

Major Amendment Letter, June 11, 2012 - Ducord

Our STN: BL 125407/0

Duke University School of Medicine
Attention: Dr. Bruce Burnett
Hock Plaza, 2424 Erwin Road, Suite 402
Durham, NC 27705

Dear Dr. Burnett:

We received your May 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 *HPC, Cord Blood* on June 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 October 8, 2012.

If you have any questions, please contact the Regulatory Project Manager, Mark L. Davidson, at (301) 827-6536.

Sincerely yours,

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

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