



CBER 21- 01

WARNING LETTER

Date: November 18, 2020

TO: info@vibranthealthcare.org - Edgar Suter, MD
Vibrant Health Care, Inc.
4900 N. Scottsdale Road
Suite 2400
Scottsdale, AZ 85251

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 Federal Trade Commission (FTC) reviewed your website at www.vibranthealthcare.org, most recently in November 2020. We also reviewed your social media websites at www.facebook.com/vibranthealthcare and www.youtube.com/channel/UCYwkJF3de5oayYPHTOHg7mA. The FDA has observed that you offer an umbilical cord derived cellular product in the United States to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people.

Your product 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 FD&C Act and/or the PHS Act, and are subject to additional regulation, including appropriate premarket review.

Vibrant Health Care, Inc. does not qualify for any exception in 21 C.F.R. § 1271.15, and your umbilical cord derived cellular product fails to meet all the criteria in 21 C.F.R. § 1271.10(a). Specifically, your product 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.” Additionally, it appears your product fails to meet other criteria in 21 CFR 1271.10(a). Therefore, your umbilical cord derived cellular product is not regulated solely under section 361 of the PHS Act, 42 U.S.C. § 264, and the regulations in

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).

A video on the Vibrant Health Care YouTube channel (posted March 18, 2020):

- x You describe this video as “[a] public service announcement from Dr. Edgar Suter on fortifying lungs to avoid coronavirus.” [<https://www.youtube.com/watch?v=8GBj-3Fpw0g>]

On June 3, 2020, during a chat on your Vibrant Health Care Facebook page, you were specifically asked, “Do you offer any stem cell products for prevention of COVID?” You stated the following in response to the aforementioned question:

- x “Yes we do offer preventative treatments that can help boost the immune system and fortify lungs against viruses.” [www.facebook.com/vibranthealthcare]

On March 17, 2020, your Vibrant Health Care Facebook page posted:

- x “How can we improve our odds of staying healthy and fighting off Coronavirus? Shelley Blanzky of Vibrant Health Care speaks with Dr. Edgar Suter regarding prevention and treatment options that are now available....Please call...to schedule a consultation with Dr. Suter.” A video accompanies this post in which Dr. Suter states, “We saw that mesenchymal stem cells, stem cells, can be helpful in even bringing people back from the brink of death . . . as far gone as on the respirator very near death who have had infusions intravenously of stem cells and have come back without lung damage, without organ system damage...I’m of the belief that...stem cell infusions intravenously...can help fortify us so that we’re less likely to get and less likely to succumb to this COVID-19 pandemic.” [www.facebook.com/vibranthealthcare]

On March 19, 2020, your Vibrant Health Care Facebook page posted:

- x “Stem cells are proving to be effective in treating critically ill Coronavirus patients. Stem cell therapy can also help build up the immune system and fortify lungs against viruses. To learn more about how stem cell therapy can help you or a loved one, please call...and schedule a free consultation” [www.facebook.com/vibranthealthcare]

A website post regarding “Stem Cell Therapy for Coronavirus”: bhedb Td [(r)7 (ng)10 (c)ed s agaiel (ant)

disease, type 1 diabetes, multiple sclerosis, inflammatory bowel disease), and you claim:

- x Your Vibrant Health Care specialist injects flowable allograft containing stem cells from donated umbilical cord tissue into the affected areas of the body. At Vibrant Health Care, we see our patients show great improvements in their symptoms after the treatment.”
[\[www.vibranthealthcare.org/services/autoimmune-conditions\]](http://www.vibranthealthcare.org/services/autoimmune-conditions)

A patient testimonial on YouTube (posted July 15, 2019):

- x “I have an autoimmune condition called ulcerative colitis...I came to Vibrant and I got some stem cell therapy...they hooked me up to an IV for 10 minutes...the next day I saw huge results.” [\[www.youtube.com/watch?v=GnTz7XwjYrU\]](http://www.youtube.com/watch?v=GnTz7XwjYrU)

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