

April 27, 2020

VIA E-MAIL

Henry N. Small, MD, PA
Houston Stem Cell
7501 Fannin St.
Suite 710
Houston, TX 77054

Dear Dr. Small:

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 www.henrysmallmd.com, as well as other information collected by FDA.

On your website, you market an umbilical cord blood derived cellular product, which you refer to as “cord blood stem cells” and “stem cell therapy,” for numerous diseases or conditions, such as Parkinson’s disease, Alzheimer’s disease, lupus, and fibromyalgia. For example, the website states:

- “Dr. Small chooses cord blood stem cells to treat his patients suffering from: Alzheimer’s disease, Back pain, Fibromyalgia, Hip and knee pain, Lupus, Neck pain, Parkinson’s disease, Shoulder pain, Spinal cord injuries, Sports injuries.”
- “Dr. Small often treats fibromyalgia patients with stem cells”
- “Henry N. Small, MD, and his team have developed an innovative treatment for fibromyalgia involving stem cell injections. The treatment is safe, effective, and may be the solution you need to address the debilitating pain of fibromyalgia.
- “Dr. Small’s goal for lupus treatment is to replace your malfunctioning cells with new, fully functional ones. To do this, Dr. Small uses noninvasive regenerative cellular therapy. During this regenerative medicine treatment, Dr. Small injects cord blood-derived stem cells where you need them. . . .”
- “Dr. Small specializes in treating your painful lupus symptoms through a variety of techniques, including regenerative cellular medicine.”

The above-referenced product appears to be a human cell, tissue, or cellular or tissue-based product (HCT/P) 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 materials reviewed, it appears that you do not qualify for any exception in 21 CFR 1271.15, and that your umbilical cord blood derived cellular product is intended for non-homologous uses. Additionally, it appears your product fails to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that your product would be regulated as a drug as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and biological product 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].

As noted above, your umbilical cord blood derived cellular 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. 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 your umbilical cord blood 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 and PHS Acts

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. 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