April 27, 2020

VIA E-MAIL

Nilda A. Abellera, MD
Founder and Chief Medical Officer
Infuze MD
940 Jacklin Road
Milpitas, CA 95035

Dear Dr. Abellera:

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://www.infuzemd.com, as well as other information available to FDA.

On your website, you and your firm market what you describe as "IV Stem Cell Therapy," which your website states is administered "directly into the bloodstream via IV, producing a large burst of stem cells that circulate through the body." You market "IV Stem Cell Therapy" to patients "to treat[] Spinal cord injury or damage[,] Parkinson's disease[,] Immunodeficiency disorders[,] Autoimmune diseases[, and] Muscular diseases." Based on other evidence collected by FDA, it appears that at least one of the IV stem cell therapy products you market is derived from human umbilical cord blood (hereinafter, "umbilical cord blood derived cellular product" or "product").

Your umbilical cord blood derived cellular 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 Infuze MD does not qualify for any exception in 21 CFR 1271.15, and that your umbilical cord blood derived cellular product is intended for nonhomologous uses. Additionally, it appears that 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 (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. Moreover, because the product is administered by a higher risk route of administration, its 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.

We note that your website also lists exosomes as one of the "Regenerative Therapies" at Infuze MD. Please be advised that, as a general matter, exosomes for clinical use 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 https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.

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