Sponsor Telecon, February 8, 2011 - Hemacord

DATE: **February 8, 2011**
Time: **3:00 -4:00 PM EST**
Sponsor: **New York Blood Center**
BLA #: **BLA 125397**
Product: **Hematopoietic stem/progenitor cells, cord (HPC-C)**

FDA Attendees: Thomas, Terrolyn; Quagraine, Mercy; Wang, Gang; Heidaran, Mohammad; Przepiorka, Donna; Bross, Peter; Hyde, John E; Rees, Renee; McCright, Brenton; Joshi, Bharat; Bauer, Steven; Ghosh, Joydeep; Serabian, Mercedes; Hoque, Atm S.; Wonnacott, Keith; Stockbridge, Lisa L; Holobaugh, Patricia; Jordan, Carla; Cato, Dennis; Ou, Alan C.; Karandish, Safa

Sponsor Attendees: Michael Zdanowski; Pablo Rubinstein; Andromachi Scaradavou; Ludy Dobrila, Eva Quinley; Edwin W. Streun; John Svagr

Summary of Discussion:

PRODUCT

1. Update on the requested information for Sterility Assay Validation Section 4.3.2.1
   The sponsor agreed to send in 2 days.

DMPQ

2. The CE issue. I have the following written request for your consideration.
   In your BLA, you claimed a Categorical Exclusion (CE) from the requirement to submit an Environmental Assessment (EA) under 21 CFR 25.31(j), i.e., action on an application for marketing approval for marketing of a biologic product for transfusable human blood or blood components and plasma. The CE claim under 21 CFR 25.31(j) was inappropriate due to the fact that the product of hematopoietic stem/progenitor cells, cord (HPC-C) submitted in your BLA does not meet the definition of a transfusable human blood or blood components and plasma product. Please consider resubmitting a revised CE claim under a different action item for the HPC-C product.

   FDA agreed to send CFR references via email.
3. Verify the FEI number for Long Island Facility. We may ask the firm to clarify if they are requesting for approval of the HPC-C units processed in their old facility.

   Sponsor stated that -------(b)(4)-------- is the FEI number received for this year's registration. FDA noted that the number was not found in the inspection database.

*FDA will discuss internally which number is appropriate then get back to the sponsor. The sponsor agree*d.

4. Proposed PLI date – the last week of April (April 25 – 29), or the 2nd week of May (May 9 – 23). April is preferred.

   FDA stated that production must be witnessed during the visit. The sponsor will get back to FDA with the final date.

CLINICAL

5. Update on revised Form 356h
   The sponsor agreed to send.
6. Update on forms for the donor health history and family history SOP
   The sponsor agreed to send.
7. Update on the SOPs for adverse events and for outcomes analysis
   The sponsor agreed to send.
8. Update on the clinical section
   FDA explained that there needs to be unique identifier for each patient for each patient included in the data set to link the information between tables.
9. Word version of the prescribing information
   Sponsor has already sent document.
10. Documents for compliance with PREA
    FDA will send guidance document.

The sponsor agreed to send all requested materials by February 23, 2011.