# WARNING LETTER

Date: June 1, 2020

TO: drs@drsherrillsellman.com – Sherrill Sellman
10 Corporate Dr
STE 300
Burlington, MA 01803

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 websites at the Internet addresses www.drsherrillsellman.com, archive.aweber.com/whatwomenmust, and www.whatwomenmustknow.podbean.com on May 22, 2020, and May 27, 2020, respectively. We also reviewed your social media webpages at www.facebook.com/drsherrillsellman and www.facebook.com/whatwomenmustknow, which link to your website www.drsherrillsellman.com, where your products can be purchased. The FDA has observed that your website www.drsherrillsellman.com offers HealthMax Nano-Silver Liquid,[1] Silver Biotics Silver Lozenges with Vitamin C, and Silver Biotics Silver Gel Ultimate Skin & Body Care (collectively, "your silver products") for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[2] 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.[3] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[4] Therefore, FDA is taking urgent measures to protect consumers from certain

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[1] "HealthMax Nano-Silver Liquid" is the name used for your liquid silver product on your websites. According to the photo of the liquid silver product on www.drsherrillsellman.com, however, it is labeled with the name "ASAP HCP HealthMax 10 Silver Supplement."

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

[3] 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 was renewed for another 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. April 21, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx).

[4] 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/).

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 and social media 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:

- "In light of all the 24/7 news stories about the COVID19 situation, I wanted to share the most effective strategies that I personally recommend and use to support and enhance my immune system. … I recommend that you incorporate this protocol into your personal program. …Patented Nano-Silver SilverSol Technology®.
    - Health Max Nano-Silver Liquid …Recommended: Maintenance dose 1 tsp am and pm Therapeutic dose – 1 TBSP 2-4 x daily" [https://archive.aweber.com/whatwomenmust/PAT6p/h/Hi_My_Personal_Protocol.ht m]

- "Most relevant is the need to provide an enhanced immune defense in our throats where viruses colonize before moving on to our lungs, digestive track [*sic*] and spleen. The powerful duo of SilverSol® nano-silver and Vitamin C, found in the new Silver Biotics® Silver Lozenges, is the latest breakthrough formula by American Biotech Labs LLC. This unique product has the proven ability to help provide added immune protection as part of the Silverbiotics Protocol." [from https://archive.aweber.com/whatwomenmust/PAT6p/h/Hi_My_Personal_Protocol.htm].

- "I'm talking about the patented SilverSol Nano-Silver-Technology® range of products as a liquid, gel or lozenges! ... It has also been tested on various kinds of viruses including SARS with great success in de-activating all forms safely [from https://archive.aweber.com/whatwomenmust/KcCoJ/h/Hi_The_Ultimate_For.htm].

In addition, statements from your March 26, 2020 podcast titled, "What Women Must Know – The Best Flu Prevention Strategies with Keith Moeller" establish that your silver products are intended for the prevention and treatment of COVID-19 and misleadingly represent the products as safe and effective for that purpose. The podcast is posted on your website www.whatwomenmustknow.podbean.com, accompanied by links directing consumers to www.drsherrillsellman.com to purchase your silver products. The podcast begins with Dr.
Sellman telling the audience that the podcast will discuss "how to virus-proof your body" because of the "big concern … in the world with this new coronavirus" [at 1:03]. The following claims and recommendations for your silver products are made in that context.

- "[M]ost viruses, you're able to give them to other people two to three days before you show any symptoms. And … it's true with the new one, this coronavirus…what a lot of people do is use this silver prophylactically, meaning as a preventative…." [at 44:45]
- "For a therapeutic, …if you feel you're coming down with something and you really want to hit it hard, you can do…three or four swigs [of your liquid silver product] a day…."[48:26]
- "[P]eople are wearing these masks now to protect them from that transmission…let's talk about how you can use the silver liquid and the silver gel for barriers of protection…." [at 49:46]
- "[T]ake that [silver] gel and dab it around your nostrils…because you breathe in these viruses, it gets transmitted that way…it's another way to … be more protected…."[53:11]

- "Here you have something [silver] that's been proven on everything it's been tested…. It's been tested on viruses …. It has no side effects, it's totally safe … there's no amount that ever has shown to be toxic …." [at 55:53]
- "[E]veryone needs to have the Silver Biotics liquid and the silver gel in their medicine cabinet at home…. What we're talking about today is how to protect yourself from these viruses…particularly this latest one that people are really concerned about, it's one of the most effective ways to protect yourself and to also use it therapeutically…." [56:24]

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 product identified above. Thus, any coronavirus-related prevention or treatment claims regarding such product 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: 2020.06.01 14:14:04 -04'00'

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

Sincerely,

RICHARD QUARESIMA
Digitally signed by RICHARD QUARESIMA
Date: 2020.06.01 08:24:41 -04'00'

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