



## **WARNING LETTER**

Date: July 6, 2020

TO: [support@lianhuaqingwencaps.com](mailto:support@lianhuaqingwencaps.com) – Lianhuaqingwencaps.com  
304 Tarrigart Drive  
Moore, SC 29369

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://lianhuaqingwencaps.com/> on June 15, 2020, and July 1, 2020, respectively. The FDA has observed that your website offers a traditional Chinese medicine (TCM) product for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>1</sup> in people. Based on our review, this product is an unapproved new drug 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 this product 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.<sup>2</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>3</sup> 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 product and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

- A graphic with the image of your product Lianhua Qingwen Capsules under the header “CAPS

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<sup>1</sup> As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

<sup>2</sup> 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>).

<sup>3</sup> 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/>).

AGAINST COVID-19 . . .” [from your website <https://lianhuqingwencaps.com/>]

- “LIANHUA QINGWEN CAPS TREATS MILD FEVER COUGH AND FATIGUE IN C-VIRUS PNEUMONIA . . .” [from your website <https://lianhuqingwencaps.com/>]
- “**Lianhua Qingwen 24 capsules** . . . has also been identified as having potential antiviral activity against coronaviruses such as SARS-CoV-2.” [from your website <https://lianhuqingwencaps.com/product/lianhua-qingwen-24-capsules/>]
- “**Traditional Chinese Medicine Lianhua Qingwen Plays an Important Role in Fighting Against COVID-19.** . . . It has been listed in the ‘Diagnosis and Treatment Plan for COVID-19 Infection’ (Trial Version 4/5/6/7) of the China Health and Health Commission and recommended drugs in the diagnosis and treatment plans of COVID-19 of the Health and Health Commission of 20 provinces. . .” [from your website <https://lianhuqingwencaps.com/product/lianhua-qingwen-24-capsules/>]
- **Research Provides Scientific Evidence for Lianhua Qingwen** . . . The antiviral effect of Lianhua Qingwen has been confirmed by a large number of scientific researches. . . Professor Yang Zifeng . . . said ‘[L]ianhua Qingwen capsule (granule) showed significant cytopathic effect of inhibiting COVID-19 virus. It is known for all that the COVID-19 virus is not only a virus, but also causes a series of over-expression of inflammation. Therefore, people have also observed that Lianhua Qingwen capsule (granule) inhibits the over-expression of human common coronavirus (HcV-229E), novel coronavirus (COVID-19) infected cells and induced inflammatory factors such as TNF- $\alpha$ , IL-6, CCL2/MCP-1 and CXCL-10/IP-10. This is consistent with clinical inflammatory factors. [sic]This just proves that Lianhua Qingwen has the multi-target effect of inhibiting novel coronavirus and resisting inflammation.’ [from your website <https://lianhuqingwencaps.com/product/lianhua-qingwen-24-capsules/>]
- “Lianhua Qingwen is widely used in epidemic prevention and control, helping the global epidemic prevention and control.” [from your website <https://lianhuqingwencaps.com/product/lianhua-qingwen-24-capsules/>]
- “Tags: 19 . . . covid . . . inhibitor” [from your website <https://lianhuqingwencaps.com/product/lianhua-qingwen-24-capsules/>]

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](mailto: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 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](mailto: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](mailto: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