July 9, 2021

UPS EXPRESS MAIL & EMAIL

Dr. Hyun Joon Lee, MD
Founder and Medical Director
Scarsdale Integrative Family Medicine, PLLC, dba
See Beyond™
2 Overhill Road, Suite 260
Scarsdale, NY 10583
sifmny@gmail.com

Dear Dr. Lee:

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 websites, your Facebook page, as well as other information available to FDA.

On your website available at https://www.seebeyondiv.com/, you market a cellular product that appears to be derived from human umbilical cord and/or human umbilical cord blood to consumers. You refer to this product on your website as "Cord Blood Stem Cell Therapy" or "Treatment using Umbilical Cord derived Stem Cell." You market this product to treat pain and various orthopedic diseases or conditions.

As recently as March 2021, on your website available at https://nadstemcell.com, you have marketed a cellular product that appears to be derived from human umbilical cord and/or human umbilical cord blood, for various diseases or conditions, including some that are serious or life-threatening, such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Parkinson's disease, Huntington's disease, diabetes, congestive heart failure, chronic obstructive pulmonary disease (COPD), and lupus. Similar marketing persists on your Facebook page, available at https://m.facebook.com/seebeyondmedicine/:

> "COPD is one of the easier ones to treat…it's very easy for stem cells to get to the lung…I've done it myself. I'm the only one who does it in this practice…we've done a lot of neurodegenerative diseases like parkinsonism, multiple sclerosis, ALS. We've done…Crohn's disease and ulcerative colitis…lupus is another one that we've treated…fibromyalgia…for my multiple sclerosis patient…after three treatments…the muscle spasms and pains diminished…I've done trigeminal neuralgia…I've injected it [stem cells] right into the nerve...I've treated a couple of Lyme patients with stem cells, chronic Lyme."

[https://m.facebook.com/story.php?story_fbid=516216865968199&id=107160872685850]

Your cellular product that appears to be derived from human umbilical cord and/or human umbilical cord blood 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 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 product is intended for non-homologous uses. Additionally, it appears this product fails to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that the 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 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].

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.

We also note that your website https://nadstemcell.com references exosomes, and a video on your Facebook page refers to use of exosomes for lung disease. Please be advised that, as a general matter, exosome products intended to treat diseases or conditions 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 premarket review and approval requirements described above. For more information, please see FDA's Public Safety Notification on Exosome Products, at www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.

This letter addresses certain issues regarding the above-referenced 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 Act, PHS Act, 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. 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