December 16, 2021

UPS EXPRESS MAIL & EMAIL

Julian Robert Gershon Jr., DO
Owner
Aspen Institute for Regenerative Medicine and Anti-Aging, LLC
225 N Mill Street, Suite 114
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9600 W. Jewel Avenue, Suite 3
Lakewood, CO 80232
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Dear Dr. Gershon:

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 website available at https://aspen-regenerativemedicine.com/, your YouTube channel available at www.youtube.com/channel/UCL5KHBSpVVPm7DMTr0nzSgg/videos?app=desktop, and other relevant information available to FDA.

You market cellular products derived from umbilical cord blood or adipose tissue, which you refer to as "Stem Cell Therapy" or "Regenerative Medicine Therapy," to treat various diseases or conditions, such as congestive heart failure, ischemia, chronic obstructive pulmonary disease (COPD), diabetes, multiple sclerosis, lupus, fibromyalgia, and irritable bile syndrome (IBS). For example:

Your website, https://aspen-regenerativemedicine.com/, states:

- "Aspen Regenerative Cardiac Cell Therapy is a new life-changing therapy for patients suffering from symptoms related to heart disease. The treatment works by taking adult Regenerative Medicines from the patient's body fat and then infusing the Regenerative Medicines via IV. Aspen Regenerative Medicine heart Regenerative Medicine therapy . . . helps to treat a variety of heart diseases including congestive heart failure, ischemia . . . The therapy works by taking a catheter connected to the heart and using the catheter to deliver the new Regenerative Medicines."

- "Our Regenerative Medicine therapy aims to cure . . . lupus."

- "Dr. Gershon along with his staff have seen great success with their patients in treating many areas. These areas include . . . fibromyalgia, COPD, multiple sclerosis, diabetes … Call today to schedule your consultation with Dr. Gershon and learn if Regenerative Medicine Therapy is [a] good fit for you."

- "We use Regenerative Medicine therapy to help treat a range of neurodegenerative diseases."

Additionally, a testimonial on your YouTube channel, www.youtube.com/watch?v=BwnkmBc5sPU, includes a video entitled, "Aspen Institute for Anti Aging and Regenerative Medicine Testimonial," featuring a patient who states: "Last July, I had a stem cell injection because I was suffering from . . . IBS which I would spend at least two or three days in bed every month suffering with pain . . . Since I had the stem cell injection, I have no more symptoms of IBS."

Your above-referenced cellular products derived from umbilical cord blood or adipose tissue 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 the above-referenced products are intended for non-homologous 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 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.

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.

We also note that you market exosomes for COPD on your Facebook page, www.facebook.com/AspenMed/videos/5870218496386607/, and for preterm brain injury, liver injury, and various types of cancer on your website, https://aspen-regenerativemedicine.com/. Please be advised that, as a general matter, exosome products intended to treat diseases or conditions in humans are also 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)] 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 the above-referenced 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 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. In addition, you can email a copy of your 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