

Proprietary Name Review Memo, March 18, 2011 - Hemacord

March 18, 2011
Our STN: BL 125397/0

New York Blood Center
Attention: Edwin W. Streun
Director, NYBC Regulatory Affairs
310 East 67th Street
New York, NY 10021

Dear Mr. Streun:

We have reviewed your submission dated January 7, 2011 to your biologics license application (BLA) for Hematopoietic Progenitor Cells, Cord (HPC-C) 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, HEMACORD is acceptable at this time.

We will perform another proprietary name review of HEMACORD 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, Terrolyn Thomas, M.S., M.B.A at (301) 827-6536

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

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