RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125397/0 Office: OCTGT

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

Applicant:
New York Blood Center, Inc.

Telecon Date/Time: 11-Apr-2011 02:00 PM Initiated by FDA? Yes

Telephone Number: 866-206-0240

Communication Categorie(s):
1. Other - Donor Eligibility

Author: Donna Przepiorka and Safa Karandish

Telecon Summary:
Telecon was scheduled to discuss donor eligibility

FDA Participants:

Ramani Sista
Mercy Quagraine
Safa Karandish
Donna Przepiorka
Peter Bross
Steve Bauer
Brent McCright
Mo Heideran
Gang Wang
Keith Wonnacott
Patrick Riggins

Non-FDA Participants:

Eva Quinley – Senior Vice President, Quality & Regulatory Affairs, New York Blood Center
Michael Zdanowski – Director of Operations, National Cord Blood Program (NCBP)
Ludy Dobrila, Ph.D. – Associated Director, Processing (NCBP)
Tao Wang – Manager, Cord Blood Validation (NCBP)
John Svagr – Director, Environmental Health & Safety, New York Blood Center
Edwin W. Streun – Director, Regulatory Affairs, New York Blood

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

1. FDA reviewed some of the requests in the March 9, 2011 letter:

a) All DE SOPs over the timespan proposed for licensure (Comment #3).
b) The plan for tracking information for multiple births (Comment #6).
c) The plan for ensuring that products from ineligible donors are quarantined and not released under licensure (Comment #7).
d) Operating characteristics for the HLA and ABO testing (Comment #8).
e) CLIA certification numbers for the laboratories doing maternal testing (Comment #9).

Discussion: Sponsor indication the information would be available within 2 weeks.

2. FDA asked for procedure CB37.0005.1 entitled "Collection Form, Maternal Interview and Hospital Record Review".

Sponsor will provide the SOP.

3. FDA asked about the process for documenting infusion of ---------(b)(4)---------- for assessing plasma dilution in birth mother

Discussion: Sponsor indicated that infusion of IV solutions is not documented. FDA will get back to sponsor with further information.

4. FDA asked for clarification regarding screening of birth mother for syphilis and discrepancy between collection and donor eligibility SOPs. Is the mother excluded if there is positive test result at time of admission in the hospital or if there is any positive test result during the pregnancy?

Discussion: Sponsor indicated that both criteria are used. That is acceptable by FDA.

5. FDA asked how the following findings are factored in the donor eligibility determination since they are not specified in the SOP CB 37.0023.1:

a. If the birth mother has been treated for or newly diagnosed with syphilis in the past 12 months (question 114 data form).

b. If the mother's physical exam medical record review indicates evidence of syphilis or risk of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, etc. (question 9 data form).

Sponsor will verify SOP.

6. FDA asked for clarification on the donor eligibility determination and/or exclusion criteria for birth mothers with risk factor for HIV. There is a discrepancy in the following 2 procedures:

    CB37.0023.1 (Donor Eligibility)- donor is determined **ineligible** if mother has had sex with HIV+ person in the past 12 months (step 6.2.3.22).

    CB37.0001.1 (Collection of Cord Blood)- **Exclusion Criteria 4.5.c**: mother has had sex with an HIV+ person during pregnancy.

Discussion: Sponsor indicated that unit will be excluded. SOP CB37.0023.1 will be corrected.

7. FDA asked how birth mother screening and testing for the following are factored in the donor eligibility determination (not specified in procedure CB37.0023.1):

    a. Parasitic blood diseases such as Babesiosis

    b. Testing for T. cruzi

Discussion: Sponsor indicated that the above are not required. FDA stated that even though the above are not a required screening and testing; any additional information regarding relevant communicable disease agents or diseases must be considered for donor eligibility determination.

8. FDA indicated that for cord units to be eligible for licensure, the maternal specimen must be tested for all the current required tests which include NAT HIV/HCV. The testing must be performed according to the test kit manufacturer's instructions. If the stored specimen used for HIV/HCV NAT testing has been in storage beyond the storage limit defined by the test kit manufacturer and the results are negative, results cannot be considered valid and therefore, it cannot be considered as tested. This additional testing is not prohibited and such units may be used under an IND. Also, units from "ineglible" donors are not qualified for licensure.

Discussion: Sponsor stated that based on the licensure guidance document, they understood that units from "ineligible" donors can be licensed. FDA explained that those units can be used under an IND as explained in the IND guidance.

9. FDA asked how licensed units and "ineligible" donors will be identified in the search inventory.

Sponsor will get back to FDA.

10. FDA indicated that since the infectious disease test kits are not approved for use with cord blood specimens, the footnote "using FDA approved assays" on the unit report must be revised. FDA recognizes that reporting test results on cord blood specimens are required by FACT.

11. FDA asked how the lot # ---(b)(4)--- anticoagulant added at time of collection is documented (not listed on the Collection Form).

Sponsor will verify the documents and provide the information.

12. FDA indicated that the major deficiency in the outcomes analysis SOP was the lack of a stated frequency for the analysis.

Discussion: Sponsor requested input of periodicity. FDA indicated that it depended on volume, reporting frequency and outcomes incidence, and without that information a periodicity for meaningful analyses could not be determined. FDA recommended that it be realistic, including semiannually or annually.

13. FDA indicated that the major deficiencies in the SAE reporting SOP was not holding CIBMTR to regulatory reporting requirements and the lack of conveyance to the end user about how and when to report an SAE.

Discussion: It was recommended that the sponsor add to the receipt form additional information about SAE reporting. Sponsor indication that there were additional notices and forms they used, especially for units released outside the NMDP system. This information will be submitted.

14. FDA asked about the revised outcomes and DE datasets. Sponsor clarified it would be submitted within 2 weeks. FDA indicated that the data needed to be received prior to inspection, since accuracy of the data would be part of the inspection.

15. FDA asked sponsor to confirm that the data were generated outside a protocol. Sponsor clarified that all of the data were collected on protocol under IND 6637. FDA indicated that all versions of the protocols would need to be submitted to the BLA. If the sponsor wanted to cross reference the IND for the protocols, they would need to state which submissions had which versions of the protocols.

16. Sponsor requested more detail about expectations for the postmarketing plan. FDA clarified that the outcomes analysis SOP and the SAE reporting SOP were sufficient to start with, and if any safety issues were identified during review of the data, additional studies could be discussed at a later time.

17. Sponsor requested clarification for the expected number of units to be processed during inspection. FDA clarified that a total of twenty units, i.e., 10 units followed by additional 10 units, over the course of the inspection would be sufficient.