

Telecon, November 8, 2011 - Hemacord

BLA #: 125397

Teleconference Date: November 8, 2011

FDA Participants:

Kimberly Benton, Stephanie Simek, Mercy Quagraine, 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 drafts of the container label to be affixed to the cryobag that had been communicated via email. NYBC provided a final version which FDA found acceptable. NYBC will submit this officially to the BLA.

FDA and NYBC discussed reformatting and text revisions needed for the Instructions for Preparation for Infusion. FDA will send revisions to NYBC and NYBC will review and return by Wednesday a.m.

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