CBER 20-05

WARNING LETTER

Date: August 17, 2020

TO: info@pagreenwellness.com –
PA Green Wellness, LLC
dba A Predictive Biotech Certified Facility
1150 1st Ave, Ste #950
King of Prussia, PA 19406

CC: eolson@predbiotech.com
Info@predictivebiotech.com –
Eric K. Olson - Predictive Biotech, Inc.,
A Predictive Technology Group Company
dba Predictive Laboratories, Inc.
2735 E Parleys Way #205
Salt Lake City, UT 84109-1660

RE: Unapproved and Misbranded Product 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 website at www.pagreenwellness.com and your social media website at www.facebook.com/PAGreenWellness, most recently in August 2020. You use these websites to promote the umbilical cord derived product CoreCyte™. FDA has learned that you offer CoreCyte™ for sale to patients in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people.

CoreCyte™ is a human cell, tissue, or cellular or tissue-based product (HCT/P) as defined in 21 C.F.R. § 1271.3(d)[2] and is subject to regulation under 21 C.F.R. Part 1271, issued under the authority of section 361 of the Public Health Service Act (PHS Act), 42 U.S.C. § 264.

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

PA Green Wellness, LLC (PA Green Wellness) does not qualify for any exception in 21 C.F.R. § 1271.15, and CoreCyte™ fails to meet all the criteria in 21 C.F.R. § 1271.10(a). Specifically,

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

[2] HCT/Ps are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 CFR 1271.3(d).

CoreCyte™ fails to meet the criterion in 21 C.F.R. § 1271.10(a)(2) that the HCT/P be "intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." While some promotional materials describe the product as being for homologous use, in fact the product is not intended to perform the same basic function or functions of umbilical cord in the recipient as in the donor, such as serving as a conduit. Using CoreCyte™ to prevent or treat COVID-19 is not homologous use as defined in 21 C.F.R. § 1271.3(c). In addition, available information regarding CoreCyte™ suggests that it fails to meet the minimal manipulation criterion set forth in 21 C.F.R. § 1271.10(a)(1) and defined for structural tissue in 21 C.F.R. § 1271.3(f)(1). The product does not appear to meet this criterion because the processing alters the original relevant characteristics of the umbilical cord related to its utility for reconstruction, repair, or replacement. Therefore, CoreCyte™ is not regulated solely under section 361 of the PHS Act, 42 U.S.C. § 264, and the regulations in 21 C.F.R. Part 1271.

CoreCyte™ is an unapproved new drug under section 505 of the 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. It is a prohibited act under section 301(k) of the FD&C Act, 21 U.S.C. § 331(k) to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

CoreCyte™ is also a biological product under section 351 of the PHS Act, 42 U.S.C § 262. In order to lawfully market a drug that is also a biological product, a valid biologics license application (BLA) must be in effect under the 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 (IND) application in effect as specified by FDA regulations, 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3); 21 C.F.R. Part 312. CoreCyte™ is not the subject of an approved BLA; nor is there an IND in effect for your product.

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 products that, without licensure, approval, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you have offered a product for sale that is

[3] 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 another 90 days twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.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/).

intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the marketing, sale, and distribution of any such unlicensed, unapproved, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your website, social media, and in your marketing that establish the intended use of CoreCyte™ and misleadingly represent it as safe and/or effective for the prevention of COVID-19 include:

- Your Director of Operations, Dawn Venable, provides prospective customers with information regarding CoreCyte™, which she refers to as PA Green Wellness's "Healthy Lung Injection." Ms. Venable also informs prospective patients that the product would protect them from the coronavirus and improve lung health.

- "PA Green Wellness is thrilled to offer an immune building injection thanks to the innovation of Predictive Biotech: 'Healthy Lungs Wellness Injection.'" [from a March 18, 2020 post on your social media website, www.facebook.com/PAGreenWellness/] This post links to a news article titled, "Predictive Technology Group Addresses Use of Mesenchymal Stem Cells in Treatment of Secondary Issues Related to Coronavirus" [Note: clicking on "Predictive Biotech" within the post links to www.facebook.com/PredictiveBiotech]

- "PA Green Wellness is now offering an injection to support lung health during the COVID-19 . . . we are working to support our community with new treatment options." [from a March 20, 2020 post on your social media website, www.facebook.com/PAGreenWellness/]

  The above Facebook post provides the link, https://www.einpresswire.com/article/512455640/pa-green-wellness-is-now-offering-mesenchymal-stem-cell-treatments-to-support-lung-health-during-covid-19?fbclid=IwAR16gzsXobIhYVhiU3AbX4-nIGFRZagpCj5RxliDN-NFJC4LWuroNWypoZ4, to your March 19, 2020 "PA Green Wellness Press Release" titled, "PA Green Wellness is Now Offering Mesenchymal Stem Cell Treatments to Support Lung Health During COVID-19." This news release refers to your product supplier as Predictive Biotech and further states:

  - "PA Green Wellness has adapted its signature wellness injection to aid in the lung health, restoration of damage and an overall reduction in inflammatory responses."[5]

  - "'This goes to support the wide range of healing and restoration that can be provided by MSC therapy . . . this technology may have the ability to reverse lung damage in patients and improve their overall health, which puts them in a much better position if they should find themselves with a COVID-19 infection.'"

- "Virtually anyone can benefit from a mesenchymal stem cell treatment, however injections

[5] It appears that you may have been offering CoreCyte™ for sale to patients to treat diseases or conditions prior to the current global outbreak. Please be advised that CoreCyte™ is not FDA approved or licensed for any indication.

> are most beneficial if you're noticing a reduction in your body's natural healing power . . . or if you've experienced an injury. Or suffer from chronic inflammation . . . that needs assistance to heal . . . our products are safe and effective." [from your website, www.pagreenwellness.com/regenerative-medicine/]

Please also be advised that FDA has not issued an Emergency Use Authorization or any other authorization to permit the emergency use of CoreCyte™ under any circumstances.

You should take immediate action to correct any violations of the FD&C Act, the PHS Act, and FDA's implementing regulations. This letter is not meant to be an all-inclusive list of violations that exist in connection with your product or operations. It is your responsibility to ensure that you and your products fully comply with the law.

We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your product as safe and effective for a COVID-19-related use for which it has not been licensed by FDA and that you do not make claims that misbrand the product in violation of the FD&C Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CBER@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 licensed, 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.[6] 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 unlicensed, 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 product is 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.

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[6] We note this Warning Letter also concerns the offer for sale of a COVID-19 related product in violation of the PHS Act.

Please direct any inquiries to FDA at **COVID-19-Task-Force-CBER@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,

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: 2020.08.17 11:49:36 -04'00'

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

Sincerely,

SERENA VISWANATHAN

Digitally signed by SERENA VISWANATHAN
Date: 2020.08.13 10:38:32 -04'00'

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