WARNING LETTER

Pro Breath MD, LLC dba Dentist Select and OraCare

MARCS-CMS 610686 — NOVEMBER 18, 2020

Product:

Drugs

Recipient:

Pro Breath MD, LLC dba Dentist Select and OraCare

467 Martino Twins Lane

Bridgeport, WV 26330

United States

kmccoy@dentistselect.net

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Federal Trade Commission

WARNING LETTER

Date: November 18, 2020

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 the Federal Trade Commission (FTC) reviewed your websites at the Internet addresses https://www.oracareproducts.com/ and https://www.dentistselect.net on October 2, 2020, and November 10, 2020, respectively. The FDA has observed that your firm offers "OraCare Health Rinse" and "OraCare Operatory Pre-Rinsing Set" products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (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).

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

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:

From your webpage titled "Human Coronavirus Testing - ORACARE" on your website https://www.oracareproducts.com/coronavirus-info.html:

- **"New Study:** "OraCare Rinse found greater than 99.99% effective against human coronavirus with no toxic effects on tissue."
- "Activated chloride dioxide (ClO2) has the ability not only to kill viruses, but new study confirms it also kills human coronavirus."
- "Study Highlight #1: OraCare kills 99.99% of human coronavirus in as little as 1 minute."
- "**Effectiveness against viruses**: OraCare eliminated greater than 99.99% of the Human Covid 229E virus at 1, 5, 15 and 60 minutes exposure times with 99.99% effectiveness at each exposure."

- **"OraCare PreRinse**: Not only can OraCare help improve your patient's oral health it can protect you as a dental professional. This study confirms OraCare's ability to kill human coronavirus as good if not better than all other rinses and with no cell toxicity even with a 60 minute exposure time."

From your webpage titled "Pre-Rinsing - ORACARE" on your website https://www.oracareproducts.com/pre-rinsing.html:

- "But as we have learned through the COVID-19 pandemic, viruses need to be more of a focal point. The pandemic also raised awareness that we as dental professionals are at a higher risk for exposure to viruses. OraCare is the BEST product for pre-rinsing because OraCare's active ingredient chlorine dioxide (ClO2) kills bacteria, viruses, fungi, and breaks up biofilm through the process of oxidation . . . It is safe and effective. Dental professionals choose activated chlorine dioxide as their pre-rinse, as many are incorporating it into their daily routine of personal protective measures . . . Not only can OraCare help improve oral health it can protect you as a dental professional."

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 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 effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CDER@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 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. 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 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 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 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 products referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.

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

/S/

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

/S/

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

[1] As explained in the next paragraph, 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 has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.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/).

Content current as of:
11/19/2020

Regulated Product(s)
Drugs

More Warning Letters

WARNING LETTER

Vibrant Health Care, Inc.

MARCS-CMS 608426 — NOVEMBER 18, 2020

Reference #:

CBER 21-01

Product:

Biologics

Recipient:

Edgar Suter, MD

Vibrant Health Care, Inc.

4900 N. Scottsdale Road Suite 2400

Scottsdale, AZ 85251

United States

info@vibranthealthcare.org

Issuing Office:

Center for Biologics Evaluation and Research (CBER)

United States

Federal Trade Commission

CBER 21- 01

WARNING LETTER

Date: November 18, 2020

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-19[1] 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 21 C.F.R. Part 1271.

Your umbilical cord derived cellular 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. 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.

Your product 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 application (IND) in effect. 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.[3]

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.[4] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[5] 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 offer a product for sale that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the marketing or sale 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, YouTube channel, and Facebook page that establish the intended use of your product and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

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

- 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:

- "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:

- "How can we improve our odds of staying healthy and fighting off Coronavirus? Shelley Blanzy 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:

- "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":

- "According to Edgar Suter, MD who has performed hundreds of successful stem cell therapy treatments, the anti inflammatory and healing properties of stem cells can help patients form a formidable barrier against the virus. This is especially true for patients who are less equipped to fight off infections due to a weaker immune system, other illnesses or aging. Per Dr. Suter, fortifying the lungs'' [sic] with umbilical cord tissue that contains millions of potent stem cells is a great way for patients to boost their ability to fight off virus and other related illnesses." [www.vibranthealthcare.org/blog/can-stemcell-therapy-help-patients-with-coronavirus]

We also note that you market your umbilical cord derived cellular product for numerous other diseases or conditions, such as diabetes, ulcerative colitis, multiple sclerosis, Crohn's disease, lupus, inflammatory bile disease, and asthma. For example:

On your website, you have a page dedicated to autoimmune diseases (including lupus, Crohn's disease, type 1 diabetes, multiple sclerosis, inflammatory bowel disease), and you claim:

- 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]

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

- "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]

A patient testimonial on YouTube, entitled "*Type 2 Diabetes and Neuromyopathy patient shares in* [sic] *stem cell therapy experience*" (posted March 4, 2020):

- "I was diagnosed with type 2 diabetes…and…neuromyopathy…I had my treatment two weeks

ago…it was intravenous…I don't have as much numbness as I did…I'm not really using the cane anymore." [www.youtube.com/watch?v=2Av3lDbvGbw]

A patient testimonial on YouTube (posted March 5, 2019):

- "I struggled with asthma for about 20 years…it was quite remarkable when I did the stem cell treatment, overnight all of that disappeared…my peripheral neuropathy had also cleared up." [www.youtube.com/watch?v=EDyswjbaspo&feature=youtu.be&t=4]

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 products as safe and effective for a COVID-19-related use for which they have not been licensed, approved, or authorized by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act.[6]

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, 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.[7] 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 product 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.

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,

/S/

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

Sincerely,

/S/

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

---

[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).

[3] We note that you also offer an amniotic fluid product. [https://www.facebook.com/pg/vibranthealthcare/services/?ref=page_internal]. Because the definition of HCT/Ps in 21 CFR 1271.3(d) excludes secreted or extracted human products, secreted bodily fluids, such as amniotic fluid, are generally not considered HCT/Ps subject to regulation under 21 CFR Part 1271. Although not an HCT/P, amniotic fluid intended to treat diseases or conditions in humans is generally regulated as a drug and biological product under section 351 of the PHS Act and the FD&C Act and requires premarket review and approval.

[4] 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 has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.)

[5] 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/).

[6] As noted above, you also market your umbilical cord derived cellular product for various other diseases or conditions. Although these claims are not the focus of this letter, please be advised that you must have an approved premarketing application on file with FDA to lawfully market your umbilical cord derived cellular product for such indications.

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

Content current as of:
11/20/2020

Regulated Product(s)
Biologics

More Warning Letters