U.S. FOOD & DRUG ADMINISTRATION

January 16, 2024

VIA UPS EXPRESS MAIL AND EMAIL

(b) (6)
Vitacell Biologics, LLC
1344 N Ellington Pkwy
Lewisburg, TN 37091-2218
(b) (6)

Dear Mr. West:

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) reviewed your firm's website, available at www.vitacellbiologics.com, in October 2023.

Based on our review of your website, you have sold Vitacell and Vitacell Pro, cellular products derived from human umbilical cord, which you refer to as "stem cells" or "stem cell therapy", and Cytocell Pro, an exosome product (collectively, "your products") in the United States. The statements on your website indicated that your products are drugs under section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(g)(1)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and also because they are intended to affect the structure or function of the body. Your products are also biological products under section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. § 262(i)] because they are applicable to the prevention, treatment, or cure of a disease or condition of human beings.

For example, your website included testimonials about uses of your products such as:

- "Vitacell Biologics helped save my life. After burning 85% of my body during a freak fire accident, I was not expected to live. Thanks to the immediate response of Dr. Mark Fedorczyk and the team at Vitacell Biologics, I not only survived, but am now able to live a grateful, thriving life. I am extremely thankful for the advantages that Stem Cells and Exosomes gave me during my recovery...."

- "Multiple Meniscus Tears…Receiving stem cell injections has changed my life…. After receiving the injections, I was able to walk, dance, and exercise pain free…. In the future, I will always choose stem cell injections over surgery."

- “I have advanced arthritis in my knee, cervical and lumbar spine. Using stem cells has kept me from undergoing surgery.” (Emphasis removed).

- “Cured my Diabetic Ulcer in 21 days!…Out of desperation, my brother-in-law (Dr. Mark) suggested I try Exosomes…it ended up being the best decision I ever made. Not only did it get better; It completely disappeared in 21 days.” (Emphases removed).

Your website also included statements regarding your products such as:

- “At Vitacell Biologics, we utilize adult stem cells derived from Human Umbilical Cord Tissue. This has the highest source of mesenchymal stem cells . . . These cells ideally assist in the treating of systemic autoimmune and inflammatory conditions. They also play a significant role in cellular signaling to repair and regenerate injured tissue.”

- "Vitacell Wharton’s Jelly Tissue Allograft is extracted and processed to yield a high concentration of:…Scaffolding cells necessary to reconstruct, repair, replace, or supplement damaged/injured tissue.”

- “Vitacell Pro…Wharton’s Jelly Tissue Allograft is extracted and processed to yield a high concentration of:…Scaffolding cells necessary to reconstruct, repair, replace, or supplement damaged/injured tissue.”

- “Cytocell Pro 25 and 50 billion Exosomes…their function is to direct tissue and wound healing by activating the patient’s own regenerative cell response.”

- “Advantages to using Umbilical Cord Wharton’s Jelly…Have strong anti-inflammatory effect.”

- “What Conditions Does Regenerative Medicine Treat?”, an FAQ following discussion of the firm’s stem cell and exosome products, is followed by a long list of various types of diseases or conditions, for example: hip and shoulder pain, wound care, degenerative arthritis of the knee, hip, shoulder, or ankle; plantar fasciitis; and muscular tears.

Your umbilical cord derived cellular products (Vitacell and Vitacell Pro) 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 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 the review of the materials described above, it appears that your firm does not qualify for any exception in 21 CFR 1271.15, and that your umbilical cord derived cellular products fail to meet all the criteria in 21 CFR 1271.10(a). Accordingly, it appears that your umbilical cord derived cellular products would be regulated as drugs as defined in section 201(g)(1) of the FD&C Act [21 U.S.C. 321(g)(1)] and biological products as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].

Specifically, your umbilical cord derived cellular products appear to fail to meet the criterion in 21 CFR 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." These products are not intended to perform the same basic function or functions of the umbilical cord in the recipient as in the donor, such as serving as a conduit. Rather, using these products for the treatment of diseases or conditions, such as hip and shoulder pain, wound care, degenerative arthritis of the knee, hip, shoulder, or ankle, plantar fasciitis, and muscular tears is not considered homologous use as defined in 21 CFR 1271.3(c).

In addition, your umbilical cord derived cellular products appear to fail 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). For example, your processing alters the original relevant characteristics of the umbilical cord related to its utility for reconstruction, repair, or replacement. The isolation of the Wharton's jelly from the umbilical cord and subsequent isolation of nonstructural cellular components from the Wharton's jelly is more than minimal manipulation because such dissociation of the structural components of the umbilical cord alters the original relevant characteristics relating to the tissue's utility to serve as a conduit by effectively altering or eliminating its physical integrity and tubular form.

Moreover, the processing of the umbilical cord from the form of a conduit into an injectable form, as your website indicated, drastically alters the physical state of the HCT/P. The umbilical cord appears to be more than minimally manipulated, because such processing appears to alter 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.

Your exosome product (Cytocell Pro) also meets the definitions of drug and biological product under section 351 of the PHS Act and section 201(g)(1) of the FD&C Act, as discussed above, and is also subject to premarket review and approval requirements. With regard to your exosome product, we direct your attention to FDA's Public Safety Notification on Exosome Products, at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products. FDA issued this public safety notification following multiple reports of serious adverse events experienced by patients who were treated with exosome products.

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 umbilical cord derived cellular products and your exosome product are not the subject of an approved biologics license application (BLA), nor is there an IND in effect for your products.

Further information about IND requirements for biological products may be obtained through the Division of Regulatory Project Management, Office of Tissues and Advanced Therapies, at 240-402-8190 or mail to: OTATRPMS@fda.hhs.gov.

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 entitled, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal.

This letter addresses certain issues regarding the above-described products 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.

Your response should be sent to 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. You may also email a 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) 402-9156.

Sincerely,

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

CC:
Dr. Mark Fedorczyk
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