June 05, 2024

VIA UPS EXPRESS MAIL

Darcy Brunk, DC
Founder
Achieve Vitality, LLC
1606 Wynn Joyce Rd.
Garland, TX 75043

Dear Dr. Brunk:

The Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) has reviewed your firm's website available at www.achievevitality.net as well as other online sources described below (last visited June 2024).

Based on the materials reviewed, you sell in the United States a cellular product derived from human umbilical cord, which you refer to as "Infiniti Matrix Therapy", "regenerative therapy" and "stem cell therapy" (hereafter "your product"), to consumers. Your statements about your product on your website establish that it is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(g)(1)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and also because it is intended to affect the structure or function of the body. Based on your website your product is also a biological product under section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. § 262(i)], because it is applicable to the prevention, treatment, or cure of a disease or condition of human beings.

According to your website:

- "Infiniti Matrix is a therapy that taps into the body's natural regenerative abilities, supporting the processes necessary for healing and optimal health…It helps your body repair injuries and recover from disease so that you can consistently look and feel your best."

- "Using Infiniti Matrix, it is now possible to kickstart your body's internal repair system, fighting back against disease and degeneration."

- "Infiniti Matrix is a simple, safe, and regenerative therapy that can stimulate and strengthen your body's internal repair system."

- “Achieve Vitality takes great pride in offering Infiniti Matrix therapy in Dallas-Fort Worth, in a large part due to the innumerable benefits it can provide for our clients including…Incomparable regenerative capabilities…An incredible capacity for fighting inflammation and improving immunity.”

- “Infiniti Matrix seeks out degeneration and work to build, repair, and create new tissue.”

- “Infiniti Matrix has powerful anti inflammatory properties reduce inflammation in the body.”

- “Infiniti Matrix modulates the body’s immune response.”

- “Whether you’re seeking recovery from injury or illness, or simply in the pursuit of optimal health at every age, Infiniti Matrix therapy can be the answer you’ve been looking for.”

- “Achieve Vitality hosts events and webinars where you can discover the ways in which Infiniti Matrix Therapy may help you leave a life of chronic illness and injury behind.”

According to patient testimonials that you posted on your firm’s Facebook page, (www.facebook.com/AchieveVitalityDallas/ last visited June 2024):

- Posted May 14, 2021: “Over the years, I've experienced a great deal of wear and tear on my body. The straw that broke the camel's back was the development of severe back pain. I saw one of the best neurosurgeons in the area. He found that I had a herniated disc at T1-T2 and severe stenosis at two levels above that. Stem cell therapy provided the solution…Three weeks later, my pain resolved and I've been pain free ever since.”

- Posted April 16, 2021: “before stem cells, arthritis was insidiously creeping through my hands. Because of extreme pain and swelling, I could no longer slide a ring on the ring finger of my right hand. But today, rings are no problem–no problem at all. As for the arthritis in my knees, it's actually a distant memory. I just don't have it anymore…My overall quality of life is so much better because of this stem cell treatment.”

Your above-referenced product is a human cell, tissue, or cellular or tissue-based product (HCT/P) 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 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 FD&C Act and/or the PHS Act, and are subject to additional regulation, including appropriate premarket review.

Based on our review of the materials described above, your firm does not qualify for any exception in 21 CFR 1271.15, and your above-referenced product fails to meet all criteria in 21 CFR 1271.10(a). Accordingly, your umbilical cord derived product is regulated as a drug as defined in section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)] and a biological product as defined in section 351(i) of the PHS Act [42 U.S.C. § 262(i)].

Specifically, your product fails to meet the criterion in 21 CFR 1271.10(a)(2) that an HCT/P be "intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." Your 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. Rather, your product is intended for use in recovery from disease, for example, which is not considered homologous use as defined in 21 CFR 1271.3(c).

In addition, your umbilical cord-derived cellular product fails to meet the minimal manipulation criterion set forth in 21 CFR 1271.10(a)(1) and defined for structural tissue in 21 CFR 1271.3(f)(1). The processing of the umbilical cord from the form of a conduit into an injectable form, as your website indicates, drastically alters the physical state of the HCT/P. The umbilical cord is more than minimally manipulated because such processing alters the original relevant characteristics of the HCT/P relating to its utility to serve as a conduit by effectively altering or eliminating its physical integrity and tubular form.

Therefore, your product is not regulated solely under section 361 of the PHS Act [42 U.S.C. § 264] and the regulations in 21 CFR Part 1271 but rather is regulated as a drug as defined in section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)] and a biological product as defined in section 351(i) of the PHS Act [42 U.S.C. § 262(i)].

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]. Your above-referenced product is not the subject of an approved biologics license application (BLA), nor is there an IND in effect.

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

www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/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 titled, "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 addresses certain issues regarding the above-described product and 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 and PHS Act and all applicable regulations.

We advise you to comprehensively review your website, product labels, and other labeling and marketing materials to ensure that you are lawfully marketing your products in full compliance with the FD&C Act, the PHS Act, and their implementing regulations. We request a written response within 30 days of your receipt of this letter. If you do not believe there is a basis for the regulatory issues raised in this letter, include your reasoning and any supporting information for our consideration.

Send your electronic response to CBERDCMRecommendations@fda.hhs.gov. If you have questions regarding this letter, contact the Division of Case Management, CBER at (240) 402-9156.

Sincerely,

Melissa J. Mendoza
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research