U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

Date: March 6, 2020

TO: david@vivifyholistic.ca – David Raes, Vivify Holistic Clinic
272 Wellington Street
Sarnia, ON, Canada, N7T 1H2

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 reviewed your website at the Internet address https://coronavirusdefense.com in February 2020. We also reviewed your Facebook website at https://www.facebook.com/vivifyholistic/ where you direct consumers to your website https://coronavirusdefense.com to purchase your products. The FDA has determined that your website offers products for sale in the United States and that these products are intended to mitigate, prevent, treat, cure or diagnose 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. 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 websites 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:

- "Regarding the Wuhan Coronavirus: Stephen Buhner . . . has done extensive research on coronaviruses . . . He has treated them very successfully using his protocols. A few days ago he posted on facebook a 4 part protocol specific for the Wuhan outbreak. The last few days I have been working very hard to set up a website coronavirusdefense.com up to sell Mr. Buhner's protocol." [from a January 27, 2020 post on your Facebook website https://www.facebook.com/vivifyholistic/]

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

- "With active infection: very strong boneset tea, to 6x day. I have used this with other corona virus infections, including SARS, it works well." [from a January 27, 2020 post on your Facebook website https://www.facebook.com/vivifyholistic/]
- "As the deadly cornavirus [sic] rapidly spreads across the globe with no antidote available . . . Stephen Harrod Buhner has created an updated coronavirus protocol specifically for the Wuhan outbreak." [from your website https://coronavirusdefense.com]
- "Formula # 4 – Loose Leaf Tea
  Boneset
  (Only use if infected)
  Acute Dosage: 1 cup 6x /day
  Chronic Dosage: 2 cup 4x /day
  Antiviral action" [from your website https://coronavirusdefense.com]
- "Each 100 ml of product will last 16 days for a preventative dose and 8 days for an infection dosage. . . .Take Extracts #1 through #3 as preventative. . . .If you are infected, take all 4 products and use the infection dosage." [from your website https://coronavirusdefense.com]

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-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 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-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. 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,

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Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

RICHARD QUARESIMA

Digitally signed by RICHARD QUARESIMA
Date: 2020.03.06 08:46:50 -05'00'

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

cc: sales@herbies-herbs.com - Herbie's Herbs