November 5, 2021

UPS EXPRESS MAIL & EMAIL

Bima Baje, Chief Executive Officer and Co-Founder and/or Co-Owner
Michael Stavitski, Co-Owner
NYC Regenerative Medicine, Inc.
dba Colts Neck Stem Cells and Regenerative Medicine
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Dear Ms. Baje and Mr. Stavitski:

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://coltsneckstemcells.com/, your Facebook page available at www.facebook.com/coltsneckstem/, and other relevant information.

On your Facebook page, you market a cellular product that appears to be derived from human umbilical cord and/or human umbilical cord blood. You refer to this product on your website and Facebook page as "stem cell therapy." You market this product to treat kidney disease, among other diseases and conditions.

For example, your firm's Facebook page states:

- "just sharing this. . .we can also do it in our clinic using umbilical cord mesenchymal stem cells. . . KIDNEY DISEASE STEM CELL MIRACULOUS SUCCESS!"

- "Colts Neck Stem Cells & Regenerative Medicine. . .STEM CELL THERAPY. . . Treatment for: Wound healing. . .over 121 autoimmune diseases. . .732-867-7330"

- ". . .busy Saturday at our clinic. Treattes [*sic*] #chronicpain. . .#parkinsonsdisease #dementia #lymedisease #multiplesclerosis. Non-invasive treatment through #stemcelltherapy."

- "her [Colts Neck Stem Cells patient] chronic wound got better in 10 days after injecting stem cells. . .she avoided amputatio[n]. #stemcelltherapy #woundhealing #chronicwound #diabeticneuropathy"

Similarly, a patient testimonial on your Facebook page, www.facebook.com/SoJannelleTV/videos/2277116832589145/, includes a video entitled, "So Healthy: Stem cell saves her leg and her life!," in which you and your firm were featured in a "So Jannelle TV" broadcast:

- Mr. Stavitski stated, "Marianne has chronic wounds that weren't healing with traditional medications. She had chronic wounds in her other leg and lost it. . .I knew that the wounds would heal dramatically with stem cells. . .we've treated many patients with different types of chronic wounds that aren't healing. . .She had a full recovery and we're quite happy about that. . .stem cell therapy gets to the underlying cause of the discomfort. . .If you're having treatment failures and you're not getting better and you can't walk and you have pain, that's the time to try stem cells"

Your above-referenced cellular product 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) and is 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 are not aware of any approved BLAs or INDs that are in effect for your 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.

We also note that you market exosomes for chronic non-healing wounds and alopecia on your Facebook page. 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