February 10, 2020

UPS EXPRESS MAIL

John Chern Shieh, MD
Medical Director and Chief Executive Officer
RejuvaYou Medical Corporation dba RejuvaYou Medical Spas
1024 Mission Street, Suite A
South Pasadena, CA 91030
info@rejuvayou.com

Dear Dr. Shieh:

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.facebook.com/RejuvaYou/ (RejuvaYou Facebook Page) as well as other online sources described below.

Based on the materials reviewed, you and your firm promote cellular products derived from human umbilical cord blood or adipose tissue to treat various diseases or conditions, including some that are serious or life threatening, and you administer these products intravenously or intranasally.

Using EventBrite.com to advertise a "Regenerative Medicine Lunch and Learn with Dr. Shieh from RejuvaYou Medical" on July 11, 2019, you discussed the nature of some of your products and promoted your products for various diseases or conditions:

> [Dr. Shieh] will be discussing the use of Stem Cells, Exosomes . . . and our unique approach to healing the body. We have treated issues such as: Degenerative Joint Disease/ Severe Arthritis, Traumatic Brain Injuries, Stroke, Cerebral Palsy Diabetes-Alzheimer's, Parkinson's Disease, Dementia, COPD, Lung Disease, Autism, Kidney Failure, Autoimmune Diseases, Wound Healing . . .

https://www.eventbrite.com/e/regenerative-medicine-lunch-and-learn-with-dr-shieh-from-rejuvayou-medical-tickets-64320250601#.

Similarly, you and your firm were featured in the South Pasadena Review on July 19, 2019 (posted on the RejuvaYou Facebook Page the same day). You were quoted as saying:

> I've used stem cell therapy to treat all sorts of patients, from children with cerebral palsy to adults with Parkinson's disease. I helped a female firefighter reverse a bad case of Chronic Obstructive Pulmonary Disease, which was caused by smoke

> burning her lungs. I successfully treated a young boy who suffered seizures and brain damage from nearly drowning in a swimming pool. I have children fly in from around the world to seek treatment for their cerebral palsy and all of them experience significant improvement in their conditions.

https://southpasadenareview.com/turn-back-time/.

You also promote your products on the RejuvaYou Facebook Page as a treatment for Cerebral Palsy, traumatic brain injuries, end-stage lung disease, and brain atrophy to consumers, including most notably to parents of children with some of these conditions.

Both your umbilical cord blood derived cellular product and your adipose derived cellular product appear to be human cell, tissue, 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 RejuvaYou Medical Corporation does not qualify for any exception in 21 CFR 1271.15, and that your umbilical cord blood derived cellular product and your adipose derived cellular product 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 both your umbilical cord blood derived cellular product and your adipose derived cellular product 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 umbilical cord blood derived cellular product and your adipose derived cellular product are intended to treat a variety of serious or life-threatening diseases or conditions. Such unapproved uses raise potential significant safety concerns. Moreover, because the products are administered by various higher risk routes of administration, 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/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm585218.htm.

Additionally, based on the materials reviewed, it appears that you also treat patients with exosomes. As a general matter, exosomes for clinical use 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.

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 23 and 24 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 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. Any 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