May 7, 2024

UPS EXPRESS MAIL & EMAIL

Patrick Retif, Chief Executive Officer
Exocel Bio, Inc.
3978 Sorrento Valley Blvd.
Suite 310
San Diego, CA 92121
sales@exocelbio.com

Dear Mr. Retif:

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.exocelbio.com/, your Facebook page available at www.facebook.com/Exocelbio/?ref=nf&hc_ref=ARQDSLkt21RzTMFojg07gDtjwF8mdfuQiRfRgRtpbX7Z0kLXDSZ_TVUCnsdyorijAO0, your YouTube channels available at, www.youtube.com/@Exovex/featured and www.youtube.com/@exovex2540/featured, as well as other relevant information available to FDA.

Based on the materials reviewed, you and your firm sells a line of exosome products, which you refer to as "Exovex" (collectively, "Exovex" or "your products") to health care providers across the United States. According to the materials FDA reviewed, your products are used for injection or topical use. You and your firm intend these products for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, as detailed below.

For example, your website states:

- "The presence of multiple growth factors is of particular significance for the desired Exovex applications in....wound healing."
- "Benefits…. Anti-inflammatory"
- "Exovex Revive...is designed for clients...targeting hair concerns such as small alopecia...eliminating inflammation..."

In addition, you state the following on your Facebook page:

- "Suffering from a dog bite, this patient was told it would take 6 months for her wound to heal...A few days after applying EXOVEX Renew topically, signs of healing were visible...Post 10 days, the results were miraculous."

- "Every day we hear incredible stories...using EXOVEX...This patient with androgenic alopecia received initially 25 billion (Reveal) ...and then 12 billion (Renew) 4 months later. See the dramatic improvement in just 8 months!"

- "Exovex can be used to treat...rosacea..."

- "Exovex exosomes can help reduce inflammation..."

- "What an amazing review from Karen, a patient who received our EXOVEX product as a treatment for her painful, long lasting frozen shoulder...EXOVEX helped give her great range of motion and helps her sleep better at night with no pain in the morning."

Additionally, the Exovex YouTube channel, www.youtube.com/watch?v=lzHGA2PTsHg, includes a video entitled, "The Power of Exosomes with Dr. Shanthala....ExocelBio," featuring one of your customers who states:

> I use these exosomes...off label can be injected...I had taken care of this patient...two dogs bit her lip...it was literally ripped apart...I used the exosomes, mostly topical...nine days it was like a magic...a lot of diabetics or any type of delayed wound healing where people are having trouble to help with wound healing, exosomes are fantastic...I use exosomes for so many different procedures...post radiation pain, it helps with pain...off label topic...exosomes can be used intravenously...I personally had what is called... Tietze syndrome. It's a costochondritis. I really had a great relief with exosomes...one of my patients also got some great relief with that.

Based on these intended uses, your products are 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]. None of your products are the subject of an approved biologics license application (BLA), nor is there an IND in effect for your products. Based on this information, the introduction or delivery for introduction of your products into interstate commerce violates the FD&C Act and the PHS Act.

For more information about exosomes, please see FDA's Public Safety Notification on Exosome Products, at 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 and PHS Acts and all applicable regulations. We request a written response within 30 days of your receipt of this letter. If you do not believe your products are in violation of the FD&C Act or PHS Act, include your reasoning and any supporting information for our consideration.

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) 402-9156. Please be advised that only written communications are considered official.

Sincerely,

Melissa J. Mendoza
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Cc: Patrick Retif, Chief Executive Officer
805 Old Easton Road
Doylestown, PA 18902