



November 25, 2019

UPS EXPRESS MAIL

Joy Kong, MD
Chief Executive Officer
Chara Biologics, Inc.
5850 Canoga Ave., Suite 400
Woodland Hills, CA 91367

Dear Dr. Kong,

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 websites for Chara Biologics, Inc. available at <https://www.charabiologics.com/> and <https://www.facebook.com/charabiologics/>.

You and your firm market your product CharaCore™ to consumers, including parents of children with autism. You state that CharaCore™ contains “umbilical, cord tissue and amniotic membrane” and describe it as an “umbilical cord-derived cellular product” that is “[s]uitable for all forms of injections, to assist the body’s ability to repair and regenerate.”

You further promote CharaCore™ for serious or life-threatening diseases or conditions. For example, case studies on your websites reference CharaCore™ as a treatment for autism in children and traumatic brain injury in young adults:

- “[A] 7-year-old autistic girl came back for her 2nd stem cell treatment. Patient first came in for treatment 8 months prior, and received 3cc CharaCore infusion. Patient was non-verbal, on diapers, and had hypotonia. Since the first CharaCore treatment, patient was able to get off diapers completely, able to tell her parents when she needed to go ‘potty,’ and able to hold it until parents could locate a bathroom nearby. She also went from completely non-verbal to being able to speak some words. . . . She is also less hyperactive, much calmer, and more interactive. . . . Parents requested 5cc CharaCore for the 2nd infusion treatment.” <https://charabiologics.com/case-studies/autism/>.
- “At Thea Center for Regenerative Medicine today, Chara’s founder/CEO Dr. Joy Kong treated a young man who suffered from traumatic brain injury as a teenager, using CharaCore - the most comprehensive and

potent stem cell product on the US market #traumaticbraininjury
#tbi #tbisurvivors #braininjury #stemcelltherapy #stemcells
#stemcellclinic #losangelesstem #stemcelltreatment
#neurologicaldisorder #regenerativemedicine #celltherapy #healing
#healfromwithin #integrativemedicine #brainregeneration #brainrepair
#beststemcellclinics” See May 23 Facebook posting at:
<https://www.facebook.com/charabiologics/>; see also
<https://charabiologics.com/videos/>.

Additionally, you further describe your products as follows:

- “Chara products can also be safely dosed at regular intervals, and . . . a remarkable anti-aging therapy, as the main effects of the product is [sic] to reduce inflammation and promote tissue repair. Dr. Kong has seen remarkable transformations in her patients, such as ones plagued by autism, cardiac issues, COPD, osteoarthritis, dementia, and autoimmune disorders like lupus or psoriasis.” <https://charabiologics.com/dr-joy-kong-featured-on-cover-of-ep-magazine/>.
- “Not FDA approved,” “experimental,” and provided by IV infusion for patients, including those with “various chronic conditions” such as “auto-immune problems, lupus, rheumatoid arthritis, psoriasis . . . lung problems, COPD, heart issues . . . or dementia” April 18 Facebook posting at: <https://www.facebook.com/charabiologics/>, and available at <https://www.blogtalkradio.com/cutvnewsradio/2019/04/12/part-2-cutv-news-radio-welcomes-back-dr-joy-kong-of-chara-biologics>.

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 a review of your websites, it appears that Chara Biologics, Inc. does not qualify for any exception in 21 CFR 1271.15, and that CharaCore™ is intended for nonhomologous uses. Additionally, CharaCore™ appears not to meet all the other criteria in 21 CFR 1271.10(a) and, accordingly, would be regulated as a drug as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and a 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 (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, CharaCore™ is intended to treat a variety of serious or life-threatening diseases or conditions. Such unapproved uses raise potential significant safety concerns. Additionally, because the product is administered by various higher risk routes of administration, including IV, 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/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.

This letter addresses certain issues regarding CharaCore™ and is not intended to be an all-inclusive review of your firm's products.¹ 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. Any response to this letter 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

¹ For example, we note that your website describes an exosome product, CharaExo™, as a “[h]elpful adjunct therapy to enhance the effects of cell therapy.” As a general matter, exosomes for clinical use in humans are 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.