WARNING LETTER

Date: July 21, 2020

TO: info@lasermedinstitute.com –

Dr. Phillip Yoo, DC
21st Century LaserSTEM Pain & Regenerative Medicine Institute d/b/a Create Wellness Clinics
12665 Garden Grove Blvd, Suite 311
Garden Grove, CA 99284

41990 Cook Street
Building B #201, Suite C
Palm Desert, CA 92211

RE: Unapproved, Misbranded & Adulterated 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.laserstemed.com, www.lasermedpaininstitute.com, www.laserstemproducts.com, and www.drphillipyoo.com on various dates since May 4, 2020. We also reviewed your YouTube.com channel at www.youtube.com/channel/UC4vo4IVgEgTyJVcZuQGuB8A (also accessible via www.DrYooTube.com and via a link from your www.drphillipyoo.com website). The FDA has observed that you offer products for sale in the United States that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people.

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 licensure, approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described in this letter, 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 unlicensed, unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Umbilical cord stem cell product

The FDA has observed that you offer an umbilical cord derived stem cell product for sale in the United

[1] As explained below, 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 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).
[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/).

States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.

Based on our review, this product is an unapproved new drug under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355. Furthermore, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

Your product is also an unlicensed biological product. In order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect under the Public Health Service Act (PHS Act). 42 U.S.C. § 262(a). Such licenses are issued only after a demonstration that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug application (IND) in effect as specified by FDA regulations. 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3); 21 CFR Part 312. Your product is not the subject of an approved BLA nor is there an IND in effect for your product.

Some examples of the claims in the videos on your YouTube channel that establish the intended use of your umbilical cord stem cell product and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

- "The best way to defend yourself is to create a strong immune system and if you're already over 50, you know, your stem cell count is down so you need to boost that up with umbilical cord cells from a donor because those cells are days old from the umbilical cord and that's the cells they used in the China study to reverse COVID patients' symptoms, and they reverse in like two, three days." [www.youtube.com/watch?v=kfUp6LSsKZ8]

- "We're using those young stem cells to help chronic pain, autoimmune disease, and, looks like the promising research shows, to fight off these viruses." [www.youtube.com/watch?v=TTwQiJRptDQ]

- "The type of stem cells we use, from the umbilical cord…we're using the adult, mature, umbilical cord because the baby is already out and healthy and born…It can be given to the recipient to regenerate their immunity or joints or pain. Wharton's jelly, that's what was used in the China study, is the highest count in stem cells and growth factors." [www.youtube.com/watch?v=kfUp6LSsKZ8]

- "If you are afraid to leave your home, we can deliver the treatments to you. We can send a doctor or nurse to come if you need stem cells. We could do it in your home, heck, we'll even do it in your car in the parking lot if you're afraid to have guests in your home…There's a lot of rapid approvals that the FDA has approved for umbilical cord stem cells, exosome therapy, natural killer cell therapy to kill the COVID virus." [www.youtube.com/watch?v=kfUp6LSsKZ8]

- "We can do these therapies, right here, safely in your hometown. Just so you know, it's not FDA approved yet, which means insurance isn't going to cover it, but under the 21st Century Cures Act, the Right to Try bill, you have the God-given right to try stem cells in the U.S. You don't have to risk your life going overseas and there's a lot of rapid approval for these studies because of the COVID pandemic by the way." [www.youtube.com/watch?v=kfUp6LSsKZ8]

- "…we have a COVID Relief Stimulus Program where if you are in financial hardship, but you do want to have stem cell therapy . . . , you could use your relief check and apply that towards a full stem cell treatment." [www.youtube.com/watch?v=kfUp6LSsKZ8]

The above-referenced umbilical cord derived cellular product is a human cell, tissue, or cellular or tissue-based product (HCT/P) as defined in 21 CFR 1271.3(d), that is subject to regulation under 21 CFR Part 1271, issued under the authority of section 361 of the PHS Act [42 U.S.C. 264].

HCT/Ps that do not meet all the criteria in 21 CFR 1271.10(a), and when no exception in 21 CFR 1271.15 applies, are not regulated solely under section 361 of the PHS Act [42 U.S.C. 264] and the regulations in 21 CFR Part 1271. Such products are regulated as drugs, devices, and/or biological products under the FD&C Act and/or the PHS Act, and are subject to additional regulation, including appropriate premarket review.

Based on the materials reviewed, 21st Century LaserSTEM Pain & Regenerative Medicine Institute does not qualify for any exception in 21 CFR 1271.15, and your umbilical cord derived cellular product is intended for non-homologous use. Additionally, it appears your product fails to meet other criteria in 21 CFR 1271.10(a). Accordingly, your product is regulated as a drug as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and a biological product as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].

Exosome product

We also note that you market an exosome product for diseases or conditions, such as macular degeneration and alpha 1 antitrypsin deficiency. For example, your YouTube videos state the following:

- "About a half-hour ago [Patient Name] had some exosomes grafted into the sphenopalatine ganglion where there are lymphatics connected to the eye, the optic nerve. Her vision was damaged. She had some type of autoimmune reaction. There was blurry vision. She couldn't read small font… [W]ithin a half-hour of exosomes, now you're reading normal, that's small font." [www.youtube.com/watch?v=KJSNksUDZwg&]

- "[A]bout two months ago we decided to try some nano or micro vascular therapy with exosomes…last month you did notice improvements in your oxygen saturation…A trillion exosomes are powerful. They are just in there and decrease the inflammation…[Patient name] does have alpha 1 trypsin deficiency which is … a genetic COPD. Supposedly there is no known treatment but with regenerative medicine we're getting these great results. So, today we're going to give him a booster. Instead of the exosomes, we're going to try some of the cord blood…[ ] Then we're also going to do another exosome but through a nebulizer…it is a different route of administration." [www.youtube.com/watch?v=Q3J_L5707eY]

Please be advised that as a general matter, exosome products intended to treat diseases or conditions in humans are regulated as drugs and biological products under section 351 of the PHS Act and the FD&C Act and are subject to premarket review and approval requirements. For more information, please see FDA's Public Safety Notification on Exosome Products, at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.

Please direct any inquiries regarding your umbilical cord stem cell product or exosome product to: COVID-19-Task-Force-CBER@fda.hhs.gov

Immune Support Bundle and Immune Boost Protection Kit Products

FDA also observed that your websites www.drphillipyoo.com and www.laserstemproducts.com offer the Biogenetix "Deluxe Immune Support Bundle" (Immune Support Bundle) and the "Dr. Phillip Yoo D.C.'s Signature – Emergency II COR-1:9 CV-19 Deluxe Immune Boost Protection Kit" (Immune Boost Protection Kit) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Both products are multi-component products that

include, among other things, a vitamin C product, "BioG-Max C," and a vitamin D product, "Liquid D 2000." Based on our review, the Immune Support Bundle and the Immune Boost Protection Kit are unapproved new drugs sold in violation of section 505(a) of the 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).

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:

- Product name "Dr. Phillip Yoo D.C.'s Signature – Emergency II COR-1:9 CV-19 Deluxe Immune Boost Protection Kit." The reference to "CV-19" (abbreviation of COVID-19) and the word "Protection" imply that the kit provides protection against COVID-19.

- From your video entitled "SARS CoV 2 Antibody Rapid Test Demonstration" [https://www.youtube.com/watch?v=Cn6XliqAbko]: "The best way to protect yourself from the virus is keep your immune system strong, so …vitamins you can take like Vitamin C, Vitamin D3" [8:46]

- On the cover image (thumbnail) of your YouTube video entitled "Dr. Phillip Yoo D.C. CORONA VIRUS COVID-19 PROTECTION PLAN FREE WEBINAR" [https://www.youtube.com/watch?v=_exYeFNsi4M]: "CORONA VIRUS COVID-19 PROTECTION PLAN … Order Your Immune Support Supplement Kit . . . at www.LaserStemProducts.com"

- From your video entitled "Dr. Phillip Yoo D.C. CORONA VIRUS COVID-19 PROTECTION PLAN FREE WEBINAR" [https://www.youtube.com/watch?v=_exYeFNsi4M]:

    - "I'm going to give you the most unbiased, updated information on how to protect yourself from this supposed coronavirus, COVID-19 pandemic …" [0:09]
    - "High dose vitamin C creates interferon to boost your immune system." [16:36]
    - "We have our Deluxe Immune Support Bundle with the vitamin D, vitamin C I talked about." [23:27]
    - "So, what can you do at home …if you want …immune-enhanced treatment is you can go to www.laserstemproducts.com. We have a lot of these supplements available and immune kits." [22:39]

In addition to making these claims on your websites, you include a printed copy of a "free guide" entitled 'How to Naturally Protect Yourself From The Coronavirus Free Guide by Dr. Phillip Yoo" with orders of the "Dr. Phillip Yoo D.C.'s Signature – Emergency II COR-1:9 CV-19 Deluxe Immune Boost Protection Kit." See http://www.drphillipyoo.com/products/dr-phillip-yoo-d-c-signature-deluxe-immune-boost-cv-19-kit. The guide recommends taking vitamins C and D "For Enhancing Your Immune System and Optimizing Your Body to Protect You From Any Virus, Including Covid-19." This guide provides additional evidence that the vitamin C and D products in your Immune Support Bundle and Immune Boost Protection Kit are intended for treatment or prevention of COVID-19.

Please direct any inquiries regarding your immune support products to: COVID-19-Task-Force-CFSAN@fda.hhs.gov.

COVID-19 test kit product

FDA observed that your website (www.drphillipyoo.com) offers a serology test for at-home testing, specifically the "Create Wellness Clinics COVID-19 Coronavirus SARS-CoV-2 Antibody At Home Rapid Telemedicine10 Minute Telemedicine Test Kit With Virtual Consultation" (referred to hereafter as "COVID-

19 Test Kit"). Based on our review, your COVID-19 Test Kit is intended for use in the mitigation, prevention, treatment, diagnosis or cure of COVID-19 in people, and thus, it is a device under section 201(h) of the FD&C Act, 21 U.S.C. § 321(h).

The COVID-19 Test Kit, which pictures on your website represent is manufactured by Eachy Biopharmaceuticals Co., Ltd., and the product's package indicates is manufactured by Shenzhen Watmind Medical Co. Ltd., is offered for sale and distributed in the United States directly to consumers for at-home use without marketing approval, clearance, or authorization from FDA. Accordingly, your product is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). Your product is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded.

We remind you that, to date, FDA has not approved, cleared or authorized any COVID-19 serology test for at-home testing. Different and potentially serious public health risks are presented with testing in the home versus a healthcare setting. Such risks include, but are not limited to, whether a lay user has the ability to collect their specimen, run the test, and interpret their result accurately. Your website, www.drphillipyoo.com, states that your product may be purchased directly by consumers and is intended to be used for at-home testing for COVID-19, including:

- "At Home Coronavirus (Covid-19) Telemedicine Testing With Virtual Consultation Now Available!"

- "Getting a corona virus test has not been easy. Here is good news, Create Wellness Clinics are now offering the areas first Covid 19 rapid telemedicine test that you take in the privacy of your own home to see if you have developed the antibodies for the Corona Virus. They ship the test kit to your home so you can avoid contact with others and a medical professional from Create Wellness Clinics will walk you through how to administer the test through a telemedicine call from the safety of your own home."

Please direct any inquiries to FDA regarding your COVID-19 Test Kit product to: COVID-19-Task-Force-CDRH@fda.hhs.gov.

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, the PHS 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/or effective for a COVID-19-related use for which they have not been licensed, approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. **Within 48 hours, please send emails to COVID-19-Task-Force-CBER@fda.hhs.gov, COVID-19-Task-Force-CFSAN@fda.hhs.gov** and **COVID-19-Task-Force-CDRH@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 are not in compliance with FDA

requirements and 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 https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products. Once you have taken corrective actions to cease the sale of your unlicensed, unapproved, uncleared, 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 adulterated or misbranded 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) listed above to be adulterated and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at the above-mentioned email addresses.

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 studies are 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,

/s/ Mary A. Malarkey -S

Digitally signed by Mary A. Malarkey -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300054353, cn=Mary A. Malarkey -S
Date: 2020.07.21 17:35:37 -04'00'

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

Sincerely,

/s/ William A. Correll Jr -S

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Date: 2020.07.21 16:31:34 -04'00'

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

Sincerely,

/s/ Timothy T. Stenzel -S

Timothy Stenzel, M.D., Ph.D.
Director
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

Sincerely,

/s/ SERENA VISWANATHAN

Digitally signed by SERENA VISWANATHAN
Date: 2020.07.20 15:15:09 -04'00'

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