



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

### AMENDED ORDER

January 25, 2017

Mr. Jason Reneau  
Chief Operating Officer  
Amniotic Therapies, LLC  
11496 Luna Road  
Suite 800  
Farmers Branch, TX 75234-9417

Dear Mr. Reneau:

On August 16, 2016, pursuant to 21 CFR 1271.440(a)(1) and (3), the United States Food and Drug Administration (FDA or Agency) issued an order to cease manufacturing, recall, and destroy human cells, tissues, or cellular or tissue-based products (HCT/Ps) to Amniotic Therapies, LLC (Amniotic Therapies) and Bryant Gaines, former Chief Executive Officer (hereinafter, August 2016 Order). A copy of the August 2016 Order is attached.

FDA issues this Amended Order following resolution of *Amniotic Therapies, LLC v. U.S. FDA*, No. 16-2412 (N.D. Tex. Nov. 28, 2016). In connection with the litigation, Amniotic Therapies submitted new information to FDA about the HCT/Ps subject to the August 2016 Order's recall requirement and met various conditions related to that requirement, as agreed by the parties. As such, FDA hereby amends the August 2016 Order solely to remove the portions requiring that Amniotic Therapies recall HCT/Ps distributed since September 11, 2014. This Amended Order does not supersede or alter any other provision of the August 2016 Order. Nor does it modify any other FDA-issued correspondence.<sup>1</sup> Amniotic Therapies remains bound by and shall perform all other requirements, obligations, and responsibilities set forth in the August 2016 Order.

FDA notes that the Agency may issue any further order, including an order of recall, upon receipt of additional information that meets the standard for such an order under 21 CFR 1271.440.

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<sup>1</sup> For example, nothing in this Amended Order modifies FDA's letter to you dated January 6, 2017, relating to corrective actions you have taken or are currently implementing, as described in your submissions to FDA between October 7 and October 28, 2016.

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Mr. Jason Reneau  
Amniotic Therapies, LLC

Sincerely,

Peter Marks, M.D., Ph.D.  
Director  
Center for Biologics Evaluation and Research

Effective Date: \_\_\_\_\_ January 25, 2017 \_\_\_\_\_ Time: \_\_\_\_\_ 9:00 AM EST \_\_\_\_\_

Attachment (1)  
Order to Cease Manufacturing, Recall, and Destroy HCT/Ps, dated August 16, 2016