

# Proprietary Name Review, 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 have reviewed your submission dated May 1, 2012 to your biologics license application (BLA) for *HPC, Cord Blood* requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, *DuCord*, is acceptable at this time.

We will perform another proprietary name review of *DuCord* closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

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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