July 17, 2018

UPS EXPRESS MAIL

John Nelson, MD
Co-founder
Mid America Stem Cell Institute
2601 Northwest Expressway
East Oil Building Suite 1200E
Oklahoma City, OK 73112

Dear Dr. Nelson:

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 Internet website, www.midamstemcell.com. Your website promotes a stromal vascular fraction (SVF) product (hereinafter, SVF product), which you also refer to as "Stem Cell Therapy" or "Stem Cell Therapy Treatment" to "help people suffering from a variety of inflammatory, autoimmune and degenerative conditions." The SVF product is administered intravenously and intrathecally, among other routes of administration. Copies of the pertinent website pages are enclosed for your reference.

Your website:

- Promotes your SVF product for many "Conditions Treated," including, but not limited to, Lupus, Crohn's disease, rheumatoid arthritis, ulcerative colitis, multiple sclerosis (MS), amyotrophic lateral sclerosis, Parkinson's disease, stroke, spinal cord injury, interstitial cystitis, asthma, chronic obstructive pulmonary disease (COPD), interstitial lung disease, allergies, and Type 2 Diabetes; and

- Claims, for example, that "[b]y receiving Stem Cell Therapy Treatment for Lupus at Mid America Stem Cell Institute, you will be treated with an executive style treatment from the moment they inquire about treatment, during treatment and continued throughout the journey after treatment . . . . Your quality of life will be improved because normal function will be restored through the process of healing the diseased or weakened cells."

Your autologous SVF product derived from adipose tissue is a human cell, tissue, or cellular or tissue-based product (HCT/P) as defined in 21 CFR 1271.3(d) and is subject to regulation under 21 CFR Part 1271, issued under authority of section 361 of the Public Health Service Act (PHS Act) [42 U.S.C. 264]. However, because this product does not

meet all the criteria in 21 CFR 1271.10(a) and Mid America Stem Cell Institute does not fall within any exception in 21 CFR 1271.15, the SVF product is not regulated solely under section 361 of the PHS Act [42 U.S.C. 264] and the regulations in 21 CFR Part 1271. It is regulated as a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 321(g)] and a biological product as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].

Your SVF product does not meet the minimal manipulation criterion set forth in 21 CFR 1271.10(a)(1), because processing to obtain SVF from adipose tissue alters the original relevant characteristics of the adipose tissue relating to the tissue's utility for reconstruction, repair, or replacement.

Based on a review of the promotional materials available on your firm's website, your SVF product is intended to treat a variety of serious and/or life threatening diseases and conditions, including Lupus, Crohn's disease, rheumatoid arthritis, ulcerative colitis, MS, amyotrophic lateral sclerosis, Parkinson's disease, stroke, spinal cord injury, interstitial cystitis, asthma, COPD, interstitial lung disease, allergies, and Type 2 Diabetes. As defined in 21 CFR 1271.3(c), homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. The basic functions of adipose tissue in the donor (before removal) include providing cushioning and support to the body. Because your SVF product is not intended to perform the same basic function or functions in the recipient as in the donor (e.g., to provide cushioning and support to the body), your SVF product fails to meet the criterion for homologous use. [21 CFR 1271.10(a)(2)].

Your firm also does not qualify for the same surgical procedure exception at 21 CFR 1271.15(b), which applies to an establishment that removes HCT/Ps from an individual and implants "such HCT/Ps" into the same individual during the same surgical procedure. The HCT/Ps your firm removes from individuals (adipose tissue) are not the HCT/Ps that are used (SVF) following processing. Therefore, your firm does not qualify for the same surgical procedure exception.

Please be advised that 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 as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312]. The SVF product is not the subject of an approved biologics license application (BLA), nor are there INDs in effect for the product.[1] Based on this information, your actions violate the FD&C and PHS Acts.

[1] You have publicly acknowledged that your firm's product is not FDA approved. On April 3, 2017, *Oklahoma's Nursing Times* reported that Mid America Stem Cell Institute planned a public presentation about "how [stem cells] can be used in treating a variety of degenerative conditions from back pain, to knee pain and chronic lung disease,

The use of your SVF product raises reported safety concerns and potential significant safety concerns. For example, this product is intended to treat a variety of serious or life-threatening diseases or conditions, all of which are non-homologous uses. Such uses raise potential significant safety concerns because there is less basis on which to predict the product's behavior in the recipient, and use of these unapproved products may cause users to delay or discontinue medical treatments that have been found safe and effective through the New Drug Application or BLA approval processes. Because the product is administered to humans by various higher risk routes of administration, including intravenously and intrathecally, if contaminated, its use could cause a range of adverse events, from infections to death.

We request that you notify this office, in writing, of the steps you have taken or will take to address the violations noted above and to prevent recurrence. 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. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at (240) 402-9155. If you believe that your product is not in violation of the FD&C or PHS Acts, include your reasoning and supporting information for our consideration. 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

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diabetes, some neurological disorders." Regarding your product, you were quoted as stating that, "[e]ven though it's not FDA approved we think it's very safe because basically we are using the patients' own stem cells from their body fat." http://oknursingtimes.com/031215/beneficial-research-for-mankind/.