

Report of Telephone Conversation, October 12, 2011 - Hemacord

Date/Time of Call: October 12, 2011 @ 2:00 A.M.

CBER Representative: Mercy Quagraine, Mohommad Heidaran (DMPQ)

Organization Representative: Pablo Rubenstein, Andromachi Scaradavou, Mike Zdanowski, Ludi Dobrila

Organization: New York Blood Center Inc.

Subject: Follow up on NYBC's proposal for Retention Samples

STN: 125397/0

Telecon with NYBC October 12, 2011 2-3 PM:

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Sponsor will send his written proposal via email and will wait for FDA response before initiating 'Change Management Control' to update their SOPs.

On a follow up question on their batch records approach, the agency (DMPQ) agreed with their approach. Regarding the status of their NDC #, Sponsor indicated that they were still in the process of securing the NDC #.

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