U.S. FOOD & DRUG ADMINISTRATION

February 23, 2024

VIA UPS EXPRESS MAIL AND E-MAIL

Sunita Bhasin, DC
Founder
Oregon Medical Centers, LLC
2515 Liberty St. NE
Salem, OR 97301
(b) (6) @yahoo.com

Dear Dr. Bhasin:

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 at www.oregonmedicalcenters.com, Facebook page at www.facebook.com/Chiropractor.Salem.OR, and YouTube channel at www.youtube.com/@Oregonmedicalcenters1 (last visited February 2024).

Based on the materials reviewed, you and your firm sell in the United States a cellular product derived from human umbilical cord, which you refer to as "regenerative medicine," "regenerative cells," "regenerative medicine therapy," "regenerative cell therapy," "stem cells," or "stem cell therapy," to consumers (hereinafter, "your product"). Through your website, Facebook page, and YouTube channel you market this product for use in the treatment of various diseases or conditions, such as treatment of osteoarthritis and peripheral neuropathy as well as for the healing and repair of damaged tissue. This indicates that this product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(g)(1)(B)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and because it is intended to affect the structure or function of the body. 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.

For example, your website includes statements about the uses of your product such as:

- "At Oregon Medical Centers we offer cutting edge technology in Stem Cell therapy with growth factors. One type of Stem Cells that we provide come from the umbilical cord…We have had excellent outcomes at Oregon Medical Center with spinal degeneration as well as Osteoarthritis of the knee as well as

shoulders."

- On the "Regenerative Medicine" page, your website states, "At Oregon Medical Centers in Aloha and Salem, Oregon, we process regenerative cells from umbilical cord tissue to ensure safety and effectiveness in our regenerative cell therapy" and also includes the following statements:

    - "Oregon Medical Centers medical team has advanced training and experience in providing safe and effective regenerative cell therapy that can help repair damaged body tissues without surgery and help relieve discomfort."

    - "Regenerative cells are injected into areas of damaged tissue such as joints, ligaments, muscles, and tendons which helps reduce inflammation and pain and improve function."

    - "After regenerative cells are injected into the area of damaged tissue, they're able to differentiate or 'become' the type of tissue needed to replace the damaged tissue."

    - "Regenerative cells bring new healthy cells to the area which decreases inflammation, repairs damaged tissue, restores function, and relieves discomfort."

    - "Who can benefit from regenerative cell therapy?" is followed by a list of various types of ailments, including pain, injuries, and other conditions.

Additionally, your firm's Facebook page includes a patient testimonial posted on April 1, 2023 stating, "I was suffering from peripheral neuropathy…it affected my feet, my legs and a little bit my hands…my biggest issue was my balance…I went to a seminar that suggested that regenerative medicine/stem cell may/would help me…I did on November 10th [stem cell injections]…three months later…I have very little numbness…no pain…it's made a big difference in my life."

We also noted that the above-referenced video posted on your firm's Facebook page on April 1, 2023, is also posted on your Oregon Medical Centers LLC Dr SUNITA BHASIN,Dc [sic] YouTube channel, which includes additional testimonials regarding use of your product in the treatment of diseases or conditions and is linked to your firm's website.

Your above-referenced product appears to be 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, it appears that your firm does not qualify for any exception in 21 CFR 1271.15, and that your above-referenced product fails to meet the criteria in 21 CFR 1271.10(a). Accordingly, it appears that your umbilical cord derived product would be regulated as a drug as defined in section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)] and a biological product as defined in section 351(i) of the PHS Act [42 U.S.C. § 262(i)].

Specifically, your umbilical cord derived cellular product appears 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.” This product is 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 this product for the treatment of diseases or conditions, such as treatment of osteoarthritis and peripheral neuropathy as well as for the healing of damaged tissue is not considered homologous use as defined in 21 CFR 1271.3(c).

In addition, your umbilical cord derived cellular product appears 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). 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.

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 product is not the subject of an approved biologics license application (BLA), nor is there an IND in effect for your product.

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 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, the 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. In addition, you may also email a copy of your official, written 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:
Sunita Bhasin, DC
Founder
Oregon Medical Centers, LLC
17575 SW Tualatin Valley Hwy
Aloha, OR 97006