U.S. FOOD & DRUG ADMINISTRATION

Scott M. Lassman, Principal
Lassman Law + Policy
1717 K Street, NW, Suite 900
Washington, DC 20006

January 7, 2021

Re: Docket Number: FDA- 2020-P-1689

Dear Mr. Lassman:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet reached resolution of the issues raised in your citizen petition (Petition) received by the Division of Dockets Management on July 20, 2020. In your Petition, you request that the Commissioner "take certain actions with respect to Biologics License Application ('BLA') 125706, for remestemcel-L (ex-vivo culture-expanded adult human mesenchymal stromal cells suspension for intravenous infusion), also known by the trade name RYONCIL, submitted by Mesoblast, Inc. ('Mesoblast') for treatment of pediatric patients with steroid-refractory acute graft-versus-host disease ('SR-aGVHD')." Because of the existence of other FDA priorities, we have not been able to reach a decision on the petition at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)(iv)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Peter Marks

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Division of Dockets Management

U.S. Food and Drug Administration
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