August 5, 2021

VIA UPS EXPRESS MAIL AND EMAIL

Lambert R. Abeyatunge, MD
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Dear Dr. Abeyatunge:

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 firm's website available at www.stemlv.com as well as other online sources described below and other information available to FDA.

Based on the materials reviewed, you and your firm market cellular products derived from either human adipose tissue or umbilical cord to consumers. You and your firm market these products to treat various diseases or conditions, including some that are serious or life-threatening, such as cardiomyopathy, congestive cardiac failure, post-myocardial infarction, spinal cord injuries, paralysis, Alzheimer's disease, Parkinsonism, multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), autism, chronic obstructive pulmonary disease (COPD), Crohn's disease, diabetes, lupus, and macular degeneration. According to materials FDA reviewed, you administer these products intravenously, by injection, "trans-nasal" (i.e., intranasal), or intrathecally.

For example, your firm's website states:

- Under the header "Our Treatments" on a page discussing stem cells, the following is listed, "Cardiomyopathy, Congestive Cardiac Failure, Post- Myocardial Infarction [*sic*]…spinal cord injuries, Paralysis, Alzheimer's Disease, Parkinsonism…Multiple Sclerosis, Amyotrophic Lateral Sclerosis (ALS)…Autism…Chronic Obstructive Pulmonary Disease (Emphysema)…Crohn's Disease…Diabetes, Lupus…Macular Degeneration..."

- "…Dr. Abeyatunge offers revolutionary stem cell therapy to help you resolve autoimmune conditions. An infusion of healing stem cells can actually reverse autoimmunity in some cases and ease your symptoms."

- "How are neurological disorders treated?... A core part of his treatment is stem cell therapy…"

- "At Stem Cell Therapy of Las Vegas & Med Spa LLC in Las Vegas, Nevada, general surgeon Lambert Abeyatunge, MD, FACS, FRCS, FRCSC, FICS, helps manage diabetes with treatments that include innovative stem cell therapy... "

On November 20, 2018, your firm's Facebook page, www.facebook.com/stemlv, posted a patient testimonial that states:

- "Dr. Abey took aim and injected a long needle right into my neck. He studied stem cells and selected my first treatment…I went from paralyzed, being mobile only when in a wheelchair, to walking awkwardly with a walker…Dr. Abey encouraged me to come back for a second treatment so the following month I was back to see him. He had noticed from the first trip that my bladder was not functioning properly, causing me to frequently use catheters. I was informed that he would adjust the treatment to include cells that would help determine the extent of damage and ability to urinate on my own. This was all his doing. On the second trip, the wheelchair was left at home. Three days later…I experienced a sensation and needed to urinate…"

- Your firm commented, "For further information to others in similar situations with paralysis due to injury or disease, the first treatment was homologous stem cells given intravenous, trans-nasal and into the whole cervical spine. The second treatment was almost 10 months later and was with a stronger dose."

On August 14, 2019, your firm's Facebook page posted:

- "So excited to be interviewed by Fox 5 about my stem cell therapy. More and more people are getting helped because of this awesome technology. Message me if you have any degenerative disease you would like me to look into. If you are visiting Las Vegas, visit our office for a free consultation. You can also go to our website….to find out the kind of treatments we do." In response, individuals asked about stem cell treatment for a variety of diseases and conditions including "MS," inclusion body myositis, type 2 diabetes, shattered spine, stage 3 cancer, Behcet's disease, bronchi ecstasies, Parkinson's and cystic fibrosis. Stem Cell Therapy of Las Vegas encouraged these individuals to call your firm, check their message or inbox, and/or that "We can help." Additionally, your firm commented, "I do Stem cell therapy for COPD and Pulmonary Fibrosis with satisfactory results. The placeta [*sic*] derived products (4) are given intravenous as well as trans bronchial via a nebulizer."

The above-referenced 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 that your above-referenced products are intended for

non-homologous uses. Additionally, it appears these products fails to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that the products 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 (IND) application in effect [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 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.

Additionally, based on the materials reviewed, it appears that you also market exosomes. Please be advised that, as a general matter, exosome products intended to treat diseases or conditions in humans are also regulated as drugs and biological products under section 351 of the PHS Act and the FD&C Act and are subject to premarket review and approval requirements described above. For more information, please see FDA's Public Safety Notification on Exosome Products, at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products. [1]

[1] Your firm's website also refers to amniotic fluid and/or the amniotic sac, which contains amniotic fluid. HCT/Ps are defined at 21 CFR 1271.3(d) as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." The definition of HCT/P excludes secreted or extracted human products; accordingly, secreted body fluids, such as amniotic fluid, are generally not considered HCT/Ps subject to regulation under 21 CFR Part 1271. Although not an HCT/P, as a general matter, amniotic fluid intended to treat diseases or conditions in humans would be regulated as a drug as defined in section 201(g) of the FD&C Act [21 USC 321(g)] and a biological product as defined in section 351(i) of the PHS Act [42 USC 262(i) and would be subject to premarket review and approval requirements.

In addition, your firm's website references stem cells from Wharton's jelly and amniotic membrane (i.e., the "amniotic sac complex (membrane, fluid)"). Please be advised that, as a general matter, allogeneic stem cell products derived from Wharton's jelly or amniotic membrane and intended to treat diseases or conditions in humans would be regulated as drugs and biological products, as noted above, and would be subject to premarket review and approval requirements.

Furthermore, the materials reviewed and other information available to FDA reveal that you market your cellular products and exosomes to treat infants and children for diseases or conditions, including cerebral palsy and hypoxic ischemic encephalopathy. Please take immediate action to discontinue any marketing or use of your cellular products or exosomes to diagnose, prevent, treat, mitigate, or cure any disease or condition.

This letter addresses certain issues regarding your adipose tissue derived cellular product and umbilical cord derived cellular 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, 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. 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) 402-9155. Please be advised that only written communications are considered official.

Sincerely,

For
Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research