DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

May 21, 2020

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

Sent via email to: kcho@sidley.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to update any or all of the following 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 (PHS Act):

1) Guidance for FDA Reviewers and Sponsors, Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs) (Apr. 2008);
2) Guidance for Industry, Potency Tests for Cellular and Gene Therapy Products (Jan.2011); and/or
3) Guidance for Industry, Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System (Mar. 2014).

Your submission was received by this office on 05/20/2020 and it was assigned docket number FDA-2020-P-1416. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Digitally signed by Karen Malvin
Date: 2020.05.22 07:04:51 -04'00'

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)

CC:
Emily Marden
Kelly Cho