# WARNING LETTER

Date: March 6, 2020

TO: amy@herbalamy.com – Amy Weidner, Herbal Amy Inc.
12575 Anakate Ln.
Nampa, ID 83686

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.herbalamy.com on February 18, 2020 and February 25, 2020, respectively. We have also reviewed your social media page at https://www.facebook.com/HerbalAmyInc/, where you provide a link your website www.herbalamy.com to purchase your products. The FDA has determined that your website offers "Coronavirus Protocol" products (Coronavirus Boneset Tea, Coronavirus Cell Protection, Coronavirus Core tincture, Coronavirus Immune System, and Elderberry Tincture) for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. FDA has determined that 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 section 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

The Secretary of Health and Human Services, under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, has determined that a public health emergency exists nationwide as a result of confirmed cases of COVID-19. 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. We request that you take prompt action to cease the sale of such unapproved and unauthorized products for 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:

- "Corona virus treatment. Stephen Buhner has analyzed how corona viruses infect tissues, what tissues they infect, and the herbs that are useful to interrupt that process, as well as the herbs useful to shut down the cytokine cascade they create. Here is his protocol. … [T]his is a rather extensive protocol because the particular corona virus that is now spreading world wide is exceptionally potent in its impacts. All the herbs are specific in one way or another for this virus. A number of the herbs are strongly antiviral for corona viruses ….. The formulations are preventative as well as specific for acute infections …."
  [from your website www.herbalamy.com/product-page/corona-virus-protocol]

[1] COVID-19 is the official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China.

- "Stephen Buhner has used this with other corona virus infections, including SARS, it works well." [from your website www.herbalamy.com/product-page/corona-virus-protocol]

You should take immediate action to correct the violations cited in this letter. The violations cited in this letter are not meant to be an all-inclusive list. 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 representing your products 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-CFSAN@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 www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products. Once you have taken corrective actions 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) listed 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-CFSAN@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. To make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act.

There currently are no vaccines, pills, potions, lotions, lozenges or other prescription or over-the-counter products available to treat or cure coronavirus disease 2019 (COVID-19). Thus, the claims cited above are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. In addition, you are advised to review all claims for your products and immediately cease making claims that are not supported by competent and reliable scientific evidence. 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,

William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Sincerely,

RICHARD QUARESIMA Digitally signed by RICHARD QUARESIMA Date: 2020.03.06 10:41:59 -05'00'

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