WARNING LETTER

Date: April 7, 2020

TO: holistichealthypet@gmail.com – Savvy Holistic Health
dba Holistic Healthy Pet
6768 Lynrose Ct.
Charlotte, NC 28226

CC: perthoffice@hampl.com.au – Holistic Animal Remedies
60 Angove Street
North Perth
Perth, Western Australia 6006

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://holistichealthypet.com/ on March 25, 2020 and April 2, 2020, respectively. The FDA has observed that your website offers "China Oral Nosode" also called "China Corona Nosode" and the "CV Respiratory Kit,"[1] both under the description, "AN330 – CORONA VIRAL IMMUNE SUPPORT AND/OR ACTIVE RESPIRATORY INFECTION FOR ALL AGES," for sale in the United States and that these products are intended to mitigate, prevent, treat, cure or diagnose COVID-19[2] in people.[3] 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). FDA also observed that these products are intended for use in the mitigation, treatment, or prevention of COVID-19 in animals, which makes them drugs under section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B). The products are not the subject of an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act, 21 U.S.C. §§ 360b, 360ccc, and 360ccc-1. Therefore, the products are unsafe within the meaning of section 512(a) of the FD&C Act, 21 U.S.C. § 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21

[1] The "CV Respiratory Kit" includes five items: "Homeoprophylasis China Oral Nosode 200C," "Herbal CV-2," "Herbal CV-3," "Herbal CV-4," and "Liposomal Vitamin C."

[2] As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

[3] Although this product is marketed on a website that focuses on pet products, your "AN330 – CORONA VIRAL IMMUNE SUPPORT AND/OR ACTIVE RESPIRATORY INFECTION FOR ALL AGES" webpage says the products are "For all Species." Further, the description under the "HEALTH INFO" tab includes information about and recommendations for viral infections and COVID-19 in people. Also, your "HELP SHEET PDF FILE" tab links to a document titled "PREVENTION OR IF UNWELL with (COVID-19) Virus that states "Vitamin C . . dosing guide for Humans."

U.S.C. § 351(a)(5). 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.[4] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[5] 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 and animals. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose or cure COVID-19 in people and animals. 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:

- The product description "AN330 –CORONA VIRAL IMMUNE SUPPORT AND/OR ACTIVE RESPIRATORY INFECTION FOR ALL AGES. Holistic Animal Remedies … For all Species"
- "China Oral Nosode is the homeopathic nosode called a homeoprophylasix [sic] of Corona Virus to Assist Immunity."
- "If active infection – use Bottle 1 in conjunction with Herbal formulas & Vitamin C (liposomal Vitamin C is the most effective form for respiratory infections)"
- "Homeopathic China Oral Nosode COVID-19 . . . The world is in 'panic mode' due to the new Coronavirus, but homeopaths are not nearly as concerned about it…and for good reasons. Homeopathic treatment has had a long history of success in treating various viruses."
- "Hearing reports from China, homeopaths there report that the symptoms of people who get the Coronavirus point toward Gelsemium (first choice) and Byronia or Eupatorium perf (as second choices). Note: We have provided these extra homeopathics into the China Oral Nosode remedy bottle."
- "Vitamin C oral dosing . . . Vitamin C protects .. [sic] against all virus e.g[.] CoronaVirus . . . See pf HELP SHEET."
- "EXAMPLE SUPPORT PROTOCOL … CV ACTIVE INFECTION . . . 1. Using a few drops of the HomeoprophylaxisChina [*sic*] oral nosode to each cup of herb dosing . . . 3. Vitamin C – special form of vitamin C * add a teaspoon in each cup of herbal dosing."
- The "PREVENTION OR IF UNWELL with (COVID-19) Virus" "Help Sheet" at https://cdn.shopify.com/s/files/1/0206/5861/8468/t/4/assets/330COVID-19-SARS-

[4] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

[5] 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/).

CoronaVirusSUPPORT-HUMAN-1583308491241.pdf, accessible from your website from the "HELP SHEET PDF FILE" tab, in part, provides a "Vitamin C ..[*sic*] dosing guide for Humans" for "TREATING FLU, BRONCHITIS, PNEUNOMIA, SARS (COVID-19) Corona Virus"

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 product(s) 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 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 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

Eric M. Nelson -S

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Eric M. Nelson
Director
Division of Compliance
Center for Veterinary Medicine
Food and Drug Administration

RICHARD QUARESIMA

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