

Acknowledgment of Filing, July 1, 2011 - HPC Cord Blood

STN: 125391/0

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

Dear Ms. Miller:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated April 29, 2011 for Hematopoietic Progenitor Cells (HPC), Cord Blood to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review goal date is March 01, 2012. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We will contact you regarding your proposed labeling no later than February 02, 2012. If post marketing study commitments (506B) are required, we will contact you no later than February 2, 2012.

While conducting our filing review, we identified potential review issues and will be communicating them to you on or before July 15, 2011.

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

Sincerely yours,

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