By Secure Electronic Mail

August 19, 2020

Ms. Tracee Gruber
Chief Operating Officer
Lucina BioSciences, LLC
2993 S. Peoria St., Suite 304
Aurora, CO 80014
tgruber@lucinabio.org

RE: Request for Recommendation for Placental Spongy Layer (Procenta®)

Dear Ms. Gruber:

This letter is in response to your inquiry and the related information provided to the Food and Drug Administration's Tissue Reference Group (TRG) on May 12, 2020. Lucina BioSciences, LLC is seeking a recommendation from the TRG whether your placental spongy layer product, branded as Procenta®, meets the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271.

Your submission describes Procenta® as a sterile, "human placental tissue allograft, which is non-viable, hydrated, fully conformable, (b) (4)

(b) (4)

To be regulated solely under section 361, an HCT/P must satisfy all four criteria at 21 CFR 1271.10(a)[1]. The TRG reviewed and discussed the materials you submitted. Based on the description of the processing steps you provide, Procenta®, when intended to serve as a cover, to offer protection from the surrounding environment, or to retain fluid, would meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

(b) (4)

[1] The four criteria can be found at 21 CFR 1271.10(a), and, as applicable, see the following guidance documents: "Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff" dated July 2020; and, "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry" dated November 2017.

(b) (4) . The recommendations in this letter pertain to the product as described in your submission, i.e., with no claims made for the use of amniotic fluid (from the same donor), other than "use strictly as a preservation media" and "storage media."

Any variation from what you describe in your request for recommendation to the TRG, (b) (4) (b) (4) could impact the applicability of this recommendation.

For questions or concerns regarding this response letter, please contact the Executive Secretary for the TRG, at TissueReferenceGroup@fda.hhs.gov or at 301-796-1411.

Sincerely,

Wilson Bryan -S

Digitally signed by Wilson Bryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Wilson Bryan -S, 0.9.2342.19200300.100.1.1=0011265579
Date: 2020.08.06 20:00:04 -04'00'

Wilson W. Bryan, M.D.
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

James P. Bertram -S

2020.08.19 17:14:54 -04'00'

James Bertram, Ph.D.
Assistant Director
Regulation, Policy and Guidance Staff
Office of Product Evaluation and Quality
Center for Devices and Radiological Health