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]

[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,

[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.

i

SERENA VISWANATHAN

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