April 1, 2020

VIA E-MAIL

Dale Carrison, D.O., FACEP, FACOEP
Medical Director
Dynamic Stem Cell Therapy
2551 N Green Valley Parkway
Building C, Suite 305C
Henderson, Nevada 89014
contact@stemcellpowernow.com

Dear Dr. Carrison:

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 https://stemcellpowernow.com/ and https://www.facebook.com/DynamicStemCellTherapy (Facebook page).

You and your firm market cellular products derived from adipose tissue and human umbilical cord (i.e. Wharton's Jelly) as "stem cell therapy" and/or "regenerative medicine treatments." You market your products for "cardiopulmonary conditions," "degenerative eye diseases," "neurological disorders," "autoimmune diseases," and "metabolic disorders." Among other diseases or conditions, you also market your products for the treatment of congestive heart failure, cardiomyopathy, chronic obstructive pulmonary disease, macular degeneration, retinal micro-hemorrhage, Alzheimer's disease, spinal cord injury, "Stroke Damage," lupus, rheumatoid arthritis, multiple sclerosis, "cognitive impairment," Crohn's disease, inflammatory bowel disease, diabetes, cirrhosis, Graves' disease, myasthenia gravis, liver disease, fibromyalgia, hypertension, and Lyme disease. Your cellular product derived from adipose tissue is administered intravenously.

You also recently began marketing your cellular products for treatment or prevention of Coronavirus Disease 2019 (COVID-19).

Your https://stemcellpowernow.com/ website further states:

- "Our stem cell therapy treatments cover a variety of conditions including diseases, disorders, injuries, neuropathy, and many more. Learn more about what your stem cells can do to help you treat these conditions as a patient of Dynamic Stem Cell Therapy."

- "Our treatments are the world's most advanced non-surgical perinatal and adipose

regenerative medicine (AKA 'stem cell therapy') treatments available."

Both your adipose derived cellular product and your human umbilical cord derived cellular product 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.

It appears that Dynamic Stem Cell Therapy does not qualify for any exception in 21 CFR 1271.15, and that your adipose derived cellular product and your human umbilical cord derived cellular product are intended for nonhomologous uses. Additionally, it appears these products fail to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that both your adipose derived cellular product and your human umbilical cord derived cellular product 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)].[1] 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 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 adipose derived cellular product and human umbilical cord derived cellular product are intended to treat a variety of diseases or conditions, including some that are serious or life-threatening. Such unapproved uses raise potential significant safety concerns. Moreover, because at least some of your products are administered by a higher risk route of administration, 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/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm585218.htm.

Manufacturers and health care professionals who have any uncertainty regarding the regulatory

[1] As you acknowledge on one of your websites, FDA has not approved any cellular product derived from adipose: "While not yet approved by the FDA, there is a great deal of evidence to suggest that adipose stem cell therapy could be an effective method of treatment for many patients" https://stemcellpowernow.com/.

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.

We also note that your Facebook page references exosomes. Please be advised that, as a general matter, exosomes for clinical use 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 the 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.

This letter addresses certain issues regarding your 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. Any 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. 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