April 6, 2022

UPS EXPRESS MAIL

John V. Prunskis, M.D.
President
The Regenerative Stem Cell Institute
Elgin – Illinois Pain Institute
Summit Green Medical Center
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Elgin, IL 60120-3861

Dear Dr. Prunskis:

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://stemcelldr.com/ (website), your Facebook page available at https://www.facebook.com/TheRegenerativeStemCellInstitute/services/?ref=page_internal (Facebook page), your YouTube channels available at https://www.youtube.com/watch?v=JfHKl4QC8L0 and https://www.youtube.com/watch?v=BT55LhpGHFY, and other relevant information available to FDA.

You market cellular products derived from adipose tissue, which you refer to as "regenerative medicine therapy", "adipose SVF therapy", and "therapy", to treat various diseases or conditions, such as cerebral palsy, asthma, emphysema, chronic obstructive pulmonary disease (COPD), and rheumatoid arthritis. For example:

Your website states:

- "The Regenerative Stem Cell Institute is devoted to advancing successful outcomes and quality care in the area of adult stem cell regenerative medicine. Therapy is offered for a variety of inflammatory and degenerative conditions under an IRB Approved Research Protocol with Board Certified physicians at eight locations in Chicagoland."

Your Facebook page states:

- "Stromal Vascular Fraction Cell Procedure…The SVF procedure involves obtaining fat (adipose) tissue-derived stem cells, which are used in various

autoimmune, neurologic, pulmonary, urologic, ophthalmologic and orthopedic applications."

Additionally, your YouTube channel, https://www.youtube.com/watch?v=JfHKl4QC8L0, includes a video entitled, "Stem Cell Therapy for Various Conditions in Chicago (855) 340-STEM," which also is on your website, where you state:

- "There's [sic] multiple diagnoses where we provide stem cell therapy…COPD, asthma, emphysema, where there's been remarkable results. We're also seeing patients with heart conditions…cerebral palsy…rheumatoid arthritis…these are conditions that our institutional review board IRB approved study is allowed to investigate and do the therapy on however I said I want to emphasize."

Your YouTube channel, https://www.youtube.com/watch?v=BT55LhpGHFY, includes a video testimonial, which also is on your website. The video features your Patient Director Chris Frantz, who describes "a positive outcome" following treatment at the Regenerative Stem Cell Institute:

- "We had a COPD patient who came in…who was given up on by his pulmonologist…told by the doctor that he needed a bilateral lung transplant…on oxygen 24/7…his case was amazing…he started receiving benefits after…only four weeks…went back to see his pulmonologist and she was basically incredulous with his treatment. He no longer needed a lung transplant, and he is now off his oxygen."

Your above-referenced cellular products derived from adipose tissue 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 the above-referenced products are intended for non-homologous uses. Additionally, it appears these products fail 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 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].

You claim that your cellular products are offered "under an IRB Approved Research Protocol." Before initiating clinical trials with an investigational drug or biological product, a sponsor must have both an IND in effect and an approval from an Institutional Review Board (IRB). IRB approval is required in addition to, not in lieu of, obtaining an effective IND from FDA for the study of the investigational drug or biological product.

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.

This letter addresses certain issues regarding the above-referenced 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. If you do not believe there is a basis for the regulatory issues raised in this letter, include your reasoning and any supporting information for our consideration.

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 can email a 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

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