June 15, 2021

VIA UPS EXPRESS MAIL AND EMAIL

Hans-Thomas Richter, PhD
NatureWorks P.S.
dba NatureWorks Acupuncture, Kitsap Stem Cells, and Stem Cell Therapy Washington
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Poulsbo, WA 98370
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Dear Dr. Richter:

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 available at www.natureworksacupuncture.com and www.stemcells-washington.com, as well as other information available to FDA.

Based on the materials reviewed, you and your firm market cellular products derived from human umbilical cord to consumers. You and your firm market these products to treat various diseases or conditions, including some that are serious or life threatening, such as autism, stroke, diabetes, chronic obstructive pulmonary disease (COPD), and Parkinson's disease. According to the materials FDA reviewed, your firm administers these products by intravenous infusion, localized injections, or intranasally. For example:

Your website, www.natureworksacupuncture.com, states:

- "MAJOR CONDITIONS TREATED… Arthritis…Asthma…Atherosclerosis…Autism… Autoimmune disease…Bell's Palsy…COPD…Crohn's/Colitis…Diabetes type 2… Fibromyalgia…Glaucoma…Hashimoto's/Thyroid disease…Hepatitis…Liver and Kidney failure…Lupus…Parkinson's…Stroke Recovery…"

Testimonials on your Stem Cell Therapy Washington and Kitsap Stem Cells website, www.stemcells-washington.com, include the following:

- In a video entitled, "Bonnie with eye stroke," the patient states, "I had an eye stroke and the doctor told me they didn't think I would be able to see again…I had stem cell therapy…I'm already starting to see a little more…It's been about a

month since the stem cell therapy, and I think I'm going to get my full eyesight back."

- In a video entitled, "Russ with Parkinson's," the patient states, "So far we've done stem cell treatment—a double one the first time and a single one the second time. It's… abated the symptoms of Parkinson's disease."

The above-referenced products 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.

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 your umbilical cord derived cellular products are intended for non-homologous uses. Additionally, your products appear not to meet all the other criteria in 21 CFR 1271.10(a) and, accordingly, they would be regulated as drugs as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and as 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 application (IND) in effect [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312]. Contrary to representations on your website implying that your umbilical cord derived cellular products have been demonstrated safe and effective and are approved by FDA, your products are not the subject of an approved biologics license application. In addition, there is no IND in effect for your products.

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 addresses certain issues regarding your umbilical cord derived cellular products 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. You may also email a copy of your official, written 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