July 14, 2021

UPS EXPRESS MAIL AND E-MAIL

Michael G. Valpiani, MD
A Better Life Stem Cell Center
8872 South Eastern Avenue, Suite 240
Las Vegas, NV 89123

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Dear Dr. Valpiani:

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 Facebook page, www.facebook.com/BetterLifeStemCellCenter/, as well as other information available to FDA.

Based on the materials reviewed, you and your firm market cellular products that appear to be derived from umbilical cord or umbilical cord blood, which you refer to as "stem cell therapy," for numerous diseases or conditions, such as diabetes and Crohn's disease.

For example, you appear in a video that your firm has posted to its Facebook page, [https://m.facebook.com/story.php?story_fbid=2459545600995552&id=265594267643658 00000], and state:

> "Stem cell therapy is no longer just about treating chronic conditions like chronic pain. Stem cell therapy can be used to . . . improve memory, to avoid some of the diseases of old age like diabetes and heart problems and lung problems…we treat patients from all over the United States. . ."

In addition, a patient video testimonial that your firm has posted to its Facebook page, [https://m.facebook.com/story.php?story_fbid=10352152133512 57&id=265594267643658], with the header "Treatment of Crohn's disease" states: "I was diagnosed with ulcerative colitis in 2002. . . I decided to try the stem cell treatment, and it really worked."

Your umbilical cord or umbilical cord blood derived cellular 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.

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 your umbilical cord or umbilical cord blood derived cellular products are intended for non-homologous uses. Additionally, it appears that these products may fail to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that they 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 products are 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 (IND) application in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312].

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-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 HCT/Ps. 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 your umbilical cord or umbilical cord blood derived cellular 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 and PHS Acts and all applicable regulations.

We request a written response within 30 days of your receipt of this letter. Your response to this letter 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 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