September 16, 2021

UPS EXPRESS MAIL AND EMAIL

Yamaha Zachariah Azar, MD, MBA, MSc
Managing Partner
Genesis Medical Center
9950 Research Drive
Irvine, CA 92678
genesismedicalcenteroc@gmail.com

Dear Dr. Azar:

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.genesismedcenter.com, www.orangecountymedcenter.com and your Facebook page at www.facebook.com/genmedcenter (collectively "websites"), as well as other online sources described below.

Based on the materials reviewed, you and your firm market what you describe as a "stem cell therapy" or "biological therapy" product derived from adipose tissue to treat various diseases or conditions, such as autism, cardiovascular issues, diabetes and other pancreatic issues, vision problems, spinal cord injuries, dementia, Alzheimer's disease, brain trauma, pulmonary fibrosis, Parkinson's disease, and multiple sclerosis (MS). Your websites also indicate that you market an exosome product to consumers to treat diseases or conditions, including pulmonary fibrosis.[1] According to the materials FDA reviewed, Genesis Medical Center administers these products through various routes of administration, including by injection or via nebulizer.

For example, your website page regarding "Biological Therapy" available at

[1] We also note that your websites mention a product derived from amniotic fluid. HCT/Ps are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient" per 21 CFR 1271.3(d). The definition of HCT/P excludes secreted or extracted human products; accordingly, secreted body fluids, such as amniotic fluid, are generally not considered HCT/Ps subject to regulation under 21 CFR Part 1271. Although not an HCT/P, as a general matter, amniotic fluid intended to treat diseases or conditions in humans, would be regulated as a drug and biological product under section 351 of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act and would be subject to premarket review and approval requirements.

www.genesismedcenter.com/stem-cell-therapy/, includes several "Customer Reviews", including a testimonial from a patient treated for pulmonary fibrosis that states:

- "I've had 2 stem cell & 2 exosome treatments for my lung disease (pulmonary fibrosis). 8 treatments total including joints for degenerative arthritis. I find out next week if my lungs have improved with the treatments with CSCAN. I feel sooo much better now. Oxygen is 94%-98%. Just had my last exosomes on Saturday via Nebulizer…Had my right wrist treated at the same time for degenerative arthritis. I'm 99% pain free after 4 treatments."

Your firm has also posted a video on its Facebook page dated April 11, 2018, with the header "Q&A with Dr. Azar: Stem Cells/Medical Detox/Heroin/Opioids/Rehab," in which you state:

- "[T]he stem cell therapy involves different protocols, and we treat joint disease, autoimmune disease, neurodegenerative diseases, also things like . . . Parkinson's, rheumatoid arthritis."

In addition, you appeared on the podcast, entitled "Born To Talk Radio Show", available at www.blogtalkradio.com/borntotalk/2019/02/21/dr-azar-from-the-genesis-medical-center, dated February 21, 2019, where you discussed use of your firm's adipose derived cellular product to treat diabetes, joint disease, autoimmune diseases, and neurocognitive diseases such as Alzheimer's, autism, and MS. You were quoted discussing your firm's "stem cell therapy" and stating:

- "Our treatment with stem cells involves getting stem cells …from the fat cells and then we utilize them for possible joint disease, possible autoimmune disease, possible Alzheimer's, possible autism."

- "We treat . . . these types of problems where you can categorize it into three different sections which is your joint disease, autoimmune disease, and then you have neurocognitive. To break it down, neurocognitive is your Alzheimer's, your autism, your MS, anything that has to do with the nervous system and the brain. And then you have your autoimmune diseases where your own body attacks itself, whether you have lupus or rheumatoid arthritis, or some of the muscular dystrophies…so we have protocols for all of these things, and we've been doing it for about three to four years now here at Genesis Medical Center."

- "Diabetes is a disease, you know, of platelet cells in the pancreas that don't produce specific products, so it is a function of the body which is not going correctly. So there are protocols that we have to kind of reset and rehabilitate those cells and that is done with stem cells that are introduced into the area."

The above-referenced adipose derived cellular product appears to be a human cell, tissue, or cellular or tissue-based product (HCT/P) 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 websites and other sources, it appears that you do not qualify for any exception in 21 CFR 1271.15, and that your adipose derived cellular product is intended for non-homologous uses. Additionally, it appears that your adipose derived cellular product does not meet all the other criteria in 21 CFR 1271.10(a). Accordingly, it appears that the product would be regulated as a drug as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and biological product 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 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].

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.

As noted above, your websites indicate that you and your firm also market exosomes. Please be advised that, 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. 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 pertains to your adipose tissue derived cellular product and exosome product 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 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. You may also email a copy of your official, written response to CBERDCMRecommendations@fda.hhs.gov. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at (240) 402-9155. 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