D. Ashley -S
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Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely

SERENA VISWANATHAN

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Date: 2020.07.06 09:18:24 -04'00'

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