January 25, 2021

UPS EXPRESS MAIL

Mr. Kasey Kahl
Chief Executive Officer and Chief Financial Officer
The Body Building, Inc.
427 West Nees Avenue
Suite 103
Clovis, CA 93611

Dear Mr. Kahl:

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://stemcellinjectionsfresno.com/ (website), as well as your Facebook page, www.facebook.com/thebodybuilding559.

Based on the materials reviewed, you market what you refer to as "BioGenix regenerative medicine product[s]," which appear to be cellular products derived from human umbilical cord or human umbilical cord blood[1] for various diseases or conditions, such as heart disease, chronic obstructive pulmonary disease (COPD), asthma, "[m]ost autoimmune disorders," diabetes, Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), stroke, and autism.

For example, your website states:

- "Our BioGenix regenerative medicine product contains primitive undifferentiated stem cells and additional growth factors which are beneficial for repair, growth and healing."

- "Stem Cell Injections Fresno | Regenerative Stem Cell Therapy" at the top of the webpage that also includes a heading entitled, "Services" and subheading "Are You A Candidate?" Under this subheading you state: "Stem cell injections are most appropriate for patients with: Heart disease[,] Lung disease (COPD, asthma)[,] Most autoimmune disorders[,] Diabetes type I/II[,] …Parkinson's

[1] You also refer to these products on your website as "BIO-5 Human Umbilical Cord Stem Cells (.50 x 10 cells per cc)," "BIO-10 Human Umbilical Cord Stem Cell (1.0 x 10 cells per cc)," and "BIO-30 Human Umbilical Cord Stem Cells (3.0 x 10 cells per cc)."

disease[,] …Alzheimer disease[,]…ALS (Lou Gehrig's Disease)…[,] Multiple sclerosis[,] …Stroke[,]… Autism[.]"

Additionally, on your Facebook page, you state:

- "These stem cells when injected, are basically a blank slate into the body that has the ability to regenerate any tissue, bone, cartilage, etc in the body. They are highly anti inflammatory and immediately dissipate ANY PAIN in the body in any area desired. They help modulate the functioning of your immune system which helps reverse the effects of auto immune disease."

The above-referenced products appear to be human cells, tissues, 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.

Based on the review of your website and Facebook webpage, it appears that you do not qualify for any exception in 21 CFR 1271.15, and that the above-referenced products are intended for non-homologous uses. Additionally, it appears that these products do not meet all the other criteria in 21 CFR 1271.10(a). Accordingly, it appears that they 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 a product 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].

As noted, the above-referenced products are 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. 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.

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.

We note that your website also lists "BIO-EX MSC Derived Exosomes-400," as one of the "Special Regenerative Treatments" available at The Body Building, Inc. Please be advised that, as a general matter, exosome products intended to treat diseases or 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 described above. For more information, please see FDA's Public Safety Notification on Exosome Products, at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.

This letter 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 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