

Major Amendment Acknowledgement, February 2012 - HPC Cord Blood

Our STN: BL 125391/0

Clinimmune Labs
Attention: Sharon Miller
12635 East Montview Blvd, Suite 300
Aurora, Colorado 80045

Dear Ms. Miller:

We received your January 31, 2012 amendment to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for Hematopoietic Progenitor Cells, Cord (HPC-C) on February 1, 2012.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the Food and Drug Administration Amendments Act of 2007.

Because we received this major amendment within three months of the action due date, we will add an additional three months to the time by which we should complete our review. Therefore, the action due date is June 2, 2012.

If you have any questions, please contact the Regulatory Project Manager, Ramani Sista, at (301) 827-5152.

Sincerely yours,

/s/

Raj K. Puri, M.D., Ph.D.
Director
Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapies Center for Biologics Evaluation and Research