September 3, 2020

UPS EXPRESS MAIL

Adrienne O'Connell, DO
Chief Executive Officer
Laguna Beach Aesthetics, Cosmetic Dermatology and Laser Center, PC
32392 S Coast Hwy, Suite 240
Laguna Beach, CA 92651

Dear Dr. O'Connell:

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 www.lagunabeachaesthetics.com, as well as other information available to FDA.

Based on the materials reviewed, you and your firm market a cellular product derived from adipose tissue to treat various diseases or conditions, such as cancer, chronic pain, Cerebral palsy, Cystic fibrosis, diabetes, epilepsy, fibromyalgia, heart disease, kidney disease, liver disease, Multiple sclerosis, Muscular dystrophy, Parkinson's disease, and spinal cord injuries. For example, your website states:

- "With intravenous stem cell therapy available from Adrienne O'Connell, DO, at Laguna Beach Aesthetics in Laguna Beach, California, you can heal and find relief from chronic conditions like arthritis, fibromyalgia, and more."

- "Stem cell therapy, also called live cell regenerative wellness therapy at Laguna Beach Aesthetics, is a modern treatment that uses some of the latest research in medicine to repair tissue damage and dysfunction related to a wide range of chronic conditions."

- "Stem cell therapy can help you manage many conditions that affect you in the long term. Dr. O'Connell might encourage you to consider adding live cell regenerative wellness therapy to your treatment plan for these or other ailments: Arthritis, Cancer, Chronic pain, Cerebral palsy, Cystic fibrosis, Diabetes, Epilepsy, Fibromyalgia, Heart disease, Kidney disease, Liver disease, Multiple sclerosis, Muscular dystrophy, Parkinson's disease, [and] Spinal cord injuries. Using stem cell therapy to help treat these conditions may reduce pain associated with them and improve your quality of life."

Your adipose tissue 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.

Based on the materials reviewed, it appears that you do not qualify for any exception in 21 CFR 1271.15, and that your adipose tissue derived cellular product is intended for non-homologous uses. Additionally, it appears 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 a 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].[1]

As noted above, your adipose tissue 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 your 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/vaccines-blood-biologics/cellular-gene-therapy-products/framework-regulation-regenerative-medicine-products.

[1] We also note that you and your firm were featured in the Stu News Laguna, Volume 12, Issue 25, on March 27, 2020 (www.stunewslaguna.com/index.php/2-uncategorised/7351-a-first-in-laguna-100518re). In the article, you were quoted discussing an umbilical cord blood derived stem cell product and stating, for example, "Our goal is to reduce pain and suffering from many of mankind's most devastating diseases and conditions by delivering the future promise of live cell therapy." Please be advised that, as a general matter, cellular products derived from human umbilical cord blood and intended to treat a variety of diseases and 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.

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 adipose tissue 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 Act, PHS Act, and all applicable regulations. We request a written response within 30 days of your receipt of this letter. Your response to this letter 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

cc: Adrienne O'Connell, DO
Chief Executive Officer
Laguna Beach Aesthetics, Cosmetic Dermatology and Laser Center, PC
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