U.S. FOOD & DRUG ADMINISTRATION

May 4, 2021

VIA E-MAIL AND UPS EXPRESS MAIL

Richard A. Ramos, DC
Owner
Ramos Chiropractic and Wellness Center
(aka Rejuvenate Stem Cell Center)
209 5th Street
Burlington, CO 80807
ramoschiro@live.com

Dear Dr. Ramos:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) has reviewed your websites available at https://rejuvenatestemcellcenter.com/ and www.ramoschiropracticandwellnesscenter.com/, and your Facebook pages available at www.facebook.com/RejuvenateStemCellCenter/ and www.facebook.com/RamosChiropracticWellnessCenter/.

FDA's review revealed that you market "umbilical stem cells" from BioGenix, which appear to be cellular products derived from human umbilical cord or human umbilical cord blood (hereinafter, "products"). You market your products for various diseases or conditions, such as chronic obstructive pulmonary disease (COPD), diffuse idiopathic skeletal hyperostosis (DISH), heart disease, diabetes, Parkinson's disease, lupus, and multiple sclerosis (MS). These products are administered by various routes of administration, including intravenously.

For example, on the Rejuvenate Stem Cell Center website, https://rejuvenatestemcellcenter.com/, you market your products using the following patient testimonials:

- "I was diagnosed with COPD 10 years ago…I received an Umbilical Stem Cell IV infusion and I have never felt better."

- "I have a hereditary condition called DISH…This condition has caused me to have limited mobility in my neck, shoulders and my back…I had my Stem Cell injection in my lower back…and I am now pain free…I am convinced that it has helped with my DISH as well."

- "Dr. Ramos suggested that I would be a great candidate for Umbilical Stem cell therapy for my chronic sciatica pain…I received my injection…I now have ABSOLUTELY no pain!!"

On your Facebook pages, you state, for example:

- "We often receive questions asking what all can Stem Cells help with…Heart Disease…Diabetes…Parkinson Disease…Lupus, MS…COPD…If you struggle with any of these give us a call to schedule a consultation." [www.facebook.com/RamosChiropracticWellnessCenter/photos/a.404920806285904/2420322828079015/?type=3&theater]

- "If stem cell can help with a heart condition, then they can help with any kind of condition…Don't just sit back and think that you have to just live with or deal with the pain your fighting or condition you have been diagnosed...There is a solution!!...#rejuvenatestemcellcenter." [www.facebook.com/RejuvenateStemCellCenter/posts/142903893866991?__tn__=-R]

The above-referenced products appear to be human cells, tissues, or cellular or tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d) that would be subject to regulation under 21 CFR 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 CFR 1271.10(a), and when no exception in 21 CFR 1271.15 applies, are not regulated solely under section 361 of the PHS Act [42 U.S.C. 264] and the regulations in 21 CFR 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.

It appears that you do not qualify for any exception in 21 CFR 1271.15, and the above-referenced products do not meet all the criteria in 21 CFR 1271(a) because the HCT/Ps are intended for nonhomologous uses. Additionally, it appears that your stem cell product derived from umbilical cord fail to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that your products would be regulated as drugs as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].

In order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [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].

As noted above, your products are intended to treat a variety of diseases or conditions, including some that are serious or life-threatening. Such unapproved uses raise potential significant safety concerns. Moreover, because the products may be administered by a higher risk route of administration, including by injection and intravenously, their use, if contaminated could cause a range of adverse events. We direct your attention to FDA's comprehensive regenerative medicine policy framework for HCT/Ps, which is intended to spur innovation and efficient access to safe and effective regenerative medicine products. The policy framework is outlined in a suite of four guidance documents available on FDA's website at https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapyproducts/framework-regulation-regenerative-medicine-products.

Manufacturers and health care professionals who have any uncertainty regarding the regulatory status of their products are encouraged to contact FDA to obtain a recommendation or decision regarding the classification of an HCT/P. For more information in this regard, or to obtain further information about IND requirements for biological products, please see pages 24 and 25 of the guidance entitled, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use" at the link to FDA's webpage provided above.

This letter is not intended to be an all-inclusive review. You and your firm are responsible for ensuring that all your products fully comply with the FD&C Act, PHS Act, and all applicable regulations. We request a written response within 30 days of your receipt of this letter. Your response should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 71, Silver Spring, MD 20993. In addition, you may also submit an electronic copy of your response to CBERDCMRecommendations@fda.hhs.gov. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at (240) 402-9155. Please be advised that only written communications are considered official.

Sincerely,

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