U.S. FOOD & DRUG ADMINISTRATION

September 21, 2023

VIA UPS EXPRESS MAIL

Timothy S. Peace, NMD
Owner and Medical Director
Peace Wellness Center PLLC
Stem Cell Rejuvenation Center LLC
640 W Maryland Ave, Ste 3
Phoenix, AZ 85013

Dear Dr. Peace:

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 firm's websites available at peacewellnesscenter.com and the-stem-cell-center.com.

Based on this review, you and your firm market "stem cell therapy" products to consumers. You represent that your stem cell therapy products are derived from sources including umbilical cord or "placental tissue" (hereinafter, collectively "products"). You and your firm market these products to treat various diseases or conditions, such as autoimmune, degenerative, and orthopedic diseases or conditions. According to the materials FDA reviewed, your firm administers these products by nebulizer, intranasally, and/or injection, including intravenous injection. For example, your website, the-stem-cell-center.com, states:

- Under the heading "Conditions We Treat":
  - "Stem cell therapy can improve your mobility, ease your pain, and make joints stronger…Joint Injuries.….Sports-related Injuries…";
  - "Stem cell therapy can promote healing…Diabetes…Lupus…Multiple Sclerosis…Rheumatoid Arthritis…"; and
  - "Initial research shows promise that stem cell therapy can ameliorate some diseases…ALS (Amyotrophic Lateral Sclerosis)… Alzheimer's Disease… Autism…Cerebral Palsy…Degenerative Disc Disease…Glaucoma…Hearing Loss…Heart Disease…Huntington's Disease…Kidney Failure…Liver Disease…Macular Degeneration…Muscular Dystrophy…Optic Nerve Injuries…Parkinson's Disease…Pulmonary Fibrosis, [sic] Ephysema, [sic] COPD…Retinitis Pigmentosa…Spinal Cord Injuries…Stroke…"

- Under the Frequently Asked Question, “How are stem cells administered to the patient?”: “All our patients receive an intravenous administration in addition to any other methods decided upon by the treating physician. This may include several different types of injections and routes of administration…”

- “Once they are prepared and the desired quantity isolated, the stem cells are injected through one or more of the following modes: Localized, Intramuscular, Nebulizer, Intranasal, Intravenous.”

Your 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 above-referenced 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 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 as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312].

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.

Additionally, based on the materials reviewed, it appears that you market exosomes. 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.

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 the above-described 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. If you do not believe there is a basis for the regulatory issues raised in this letter, include your reasoning and any supporting information for our consideration.

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 may 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) 402-9156. Please be advised that only written communications are considered official.

Sincerely,

Melissa J. Mendoza -S

Digitally signed by Melissa J. Mendoza -S
Date: 2023.09.21 15:36:58 -04'00'

Melissa J. Mendoza
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research