WARNING LETTER

Date: December 21, 2020

TO: info@sparrowclinic.com – Sparrow Health & Performance, LLC
2000 Southlake Park
Suite 150
Hoover, AL 35244

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.sparrowclinic.com on various dates since September 17, 2020. We also reviewed your social media websites at https://www.facebook.com/sparrowclinic and https://www.instagram.com/sparrowclinic/, where you direct consumers to your website, https://www.sparrowclinic.com, to purchase your products. The FDA has observed that your website offers the products Organic Liposomal Vitamin C, Nanoemulsified D3K2 (sometimes referred to on your websites as "Liquid Liposomal Vitamin D3 with K2" or "Liposomal Vitamin D3"), and Immune Support Package (which includes your Organic Liposomal Vitamin C, Nanoemulsified D3K2, and Virus Be Gone products, with Smart Silver as an optional add-on) for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] 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.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3] 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

[1] As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).
[2] 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 three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx).
[3] 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/).

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:

From your Immune Support Package product webpage [https://www.sparrowclinic.com/store/immune-support-package]:

- "So we put together some of our own go-to's to help you in your proactive coronavirus (or whatever else) prevention plan. . . . What is included? . . . Virus Be Gone . . . This blend is a family favorite that can be taken daily to keep viruses at bay. The dosage may also be increased to more frequent smaller doses to combat an existing viral infection."

From your social media websites:

- "We noticed an uptick in orders & changes in buying patterns, we are told it is due people preparing for the Coronavirus. . . . we decided to create a kit of our top sellers for natural immune support . . .
  Immune Support Package—Sparrow
  Looking for coronavirus prevention? We did the work to provide a kit . . ."
  [from a March 2, 2020 post on your Facebook social media website, https://www.facebook.com/sparrowclinic, which links to your Immune Support Package product webpage, https://www.sparrowclinic.com/store/immune-support-package]

- You state: "We've been saying this all along! Our organic liposomal vitamin c boasts a 90% absorption rate. . . Order yours here:
  https://www.sparrowclinic.com/store/orgranic-liposomal-vitamin-c . . .
  https://nypost.com/2020/03/24/new-york-hospitals-treating-coronavirus-patients-with-vitamin-c/?fbclid=IwAR0i5XjrS1Z64g2l4guYyHf8xYswmAGZHAX14xDXyJ-SopOFxRWxGpN4PFI"
  Immediately below this hyperlink to a New York Post article, there is an image of a spilled bottle of pills, with the caption "New York hospitals treating coronavirus patients with vitamin C"
  [from a March 24, 2020 pinned post on your Facebook social media website, https://www.facebook.com/sparrowclinic]

- You post an image of your Nanoemulsified D3K2 product and state: "NOW IN STOCK LIPOSOMAL VITAMIN D3 . . . 'Vitamin D supplementation reduces the risk of respiratory infection, regulates cytokine production and can limit the risk of other viruses such as influenza. A respiratory infection can result in cytokine storms – a vicious cycle in which our inflammatory cells damage organs throughout the body – which increase mortality for those with COVID-19. Adequate Vitamin D may potentially provide some modest protection for vulnerable populations.'. . ."
  [from March 27, 2020 posts on your Facebook and Instagram social media websites, https://www.facebook.com/sparrowclinic and https://www.instagram.com/sparrowclinic/]

- You post a graphic with images of your Organic Liposomal Vitamin C product and, in the accompanying caption, you state: "Vitamin C is currently being used in some hospitals to treat the coronavirus & seriously ill.
  Can't get your regular wellness IVs? Our organic liposomal supplements boast such high rates of absorption that they can be a convenient alternative in times like these . . . #coronavirus"

[from a March 24, 2020 post on your Instagram social media website, https://www.instagram.com/sparrowclinic/]

- You post a graphic, which states, "'The coronavirus patients who received vitamin C did significantly better than those who did not get vitamin C. . . .'" In the accompanying caption, you state: "A recent article by the New York Post stated New York's largest hospital system is giving vitamin C to treat seriously sick COVID-19 patients. . . . Our organic liposomal vitamin C boasts a 90% absorption rate while most are around 20%. . . . Available on our site while supplies last with FREE Shipping.

  #coronavirus #coronaviruspandemic #covid_19"
  [from a March 25, 2020 post on your Instagram social media website, https://www.instagram.com/sparrowclinic/]

The above noted website claims are supplemented by metatags used to bring consumers to your website www.sparrowclinic.com through Internet searches. The metatags are:

- "Human Coronavirus: Immune Support Kit"
- "Looking for coronavirus (COVID-19) prevention? We did the work to provide a kit with our essentials for supporting the immune system naturally."

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-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 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-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. 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,

William A. Correll Jr -S
Digitally signed by William A. Correll Jr -S
Date: 2020.12.21 15:07:03 -05'00'

William A. Correll, Jr.
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN
Digitally signed by SERENA VISWANATHAN
Date: 2020.12.07 11:07:23 -05'00'

Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission

cc: contact@privacyprotect.org