October 30, 2020

UPS EXPRESS MAIL

John D. Young, M.D.
Medical Director
Young Foundational Health Center, LLC
7241 Bryan Dairy Road
Largo, FL 33777

Dear Dr. Young:

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 Young Foundational Health Center, LLC available at www.youngfoundationalhealth.com, your Facebook page available at www.facebook.com/dryoungfhc and via a link from your website, your YouTube channel available at https://www.youtube.com/channel/UCZuzcaS5-W4Jcd1pVrB9vuQ/ and via a link from your website, as well as other information available to FDA.

On your website, you market a cellular product for various diseases or conditions, such as autism, cerebral palsy, severe neck injury, and rheumatoid arthritis. You sometimes refer to the product as "umbilical cord stem cells" or "stem cell therapy," and, based on the materials reviewed, the product appears to be derived from human umbilical cord blood. You claim to have administered your product thousands of times over the past three years, and you describe administering stem cells "to problematic areas via injection or [intravenously]."

You also market your product on your Facebook page for various diseases or conditions. For example, your Facebook page states: "Stem Cell Therapy is used in treating: Autism, joint disease, chronic illnesses, auto-immune diseases and more! We administer Stem Cell therapy via injection or IV."

Similarly, you market your product on your YouTube channel for various diseases or conditions, including genetic mitochondrial disease, diabetes, stroke, dementia, cerebral palsy, and Down syndrome. For example:

> In a video on your YouTube channel available at www.youtube.com/watch?v=MrizvZZ-Ogs, entitled "AutismOne Conference 2019", you state:

- [A seminar attendee asks you about stem cells for diagnosed mitochondrial disease.] "I had a family that brought in their two kids with a genetic mitochondrial disease. I said to the lady… I don't think this is going to work.... We gave it, and sure enough they got better..."

- [A seminar attendee asks you about treating diabetes.] You replied, "For Type II [diabetes], it [use of stem cells] always does improve insulin resistance, always."

In a video on your YouTube channel available at www.youtube.com/watch?v=KFrVR5bf3qc, entitled "Young Foundational Seminar 2019", you state:

- "With my patients I have also used umbilical cord stem cells….in my stroke patients, in my dementia patients, about 80 to 85% of them, you will start to see that brain start to come back...Umbilical cord stem cells look for damage...They [stem cells] can become a bone, brain tissue, nostril hairs ... And it has been very, very helpful."

- "I have a lot of patients with cerebral palsy. I use a lot of stem cells... We've been very, very pleased with our results."

In a video on your YouTube channel available at www.youtube.com/watch?v=LOToH6mLy5Y, posted on July 30, 2020, you describe using your product to treat a pediatric Down syndrome patient:

- "She was classified as highly un-educatable .... We gave her umbilical cord stem cells and she gets them two to three times a year. And it's kind of a follow-up on German studies where they used sheep stem cells back in the '70s …. They raised the kids' IQ by about 10 to 20 points .... After about a year, her report card came back highly educatable."

The above-referenced 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 website and other sources, it appears that you do not

qualify for any exception in 21 CFR 1271.15, and that your product is intended for non-homologous uses. Additionally, it appears that your 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)].[1]

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].

As noted above, your product is 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. Moreover, because your product is administered by a higher risk route of administration, its 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, 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.

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.

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[1] As noted above, although it appears that your product is derived from human umbilical cord blood, you sometimes refer to it as "umbilical cord stem cells." Please be advised that, as a general matter, cellular products derived from human umbilical cord and intended to treat a variety of 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.

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