

Telecon, November 9, 2011 - Hemacord

BLA #: 125397

Teleconference Date: November 9, 2011

FDA Participants:

Kimberly Benton, Stephanie Simek, Mercy Quagrainne, Lisa Stockbridge, Loan Nguyen

NYBC Participants:

- Pablo Rubinstein, M.D. – Vice President, New York Blood Center (NYBC) and Director, National Cord Blood Program (NCBP)
- Eva Quinley – Senior Vice President (NYBC), Quality & Regulatory Affairs
- Michael Zdanowski – Director of Operations (NCBP)
- Ludy Dobrila, Ph.D. – Associate Director, Processing (NCBP)
- Andromachi Scaradavou, M.D. – Medical Director (NCBP)
- Christine Driscoll – Director, Regulatory Affairs (NYBC)

FDA and NYBC discussed text revisions needed for the Instructions for Preparation for Infusion. FDA will send revisions to NYBC after the tcon. NYBC will review and combine with the rest of the Prescribing Information, and submit to FDA.

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