Telecon, October 7, 2011 - Hemacord

Date/Time of Call: October 7, 2011 @ 2:30 P.M.

CBER Representative: Mohammad Heidaran, Biologist, CBER/DMPQ
Laurie Norwood, Deputy Director, DMPQ
John Eltermann, Director, DMPQ
Chiang Syin, Branch Chief, DMPQ

Organization Representative: Eva Quinley
Andromachi Scaradavou
Michael Tarnawski
Pablo Rubenstein
Michael Zdanowski

Organization: **New York Blood Center Inc.**

Subject: Retention Sample, Batch Record, BSC Monitoring

STN: **125397/0**

The following outstanding deficiencies were discussed:

- We mentioned to NYBC that retention sample is a regulatory requirement
- Since DMSO is ---(b)(4)--- added to the final product, the BSC, where the DMSO addition is performed, should be monitored according to (b)(4) classification.
- We pointed out that the Batch record was deficient as it did not contain detailed information about critical steps of manufacturing process.

NYBC agreed to monitor BSC according to (b)(4) classification. In addition they agreed to retain a sample of the UCB and to provide FDA with a proposal on how to do so. We also agreed to have further discussion to revise the batch record on Wednesday October 12th.