



WARNING LETTER

Date: May 11, 2020

TO: alannah.connealy@gmail.com; orders@perfectlyhealthy.com
Leigh Erin Connealy, M.D.
Center for New Medicine/Perfectly Healthy by Connealy MD
6 Hughes, Suite 100
Irvine, CA 92618

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.perfectlyhealthy.com, www.cfnmedicine.com, www.cancercenterforhealing.com, and www.shopcfnmedicine.com on April 24, 2020 and April 30, 2020, respectively. We have also reviewed your social media sites at www.youtube.com/channel/UCwWXwsxn8KGL0UPmJc13IuQ, www.facebook.com/ConnealyMD, and www.facebook.com/CenterForNewMedicine, where you direct consumers to your websites www.perfectlyhealthy.com and www.cfnmedicine.com to purchase your products. The FDA has observed that your websites offer the products Camu Camu's Vitamin C, Vitality C, Immunity Kit, Vitamin D3-K2, Liquid Silver, and Power Immune for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ 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 an 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

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, 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 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>).

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 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:

- “We offer immunity building protocols and treatments that may help during the spread of the COVID-19 virus. These include:
 - [Vitamin D3-K2](#)
The immune system uses vitamin D to make antimicrobial weapons that puncture holes in ...viruses.
 - [Liquid Silver](#)
Colloidal Silver has been a very effective way to kill ...virus[es] ... for many years.
 - [Power Immune](#)
We have used this blend for many years at the Center for New Medicine. This blend contains Echinacea, Berberine, Elderberry, and Agaricus. It has been shown to fight ...viruses
 - [Camu Camu’s Vitamin C](#)
Sourced from the Camu Camu plant and pure high dose Vitamin C to build the immune system. Vitamin C is a highly effective antioxidant that protects the body’s cells from pathogens. ... Vitamin C deficiency can result in impaired immunity and susceptibility to infections.”
[from your websites <https://www.cfnmedicine.com/covid19-1> and <https://www.cancercenterforhealing.com/covid-19-response/>]
- “What am I taking to build my Immune System?
Camu Camu's Vitamin C. High dose Vitamin C is an antidote to viruses. It has been used for many years. ... #covid2019” [from a March 9, 2020 post on www.facebook.com/ConnealyMD/]
- “The #Coronavirus is on everyone's mind right now. The key to not catching the virus is to keep your immune system as strong as possible. Perfectly Healthy's Immunity Kit created by Leigh Erin Connealy MD is a potent combination of Vitamin C, Echinacea, Agaricus, and Berberine.” [from a March 11, 2020 post on <https://www.facebook.com/CenterForNewMedicine>]

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/>).

- “Everyone's been asking Leigh Erin Connealy, M.D., our Medical Director, about her immune building protocols to protect themselves from the Coronavirus. ... Get 15% OFF her Immunity Kit ...”
[from a March 11, 2020 post on <https://www.facebook.com/CenterForNewMedicine>]
- From a video entitled “COVID-19 Prevention: What To Do Now” on your YouTube channel homepage [www.youtube.com/channel/UCwWXwsxn8KGL0UPmJc13IuQ]:
 - “So what am I doing to build my immune system? First of all, lots and lots of vitamin C. Vitamin C is the antidote for chemicals and viruses ... so please arm yourself with lots of vitamin C. We have the Camu Camu food-based Vitamin C and we have Vitality C.” [from your video entitled “COVID-19 Prevention: What To Do Now” at 0:01-0:24, <https://youtu.be/OZlrY5k2NKg>]
 - “[T]hen we also have our Power Immune. Now our Power Immune is a unique combination ... which is Agaricus blazei, echinacea and berberine. Two immune boosting agents, and berberine is an anti-viral, anti-bacterial substance. You can't go wrong.” [from your video entitled “COVID-19 Prevention: What To Do Now” at 0:33-0:55, <https://youtu.be/OZlrY5k2NKg>]

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 or service 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 for the products identified above are not supported by competent and reliable scientific evidence. Additional examples of claims for products or services that are not supported by competent and reliable scientific evidence include:

- “The #Coronavirus pandemic can be dramatically slowed down by boosting our immune systems with Vitamin C, Vitamin D3, Magnesium, Zinc, and other supplements. It’s crucial to maximize your body’s immune system to prevent and combat viruses. Here are @connealymd’s immune-boosting supplement recommendations for the Coronavirus: Vitality C...Vitamin D3-K2...Super Ionic Silver 24ppm...Maser Immune...Great Immune... You can shop all of these at Perfectly Healthy [with link to <https://www.perfectlyhealthy.com/> to purchase products].” [from a February 13 post on <https://www.facebook.com/pg/ConnealyMD/>]
- You post a video titled “CANCER AND COVID-19,” with Dr. Connealy. In the video, Dr. Connealy states: “I want to talk to you about Cancer and the Coronavirus...Cancer is a chronic condition that does have immune components...Targeted support would be Vitamin C, oral or intravenous, because we know that intravenous Vitamin C is very very powerful for augmenting the immune system...all of our patients are taking Vitamin D and I tell people to take extra Vitamin D during this time of crisis. And then I would recommend that you take specific immune support. We have several different formulas that we do. We have Master Immune, and we have the Great Immune, and we have Power Immune.” [from a March 20 post on <https://www.facebook.com/pg/ConnealyMD/>]
- You post an article titled “Evidence That Vitamin D Supplementation Could Reduce Risk of Influenza and COVID-19 Infections and Deaths,” and provide the link to

<https://www.shopcfnm.com> to purchase the product. [from a April 7 post on <https://www.facebook.com/pg/ConnealyMD/>]

- “Ozone destroys viruses! It stimulates the body into [] health optimized modes to eradicate disease and improve bodily functions at the cellular level. Healthy cells have complex enzymes systems as protectors, viruses, on the other hand, have no protections against oxidative stress, making them vulnerable to ozone...Center for New Medicine offers services and products that are intended to deal exactly with situations like COVID-19.” [from a March 26 post on <https://www.facebook.com/pg/CenterForNewMedicine/>]
- “Ozone therapies are known to stimulate the body into a health optimized mode to eradicate disease and improve bodily functions at the cellular level...The reason for ozone’s capacity to kill viruses and bacteria is based on its very high oxidation potential...Center for New Medicine offers services and products that are intended to deal exactly with situations like COVID-19.” [from a April 3 post on <https://www.facebook.com/pg/CenterForNewMedicine/>]
- “The strength of the immune system plays a large role in whether or not one will become ill. Here are some things we recommend to keep the immune function operating at optimal levels during COVID: Immune Boosting Supplements: Zinc, Elderberry, Vitamin D3, Silver, and Power Immune.... Intravenous Vitamin C - Vitamin C is an amazing immune support and a great preventative.” [from a April 8 post on <https://www.facebook.com/pg/CenterForNewMedicine/>]
- In a post on April 28, you state: “The media has been buzzing all weekend about UV Light Treatments and #Coronavirus. UV Light Therapies must be done properly and safely in a medical clinic to be effective. We use, and have been using for years, a UV Light Therapy called ‘Photodynamic Endolaser,’ which is known to strengthen the immune system and improve overall health...We are open during COVID-19 and helping new patients take preventative measures to protect themselves.” [from a April 28 post on <https://www.facebook.com/pg/CenterForNewMedicine/>]
- We offer immunity building protocols and treatments that may help during the spread of the COVID-19 virus. These include:...
 - [Vitamin C IV](#)
Our Vitamin C IV boosts the immune system function....
 - [Infrared Sauna](#)
Infrared saunas promote healthy metabolism, boost the immune system, kills bacteria, heals inflammations, etc....
 - [Ozone Therapy](#)
Healthy cells have complex enzymes system as protectors, viruses, on the other hand, have no protections against oxidative stress, making them vulnerable to ozone. These treatments are beneficial in both treatment and prevention of

viruses.

- [Photodynamic Endolaser](#)

Is known to strengthen the immune system and improve the overall health of the patient.

[from your websites <https://www.cfnmedicine.com/covid19-1> and <https://www.cancercenterforhealing.com/covid-19-response/>]

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
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition
Food and Drug Administration

Sincerely,

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

Drafted: HFS-608: A.Dotson: 03/18/2020
OCC clearance: 04/27/20 with comments to add URL
FTC signed: 05/01/2020
Clearance:OC/DE/DSLAB:C.Lawlor: 05/11/2020
Cleared:OC/DE: A.Barringer:05/12/2020
Cleared: HFS-600: W.Correll:05/XX/2020
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