



Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Cellular, Tissue, and Gene Therapies
Division of Cellular and Gene Therapies

From: Steven S. Oh, Ph.D., Acting Deputy Director, Division of Cellular & Gene Therapies
Raj Puri, M.D., Ph.D., Director, Division of Cellular & Gene Therapies, OCTGT, CBER

Date: August 26, 2016

BLA/ STN#: 125594/0

Applicant Name: Cleveland Cord Blood Center

Date of Submission: June 9, 2015 (received June 10, 2015)

Action Goal Date: September 1, 2016

Proprietary Name/ Established Name: CLEVECORD

Non-Proprietary Name: HPC, Cord Blood

Indication: HPC (hematopoietic progenitor cells), Cord Blood is an allogeneic cord blood hematopoietic progenitor cell therapy indicated 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: Yong Fan M.D., Fatima Abbasi, M.S., Joydeep Ghosh, Ph.D., Safa Karandish, B.S., MT (ASCP)

Branch Chief: Steven S. Oh, Ph.D.

Material Reviewed/ Consulted: CMC Review dated August 23, 2016

I agree with the recommendation for approval as stated in the CMC review memo dated August 23, 2016, and have no additional comments.

Steven S. Oh, Ph.D.

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