



Our STN: BL 125594/0

MAJOR AMENDMENT ACKNOWLEDGEMENT

May 13, 2016

Cleveland Cord Blood Center
Attention: Wouter Van't Hof, PhD
25001 Emery Road
Suite 150
Warrensville heights, OH 44128

Dear Dr. Van't Hof:

We received your April 29, 2016 amendment to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for HPC-Cord Blood on May 2, 2016.

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 September 8, 2016.

If you have any questions, please contact the Regulatory Project Manager, Lori Tull, at (240) 402-8361.

Sincerely yours,

Raj K. Puri, MD, PhD
Director
Division of Cellular and Gene Therapies
Center for Biologics Evaluation and Research