



MEMORANDUM

From: Kimberly Benton, Ph.D., Deputy Director, Division of Cellular & Gene Therapies
Raj Puri, M.D., Ph.D., Director, Division of Cellular & Gene Therapies, OCTGT, CBER

Date: January 27, 2016

BLA/ STN#: 125585

Applicant Name: Bloodworks

Date of Submission: January 28, 2015

Action Goal Date: January 28, 2016

Proprietary Name/ Established Name: N/A

Non-Proprietary Name: HPC, Cord Blood

Indication: HPC, Cord Blood is an allogeneic cord blood hematopoietic progenitor cell therapy intended for use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment. The risk benefit assessment for an individual patient depends on the patient characteristics, including disease, stage, risk factors, and specific manifestations of the disease, on characteristics of the graft, and on other available treatments or types of hematopoietic progenitor cells.

Product Reviewers: Brian Niland, Ph.D., Prajakta Varadkar, Ph.D., Heba Degheidy, Ph.D., Joydeep Ghosh, Ph.D., Safa Karandish, B.S., MT (ASCP)

Branch Chief: Steven Oh, Ph.D.

Material Reviewed/ Consulted: CMC Review dated January 27, 2016

I agree with the recommendation for approval as stated in the CMC review memo dated January 27, 2016, and have no additional comments.

Kimberly Benton, Ph.D.

Raj K. Puri, M.D., Ph.D.