

Richard A. Quaresima Acting Associate Director Division of Advertising Practices United States of America FEDERAL TRADE COMMISSION Washington, D.C. 20580

April 28, 2020

WARNING LETTER

VIA EMAIL TO info@newleafcenters.com New Leaf Wellness, LLC Attn: Dr. Robert Sieman, DO 3930 Westown Parkway Suite A West Des Moines, IA 50266

Re: Unsubstantiated claims for Coronavirus treatment or prevention

To Dr. Sieman:

This is to advise you that FTC staff has reviewed your website at <u>https://newleafcenters.com</u> on April 22, 2020. We also reviewed your social media websites at <u>https://www.instagram.com/newleafcenters, https://www.twitter.com/newleafcenters</u>, and <u>https://www.facebook.com/newleafwellnesscenters/</u>, where you advertise services such as IV therapy, peptide therapy, and hormone therapy, and direct consumers to your website <u>https://newleafcenters.com</u> and to a phone number to call your office. We have determined that you are unlawfully advertising that certain products treat or prevent Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus treatment or prevention claims on your websites include:

• "Thymosin Alpha-1 (Ta-1). Ta1 may have clinical benefits in disorders where immune responses are impaired or ineffective, such as ... [a]ny viral disease Thymosin modulates the immune system! This should be used as a treatment adjuvant and a prophylactic ad [sic] can help with may [sic] conditions beyond viral illness! Most will dose it at 450mcg daily. Call to schedule 888-728-7555! #stayhealthy #coronavirus #covid19 #coronavirusinformation ... #keepprotected" [from your March 15, 2020 post on https://www.instagram.com/newleafcenters]

- "IMMUNE BOOST. 30ml Vitamin C IV w/ Glutathione Push. \$100.... Beat Covid 19 with Glutathione ... Protect yourself. Glutathione acts as an important antioxidant in your body. That means it helps combat free radicals. These are molecules that can damage your body's cells.... #coronavirus #covid19 #coronavirusinformation ... #keepprotected" [from your March 16, 2020 post on https://www.instagram.com/newleafcenters]
- "Beat Covid 19 with Hormones and Glutathione . . . Protect yourself. Glutathione acts as an important antioxidant in your body. That means it helps combat free radicals. These are molecules that can damage your body's cells. . . . #coronavirus #covid19 #coronavirusinformation . . . #keepprotected" [from your March 18, 2020 post on https://www.instagram.com/newleafcenters]
- "Thymosin Alpha 1.... TA1 is a peptide that is amazing for the immune system. Patients can take it prophylactically to protect themselves from getting thecoronavirus [sic]. Call 888-728-7555 to place your order today! #cronavirus [sic] #cronabirus19 [sic] #COVID19 #cronavirusnews [sic] #Pandemic! [from your March 24, 2020 post on <u>https://www.instagram.com/newleafcenters</u>]
- "Dr. Sieman [the medical director of New Leaf Wellness] has achieved the 'Record of Achievement' from World Health Organization for COVID-19 and 'Certificate of Completion on The Coronavirus Disease Pandemic' from NetCE who supports the improvement of patient care, NetCE is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), Pictured is Dr Sieman with the Certificate of Completion on The Coronavirus Disease Pandemic for both IA and OK. #cronavirus [sic] #cronabirus19 [sic] #COVID19 #cronavirusnews [sic] #Pandemic! #slowthespread #slowthespreadofcovid19." [from your March 26, 2020 post on https://www.instagram.com/newleafcenters; see also your March 29, 2020 post on https://www.twitter.com/newleafcenters]
- "Watch 'Best Peptides for COVID-19 (Coronavirus) Prevention'" [from your March 24, 2020 post on https://www.twitter.com/newleafcenters]
- "[*Jeff Angelo from WHO Radio*]: I'm at New Leaf Wellness because of course I want to continue to maintain my good health during the COVID-19 outbreak This is certainly at the top of everybody's mind, Angela, boosting your immune system right now, so what are some of the things that New Leaf is offering . . .

[Angela, New Leaf Wellness]: First and foremost, hormone replacement . . . certainly doing some Vitamin C injections, some Vitamin C IVs . . . always a great way to push that Vitamin C into the system . . . B12 injections . . . we also do a peptide called Thymacin Alpha-1, and it's amino acids that actually super boost your immune system and you might've heard a little bit in the news about that as preventative, as far as boosting your immune system during this time of COVID-19."

[from your "Angela and Jeff Angelo from WHO Radio" video posted on April 4, 2020 at 9:51am on <u>https://www.facebook.com/newleafwellnesscenters/]</u>.

• "[*Angela, New Leaf Wellness*]: We've talked about how it's important to continue on hormone replacement through this very difficult time with COVID-19 and boosting your immune system. . . .

[*Dr. Sieman*]: The hormone therapy will help with your immune mechanisms. If all of a sudden you stop your hormone therapy, that's gonna really affect your body and make you more susceptible to contracting the COVID virus In addition, vitamin C in high doses, vitamin D3, glutathione, and IV therapy with high doses of vitamin C will also help . . . reduce the potential for developing a COVID virus. You want your immune mechanisms to work at its utmost during this time to ward off the potential for getting any infection. . . . Therefore, it is important to maintain your hormone therapy, to maintain your immune mechanisms, and hopefully you'll be able to ward off any potential for developing the COVID virus. . . .

[*Angela, New Leaf Wellness*]: We continue to say thank you to our existing patients that are continuing on their hormone therapy, you guys are ahead of the game. We welcome all new patients; we're here for you in this crisis of COVID-19. Again, we do the vitamin C injections, we do the high-dose vitamin C IVs, you can get vitamin D3 here in our clinic" [from your "Keep Your Immune System Strong!" video posted on March 26, 2020 at 11:49am on https://www.facebook.com/newleafwellnesscenters/]

• "[*Angela, New Leaf Wellness*]: Today we're going to focus on vitamin C IVs and why they're so important . . . we're joined by our nurse practitioner, Jenny, and

Jenny's going to go over . . . some benefits of vitamin C and how it can work for you.
[*Jenny*]: Absolutely. So, Vitamin C, so, so important. We're actually hearing on the news now that patients who are diagnosed or suspected of having COVID-19 are being treated with high-dose Vitamin C IVs. Our IVs are a simple procedure that we

being treated with high-dose Vitamin C IVs. Our IVs are a simple procedure that we can do here in the office, get you in and out in less than an hour, and get you a hefty dose, something that you cannot take orally. . . . getting the higher concentration through the IV, we bypass all the intestinal tract, liver, and kidney clearance and get that straight to your immune boosting function" [from your "Immune Boost" video posted on March 25, 2020 at 12:18pm on https://www.facebook.com/newleafwellnesscenters/]

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 or services identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products or services are

New Leaf Wellness, LLC April 28, 2020 Page 4

not supported by competent and reliable scientific evidence. You must immediately cease making all such claims.

You are also advised to review all other claims for your products and immediately cease making claims that are not supported by competent and reliable scientific evidence.

Within 48 hours, please send a message to Richard Cleland, Assistant Director 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 Richard Cleland at 202-326-3088.

Very truly yours,

Richard A. Quaresima Acting Associate Director Division of Advertising Practices