April 28, 2020

VIA UPS EXPRESS MAIL

David C. Lee, MD, Chief Medical Officer
Ross Ward, MD, Clinical Medical Director
BrioMD Lab LLC dba BrioMD
814 W Pine Street
Hattiesburg, MS 39401-4259

Dear Drs. Lee and Ward:

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://briomd.com/.

You and your firm market "perivascular cells" or "perivascular cellular therapy" (product) for the treatment of "respiratory conditions," "immunologic and autoimmune diseases," "neurologic conditions" and "musculoskeletal conditions."

You market your product to treat various diseases or conditions, including some that are serious or life-threatening, such as: asthma, chronic obstructive pulmonary disease (COPD), emphysema, pulmonary fibrosis, Crohn's disease, diabetes, systemic lupus erythematosus, multiple sclerosis, chronic migraine headaches, concussions/post-traumatic stress disorder (PTSD), degenerative disc disease, traumatic brain injury, and rheumatoid arthritis. Additionally, your website states that "BrioMD is continually working on treatment options and protocols for conditions and diseases not listed on the website."

Your website further states: "We have developed a safe and effective treatment option [in] which we harvest and use your own perivascular cells to provide maximum healing and treatment benefits."

Your 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.

It appears that BrioMD does not qualify for any exception in 21 CFR 1271.15, and that your

product is intended for nonhomologous 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 a 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 product is intended to treat a variety of serious or life-threatening diseases or conditions. 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 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 to this letter 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