July 15, 2021

UPS EXPRESS MAIL & E-MAIL

Angela Jayes, MSN, NP-C, Owner
The Dahlia Center, LLC
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info@thedahliacenter.com

Dear Ms. Jayes:

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.ohiorejuvenationclinic.com/ and Facebook page, www.facebook.com/thedahliacentermedina/, as well as other information available to FDA.

FDA has obtained information revealing that you have offered a cellular product derived from umbilical cord to treat Coronavirus Disease 2019 (COVID-19) or to prevent COVID-19 associated respiratory conditions via intravenous administration.

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named 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, there was a Presidential declaration of national emergency in response to COVID-19.[2]

[1] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[2] 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-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

In addition, on your website and Facebook page, you and your firm market "umbilical stem cells", which appear to be cellular products derived from human umbilical cord or human umbilical cord blood (hereinafter, "products")[3]. You market these products for various diseases or conditions, such as leukemia, prostate cancer, diabetes, Parkinson's disease, cerebral palsy, Alzheimer's disease, multiple sclerosis (MS), macular degeneration, chronic obstructive pulmonary disease (COPD), lupus, congestive heart failure, Guillain-Barré syndrome, and Ankylosing spondylitis. These products appear to be administered by various routes of administration, including intravenously or by inhalation. For example:

A post to your firm's Facebook page states:

- "The Dahlia Center offers the most advanced quality and cutting edge treatments in regenerative medicine…We have created specialized protocols for people who suffer from: Diabetes…Chronic Degenerative Diseases…Autoimmune Diseases…[o]r just for preventing any disease…If you wish to set up a FREE consultation and receive a personalized treatment plan contact us!" [www.facebook.com/thedahliacentermedina/photos/a.375287953038673/718714792029319/?type=3&theater]

In videos posted on your firm's Facebook page, you state:

- I've had a few patients with leukemia and a couple patients with prostate cancer that have had stem cells and they've done very well." [www.facebook.com/thedahliacentermedina/videos/921606748232866/?__so__=channel_tab&__rv__=all_videos_card]

- "I had a gentleman…had congestive heart failure, had severe COPD…I did an IV on him…two weeks after I get the phone call, he is out driving, off hospice and he feels great…Have I heard of people that have been treated with stem cells with Alzheimer's?... I've actually had some that I've done…it can actually help." [www.facebook.com/370284770205658/videos/1087234531473147/?__so__=channel_tab&__rv__=all_videos_card]

- "I have provided people with stem cells…the most amazing is this gentleman…with Parkinson's, and he came into my office and he's hunched over...he could not talk to me…he had IV…he came back at 90 days, he's completely upright and he was able to ask me questions…I just treated a

[3] Your Facebook page also refers to an amniotic fluid product, (b) (4). HCT/Ps are defined at 21 CFR 1271.3(d) as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 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.

gentleman…he has cerebral palsy, but he's also severely diabetic…his blood sugars went from 400 and 500's down to 150's to 200's within 30 days and … he was more active, and he is just doing better." [www.facebook.com/370284770205658/videos/876417699374710/?__so__=channel_tab&__rv__=all_videos_card]

- "We had a lady fly in from Chicago and we did a new lupus protocol on her… It's an infusion." [www.facebook.com/370284770205658/videos/876417699374710/?__so__=channel_tab&__rv__=all_videos_card]

- "[M]acular degeneration…you have one part of your vision that's still there, so it's usually a spot, and with this [*sic*] two ladies that I treated, the spot became clear…If anything is still alive, then the stem cells can help regenerate it." [www.facebook.com/thedahliacentermedina/videos/694766534272478/?__so__=channel_tab&__rv__=all_videos_card]

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 the materials described above, it appears that the Dahlia Center does not qualify for any exception in 21 CFR 1271.15, and that the above-referenced products are intended for nonhomologous uses. Additionally, it appears these products may fail to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that the products 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 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.

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. 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) 402-9155. 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

Cc:

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