



**FDA U.S. FOOD & DRUG  
ADMINISTRATION**



## **WARNING LETTER**

Date: September 29, 2020

TO: [info@tonicherbshop.com](mailto:info@tonicherbshop.com) – Tonic Therapeutic Herb Shop & Elixir Bar  
140 E German St.  
Shepherdstown, WV 25443

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://www.tonicherbshop.com> on September 17, 2020 and September 28, respectively. The FDA has observed that your website offers various herbal products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>1</sup> 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.<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 herbal products

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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 has been renewed for an additional 90 days twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.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/>).

and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “Buhner’s Active Infection Protocol . . . 8 fl oz. (48 servings)[,] Stephen Burner’s protocol (from his article: ‘SARS-CoV-2 (COVID-19): HERBAL PROTOCOLS FOR THE TREATMENT OF INFECTION AND POST-CORONAVIRUS SYNDROME’)” [from your website <https://tonicherbshop.com/product/buhners-active-infection-protocol/>]
- “Herbal Support for COVID-19 . . . Below I will hi-light [sic] some herbs that can help prevent infection and reduce the severity of symptoms. . . . The current strain of Coronavirus has been labeled COVID-19. Coronaviruses are a class of enveloped viruses that spread primarily through respiratory droplets and other bodily fluids. They produce symptoms similar to the flu, including fever, cough, and shortness of breath. . . . Another thing that can happen when we become infected by this virus is something called a cytokine cascade. . . . I’m not writing this to incite fear; I’m taking time to explain this so that you can understand some of the ways in which herbs can support us through an infection. There are dozens of antiviral herbs in this world, but I’m choosing a few select ones that seem to fit this virus the best. . . . Japanese Honeysuckle -a potent antiviral herb with a long history of use in Eastern medicine. . . . Chinese Skullcap (Huang Qin)- another Chinese herb used for fever and infection. . . . The root is antibacterial and antiviral (it blocks the virus from attaching to ACE-2). It also protects the liver, spleen & lymph and reduces the inflammatory cytokine cascade. . . . Elderberry prevents viruses from attaching to host cells and is a great herb to use to prevent infection. It can also be used to shorten the duration of infection when taken frequently during the first stages. . . . Licorice – an adaptogen, immune amphoteric, antiviral and demulcent herb. . . . As an immune-amphoteric, it can strengthen a weak immune system while simultaneously reducing a hyperactive immune response (i.e. cytokine cascades). . . . Cordyceps – also known as caterpillar fungus, is tonic for the immune system, blood, kidneys & lungs . . . Another immune amphoteric (like licorice) it can reduce excessively high immune activity (cytokine cascade) or enhance excessively low immune activity. . . . Astragalus – immune tonic with special affinity for the lungs. . . . It is known to stimulate the body’s natural production of interferon, a chemical that helps our own cells communicate during a viral infection. . . . You can find astragalus in our Elderberry Chai . . . If you do get sick and need symptomatic relief, expectorants & diaphoretics can support your respiratory system: Hyssop, thyme, elder flower, peppermint (try our Gypsy Cold Tea . . .) Following viral infection, it’s good to support the lymphatic system with herbs like Cleavers, Red Clover, Calendula, Violet, Nettle, Mullein or Chickweed to help with the resolution phase. (try our Love Your Lymph Tea . . .) 10 ways to keep your immune system strong to prevent infection . . . Medicinal mushrooms strengthen the immune system. . . . Reishi, Chaga . . . and others can be taken as a tincture, capsule or decoction . . . Is Elderberry Safe? . . . I would personally use elder to treat myself or my family if I suspected that one of us caught the coronavirus.” [from your website <https://tonicherbshop.com/herbal-support-for-covid-19/>]

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 website, 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 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](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 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](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