May 11, 2020

VIA EXPRESS MAIL

Rebecca Rogers
Chief Executive Officer and Clinic Director
Sparrow Health & Performance, LLC
2000 Southlake Park, Suite 150
Hoover, AL 35244

Dear Ms. Rogers:

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.sparrowclinic.com and your Facebook page www.facebook.com/sparrowclinic/.

On your website and Facebook page, you and your firm offer cellular products derived from adipose (fat) tissue as "stem cell therapy" to treat the following diseases or conditions: "arthritis, asthma, autoimmune, cardiomyopathy, CIDP, COPD, Crohn's disease, degenerative spine and disc disease, Lichen Sclerosis, Lupus, Multiple Sclerosis, Muscular Dystrophy, Myasthenia Gravis, Neuropathy, Orthopedics, Parkinson's disease, Peyronie[']s disease, relapsing polychondritis, Scleroderma, stroke recovery and urological conditions." These products are to be administered by various routes of administration, including intravenously.

Most recently, you offer your adipose tissue derived cellular products to mitigate, prevent, treat, or cure 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] In response to this emergency, you state the following on your website:

[1] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists (January 31, 2020), renewed April 21, 2020, available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx*.

[2] President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-*

> In response to the current health crisis, our team would like to provide you with an opportunity to receive your own stem cells. We have the option of providing patients with immediate (point of care) production of SVF (stem cells produced from your own fat used the same day) and/or the option of having mini liposuction and then banking your own adipose stem cells for expansion into very high numbers (similar to China). These stored "personal stem cells" will allow you to have cells available urgently should you contract a potentially lethal virus and become eligible for "right to try" access to your cells. Having a frozen line of one's own personal mesenchymal stem cells could prove life-saving should someone become a victim of the current viral pandemic.

Your adipose tissue derived cellular products appear to be a human cell, tissue, 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. 21 CFR 1271.20.

It appears that Sparrow Health & Performance, LLC does not qualify for any exception in 21 CFR 1271.15, and that your adipose tissue derived cellular products are intended for nonhomologous uses. Accordingly, it appears 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 products may be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application 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 above, your adipose tissue derived cellular products are intended to treat a variety of serious or life- threatening diseases or conditions. Such unapproved uses raise potential significant safety concerns. Moreover, because your products appear to be administered by various higher risk routes of administration, their use, if contaminated could cause a range of adverse events. We direct your attention to FDA's comprehensive regenerative medicine policy framework for HCT/Ps, intended to spur

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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/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm585218.htm.

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 23 and 24 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 also note that your website lists exosomes as one of your "services." 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 addresses certain issues regarding your adipose tissue derived cellular 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. 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