November 20, 2019

UPS EXPRESS MAIL

Sara Oracle
Chief Executive Officer and President
RichSource Stem Cells, Inc.
102 NE 2nd Street
#129
Boca Raton, FL 33496

Dear Ms. Oracle:

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 the website for RichSource Stem Cells, Inc., available at https://richsourcestemcells.com (website), which offers RICHGEN products you describe as a combination of amniotic fluid and membrane, Wharton's jelly, and placental tissue (hereinafter, collectively RICHGEN) for sale to physicians throughout the United States. https://richsourcestemcells.com/faq#.

Your website promotes RICHGEN as a "regenerative therapy" and a flowable "regenerative allograft product" for numerous diseases and conditions, such as cancer, tumors, diabetes, Lyme's disease, asthma, COPD, various orthopedic conditions, and "topical wound healing." See https://richsourcestemcells.com/wp-content/uploads/2019/03/General-APPLICATION-GUIDE-03.15.19.pdf; https://richsourcestemcells.com. Without substantiation, you describe RICHGEN as "demonstrated clinically to provide an effective option for treating various conditions . . . ." See https://richsourcestemcells.com/faq#.

Furthermore, your website markets RICHGEN as a treatment for arthritis, neuropathy, joint pain and various orthopedic conditions, and asthma using patient testimonials under the following headings:

- "Elbow, Shoulder, Hip and Pelvis RICHGEN Regeneration;"
- "Arthritis and Neuropathy Improved with RICHGEN;"
- "Hip Pain Resolved Using RICHGEN;"
- "Asthma – Respiratory with RICHGEN;" and
- "Knees and Spine Pain Free with RICHGEN."

RICHGEN appears to be a human cell, tissue, or cellular or tissue-based product (HCT/P) as defined in 21 CFR 1271.3(d) that 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].

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 a review of your website, it appears that no exception in 21 CFR 1271.15 applies, and the products offered by RichSource Stem Cells, Inc. are intended for nonhomologous uses. Additionally, they appear to not meet all the other criteria at 21 CFR 1271.10(a), and accordingly, 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 as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312].

We note that your product is 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. Additionally, because the product is administered by various higher risk routes of administration, including via spinal injections, 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 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 RICHGEN and is not intended to be an all-inclusive review of your firm's products. You and your firm are responsible for ensuring that all your products fully comply with the PHS and FD&C Acts and all applicable regulations. Any response to this letter should be sent to me at 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

Cc: Sara Oracle
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