Acknowledgment Letter, January 28, 2011 - Hemacord

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

Dear Mr. Streun:

We have received your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

Our Submission Tracking Number (STN): BL 125397

Name of Biological Product: Hematopoietic Progenitor Cells, Cord (HPC-C)

Indication: For hematopoietic reconstitution in patients with hematologic malignancies, Hurler Syndome (MPS I), Krabbe Disease (Globoid Leukodystrophy), X-linked Adrenoleukodystrophy, primary immunodeficiency diseases, bone marrow failure, beta thalassemia.

Date of Application: January 7, 2011

Date of Receipt: January 10, 2011

Action Due Date: November 10, 2011

Please note that you are also responsible for complying with the applicable provisions of sections 402(i) and (j) of the Public Health Service Act (PHS Act) (42 U.S.C. §§ 282(i) and (j), which was recently amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No. 110-85, 121 Stat.904).

We request that you submit all future correspondence, supporting data, or labeling relating to this application in triplicate, citing the above STN number. Send all correspondence to the following address:

Center for Biologics Evaluation and Research
Attn: Office of Cellular, Tissue and Gene Therapies
Document Control Center, HFM-99, Room 200N
1401 Rockville Pike
Rockville, MD 20852-1448

Applicants who sent applications via the Food and Drug Administration Electronic Submissions Gateway (ESG) should continue to use those procedures. The ESG is an Agency-wide solution for accepting electronic regulatory submissions that enables the secure submission of regulatory information for review. Instructions for setting up an ESG account can be found at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

We will notify you within 60 days of the receipt date if the application is sufficiently complete to permit a substantive review.

If you have any questions, please contact the Regulatory Project Manager, Terrolyn Thomas, M.S., M.B.A., at (301) 827-9161.

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