August 11, 2020

UPS EXPRESS MAIL

Regan J. Archibald, LAC
East West Health Solutions, Inc.
dba East West Health
34 S. 500 East Suite 202
Salt Lake City, UT 84102

Dear Mr. Archibald:

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 website available at www.acueastwest.com, as well as other online sources described below.

Based on the materials reviewed, you and your firm market cellular products derived from umbilical cord or amniotic membrane to consumers. You market these products for various diseases or conditions, including some that are serious or life threatening, such as: neurodegeneration, cognitive impairment, multiple sclerosis (MS), Parkinson's disease, amyotrophic lateral sclerosis (ALS), traumatic brain injury (TBI), concussion, autoimmune disease, Lyme disease, lung and heart disease, macular degeneration, and chronic obstructive pulmonary disease (COPD). According to the materials FDA reviewed, East West Health administers these products intranasally, intravenously, or by injection.

For example, your firm's YouTube Channel includes a YouTube video, www.youtube.com/watch?v=zn9c1JtMxPA, entitled "Brain Regeneration with Intranasal Cell Therapy," which states:

- "I was the first patient at East West Health to get stem cell therapy in my shoulder… I also treated myself intranasally… I said, you know what, I've had a handful of strokes and I want to heal the tissue that's been damaged before it shows up symptomatically as memory loss or as … Alzheimer's, dementia, whatever it may be."

- "I was treated with Intranasal stem cell therapy for concussions, heavy metal exposures, and autoimmunity. To date, I've noticed a marked improvement in all my senses: hearing, seeing, taste, and smell along with improved memory and cognitive performance."

- "Who can we help? Well, anyone with neurodegeneration. If you are just looking to improve your brain health, this could be a good viable solution for you. If you are looking for… any help with cognitive performance, … If you are looking to get help in protecting your brain with MS, Parkinson's, ALS, traumatic brain injury, concussions, autoimmune, Lyme disease, … lung and heart issues, this is something that might be helpful to facilitate the health of your overall brain. … [F]or those of you who have issues, we do one unit intranasally… and possibly one unit intravenously, and then we'd repeat that in 30 days…. It's very simple. It's safe."

Similarly, a video available on East West Health's website, entitled "Your Stem Cell Transformation," https://acueastwest.com/stem-cell-therapy-for-joints.html, states:

- "So many conditions that we see effectively treated anything from Achilles tendonitis to COPD in the lungs, back pain, rheumatoid arthritis, thyroid issues, … all these things can be very effectively treated."

- "Using the umbilical and amnion birth tissue, not only do you get these potent cells, these medicinal signaling cells, but you also get all of the healing regenerative properties that exist to help the baby grow, and the baby thrive."

- "Our stem cell treatments are like none others. We use the right products, that's got the highest density, the highest quantities of these amazing healing properties."

The above-referenced products appear to be human cell, tissue, or cellular or tissue-based products (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 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 that your umbilical cord derived product and amniotic membrane derived product are intended for non-homologous uses. Additionally, your products appear not to meet all the other criteria in 21 CFR 1271.10(a) and, accordingly, 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 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 or prevent a variety of serious or life-threatening diseases or conditions. Such unapproved uses raise potential significant safety concerns. Moreover, because your products are administered by higher risk routes of administration, including intravenously and intranasally, 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-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 23 and 24 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 and amniotic membrane 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 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 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. 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