November 10, 2020

Peter Choi
Sidley Austin, LLP
1501 K Street, N.W.
Washington, DC 20005

Re: Docket No. FDA-2020-P-1416

Dear Mr. Choi:

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 received by the Dockets Management Staff on May 20, 2020. Your petition, submitted on behalf of Cell2in Inc., requests that FDA update certain guidance documents to "identify real-time glutathione monitoring methods as an acceptable means of measuring potency for purposes of submitting a Biologics License Application (BLA) for cell-based therapies, including stem cell therapies, under Section 351 of the Public Health Service Act."

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)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

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

cc: Emily Marden
cc: Kelly Cho
cc: Division of Dockets Management