October 1, 2020

UPS EXPRESS MAIL

Michael Johnson, Board Certified Chiropractic Neurologist
Founder and Clinical Director
Optimal Health Stem Cell and Wellness Institute dba OHSTEMCELL
2000 S Memorial Dr. #201
Appleton, WI 54915

Dear Dr. Johnson:

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.ohstemcell.info, your Facebook page available at https://www.facebook.com/OptimalHealthStemCell/, and the videos on your YouTube channel available at https://www.youtube.com/channel/UCSO9eG6UNdYYUAHHw-75o3w. You market cellular products derived from human umbilical cord, adipose tissue, and amniotic membrane.

On your website, you market your umbilical cord derived cellular product for a variety of diseases or conditions, including some that are serious or life-threatening. For example, you market this product for autoimmune disease, autism, chronic inflammatory demyelinating polyneuropathy, chronic obstructive pulmonary disease, emphysema, diabetes, heart disease, kidney disease, Lyme disease, mast cell activation disorder, multiple sclerosis, multiple system atrophy, Parkinson's disease, peripheral neuropathy, traumatic brain injury, Raynaud's disease, rheumatoid arthritis, lupus, stroke, Hashimoto's disease, and transverse myelitis.

On your Facebook page, you market cellular products derived from human adipose tissue and amniotic membrane for a variety of diseases or conditions, including some that are serious or life threatening. For example, you market these products for "Peripheral Neuropathy in the hands and feet," "Neurological Disorders…MS, Parkinson's, Stroke Rehab," "Autoimmune Disorders…Lupus, RA, Sjogren's," "Fibromyalgia, Chronic Fatigues Syndrome, Adrenal Fatigue," "COPD," "Heart Disease," and "Diabetes." Based on the materials reviewed, these products are intended for intravenous or intrathecal administration. Your Facebook page states, for example:

- "**INTRATHECAL INJECTIONS!** We use intrathecal injections into the spine with chronic neurological patients like MS, Parkinson's and stroke rehab patients. An intrathecal injection allows the stem cells to cross the blood-brain barrier. Having the stem cells cross the blood-brain barrier helps the neurological patient to heal faster!"

- "The Optimal Health Stem Cell and Wellness Institute is dedicated to helping patients that are suffering from chronic pain and other chronic conditions …Go to www.optimalhealthstemcell.com for condition specific videos on stem cell therapy. Call The Optimal Health Stem Cell and Wellness Institute … to see if you are a candidate for stem cell therapy!"

Your products derived from human umbilical cord, adipose tissue, and amniotic membrane appear to be human cells, tissues, or cellular or tissue-based products (HCT/Ps) 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 Optimal Health Stem Cell and Wellness Institute does not qualify for any exception in 21 CFR 1271.15, and that your products derived from human umbilical cord, adipose tissue, and amniotic membrane are intended for nonhomologous uses. Additionally, it appears these products fail to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that the products would be regulated as drugs as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and biological products 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 products derived from human umbilical cord, adipose tissue, and amniotic membrane are 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 at least some of these products are administered by higher risk routes of administration, including intravenously and intrathecally, their 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/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.

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 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. 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