April 10, 2020

VIA E-MAIL

Duncan Ross, Ph.D.
Chief Executive Officer

Douglas Spiel, MD
Clinical Consultant
Kimera Labs, Inc.
2831 Corporate Way
Miramar, FL 33025
INFO@kimeralabs.com

Dear Drs. Ross and 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 Kimera Labs, Inc. (Kimera Labs), available at https://kimeralabs.com and other information available to FDA.

Kimera Labs markets exosome products to treat numerous diseases or conditions, including some that are serious or life-threatening. These products are administered by various routes of administration, including intravenously. Kimera Labs also supplies its products to health care providers such as Dr. Spiel, who is both a Clinical Consultant for Kimera Labs and President of Regenerative Solutions of New Jersey. Regenerative Solutions of New Jersey markets these products to mitigate, prevent, treat, or cure Coronavirus Disease 2019 (COVID-19).

You and your firm market your exosome products to treat diseases or conditions such as Parkinson's disease, Multiple Sclerosis, brain injuries, diabetes, stroke, and spinal cord injuries. For example, in various YouTube videos you state:

- "I've noticed when we start treating Central Nervous System disease, spinal cord injuries, brain injuries, neurodegenerative problems like Parkinson's, problems like MS we set the bar very very high . . . when we administer exosomes, I've seen some really remarkable things. I've been able and I've been privy to the benefits of seeing people who have been locked in wheelchairs and paraplegic starting to stand and walk. Seeing people that have been living their lives on drugs to maintain their blood pressure take the drugs away. People who walk on canes

with Parkinson's disease being able to throw the canes away and run and catch footballs." Video of Dr. Spiel, available at https://www.youtube.com/watch?v=IuyMqc2ThUU (Dr. Spiel Video).

- "We're able to inject exosomes intravenously for degenerative conditions, we're able to inject exosomes for arthritic and degenerative disease states such as c-spine, shoulders, knees . . . . Disease states such as Psoriasis and Rosacea we've seen really beautiful results when treating these conditions topically. We give the patients exosomes intravenously, beautiful results." Video of Greg Chernoff, MD, Clinical Investigator Kimera Labs, available at https://www.youtube.com/watch?v=KfAENm4Uyv8.

- "One of the things we've been doing is treating patients who have Diabetes-Type 1 Diabetes. I've given people exosomes and I've noticed 60% reduction in their insulin levels. . . . we can help fight some of the ravages of diabetes." Dr. Spiel Video.

- "I've had the good fortune of working with Dr. Ross for the last two years. . . . Together we've worked through a myriad of different afflictions and how we can utilize the exosomes . . . . with the help of Duncan, we've been able to treat patients with a range of afflictions ranging from neurodegenerative diseases and strokes and CNS disorders to many of the musculoskeletal manifestations of disease to simple things like neuropathy." Dr. Spiel Video.

- "If I ran an ER and you came in with a stroke or a heart attack immediately, I'd give you IV exosomes." Dr. Spiel Video.

- "I think that a lot of the problems particularly inflammatory or degenerative problems that we were treating in orthopedics with surgery we can now treat with various different exosome-based products and therapies." Video of Jason Sanders, MD, President of Kimera Labs, available at https://www.youtube.com/watch?v=Cm-9LH8NJ_k.

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