April 10, 2020

VIA E-MAIL

Douglas Spiel, MD
President
Regenerative Solutions of New Jersey (aka Stem Cell Center of New Jersey)
1921 Oak Tree Road, Suite 104
Edison, NJ 08820
info@StemCellCenterofNJ.com

Dear Dr. Spiel,

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 the website for Regenerative Solutions of New Jersey, available at https://regenerativesolutionsnj.com/ (website) and your firm's other online materials..

You and your firm market exosome products from Kimera Labs, Inc. for numerous diseases or conditions, including some that are serious or life-threatening. These products are administered by various routes of administration, including intravenously.

Most recently, you market these exosome products on your Facebook page to mitigate, prevent, treat, or cure Coronavirus Disease 2019 (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[2]. You state the following on your Facebook page:

- "Coronavirus is here! Could Kimera Exosomes Help?"

[1] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

[2] President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

- "Exosomes are able to help in the fight against COVID-19. Treatments are available right now which have been shown to strengthen your immune system against Novel Coronavirus, and aid in mitigating advanced symptoms such as acute respiratory distress syndrome. Learn more at www.regenerativesolutionsnj.com/virus-protection and call us at 732-548-2000 to schedule an immediate appointment!"

- "With COVID-19 dominating the headlines, preventative measures are essential to maintaining a healthy immune system. MSC Exosomes have been shown to modulate the immune system to protect against coronavirus and other viruses. As a medical provider, we will be open during all regular hours throughout the ongoing situation and remain dedicated to serving you and your health. Visit www.regenerativesolutionsnj.com or call us at 732-548-2000 to learn more and to schedule an immediate appointment!"

See www.facebook.com/pg/regenerativesolutionsnj/posts/.

You and your firm also market these exosome products for numerous other diseases or conditions, such as Chronic Obstruction Pulmonary Disease (COPD), spinal cord injury, Parkinson's disease, Alzheimer's disease, Lupus, and Multiple Sclerosis (MS). For example, you state:

- "Spinal cord patients . . . what we've noticed is the regenerative ability of the exosomes as applied into the cerebral spinal fluid has been very very helpful in rejuvenating some of these patients...I've actually see [*sic*] the flurry of these patients with catastrophic injuries...the patient with the MRI...was given about a 10% chance to walk when they came in last December, they were able to walk and stand with crutches...about 3 months afterwards walking for the first time without any crutches at all and we've probably got about 18 to 20 of those that I've done personally."

- "Lupus is an autoimmune disease. Placental exosomes from Kimera are very useful in this. I've given them via a multitude of different delivery systems."

- "Results for MS, I have a number of MS patients. I have a number of patients with Parkinson's disease and Alzheimer's who respond very well to exosome treatments."

- "I do have a patient who had both seizures and Hashimoto's which is an autoimmune thyroiditis. After giving them exosomes, the thyroid function normalized. Over the last 4 – 6 months the patient has been on zero thyroid meds and I have EEGs before and after treatment showing decreased epileptiform seizures."

- "For much of the small fiber neuropathies, I've done perineural injections. They are administered under ultrasound guidance. They can be given systemically, the exosomes."

- "For spinal cord injuries, I have not injected exosomes directly into the spinal cord, only the cerebral spinal fluid...What I do intrathecal injections, in many cases I'm doing a full work up."

- "I've used [exosomes] effectively for concussion."

- "We have patients that come to me with spinal cord injuries. One such patient's coming back again next week. ... After a number of treatments now he is no longer incontinent, and he walks 200 yards with assistance."

See https://www.facebook.com/regenerativesolutionsnj/videos/dr-doug-spiel-live-discussing-exosomes-and-answeringquestions/378936999381589/?__so__=permalink&__rv__=related_videos and https://www.youtube.com/watch?v=u7a01Vv0fbo#action=share.

Similarly, on your website, you market your exosome products to treat, for example:

- "GI DISORDERS" (ex. Crohn's Disease and Ulcerative Colitis), https://regenerativesolutionsnj.com/gi-disorders/;

- "NEUROLOGICAL DISORDERS" (ex. Multiple Sclerosis, Parkinson's Disease, and Stroke), https://regenerativesolutionsnj.com/neurological-disorders/; and

- "COPD", https://regenerativesolutionsnj.com/copd/.

It appears that the above-referenced exosome products would be regulated as drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the Public Health Service Act (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].

This letter is not intended to be an all-inclusive review of your products. You and your firm are responsible for ensuring that all your products fully comply with the PHS and FD&C 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. 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