[redacted]

Date: July 21, 2020

TO: info@lasermedinstitute.com – Dr. Phillip Yoo, DC
21st

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

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 whiiice w i deld.6 (on)11.3 7f.

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,

Mary A. Malarkey -S

Digitally signed by Mary A. Malarkey -S
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ou=FDA, ou=People,
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Date: 2020.07.21 17:35:37 -04'00'

Sincerely,

/s/

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

Sincerely,

/s/ Timothy T. Stenzel

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/rFood and Drug Administration ,Tf.14MC /P <</MCID 33 >>BDC oj 3