

Teleconferences with MD Anderson Cord Blood Bank

Application number: BLA 125657/0
Product name: Allogeneic HPC, Cord Blood
Applicant: MD Anderson Cord Blood Bank
Committee Chair: Mercy Quagraine, PhD

Teleconference date and time: October 31, 2017 09:00-10:00

FDA attendees:

Virginia Ocampo, MT, CBER/OTAT/DRPM
Mercy Quagraine, PhD, BLA Chair, Product Reviewer, CBER/OTAT/DCGT
Safa Karandish, MT, CMC (DE eligibility and product collection) Reviewer, CBER/OTAT/DHT
Hanh Khuu, MD, CMC (DE eligibility and product collection) Reviewer, CBER/OTAT/DHT
Mercedes Serabian, MS, CBER/OTAT/DCEPT
Ramjay Vatsan, PhD, Acting Branch Chief, CBER/OTAT/DCGT

MD Anderson Cord Blood Bank attendees:

Dr. Elizabeth Shpall (CBB Director)
Dr. Chitra Hosing (CBB Medical Director)
Suzanne Dworsky (CBB Administrator)
Jeffrey Wilson (Assistant Director)
Donna Reioux (Manager, CBB Quality Assurance)
Erin Eaton (CBB Program Manager)
Krystle Pool Sam (Manager, CBB Collections)
Mil Fontenot (Supervisor, Laboratory)

APPROVED

By Hanh M. Khuu, M.D. at 2:24 pm, Nov 13, 2017

The following were discussed during the above telecon:

Donor Eligibility and Cord Blood Collection:

- In the filing letter dated 8/22/2017, FDA asked sponsor to explain how out-of-range temperatures are handled and whether the affected units are accepted for banking. In the written response, sponsor explained that out-of-range temperature events are reported to QA for investigation and that all cord blood units are checked in for processing, that all units undergo terminal testing and that units meeting release criteria are made available for clinical use. It appears sponsor accepts units that are outside the temperature range defined in SOP. FDA explained that temperature monitoring during

product storage and transport is an important parameter to demonstrate process control. FDA asked the sponsor to modify the acceptance criteria in the SOP.

- Regarding SOP S 010.011.002, it was unclear that the (b) (4) application would not allow ineligible cord blood units to be licensed. **Sponsor confirms that when the ineligible status is selected, the licensed status become unavailable.**
- Regarding SOP S 016.010.002, for training nursing personnel at remote collection sites to perform donor screening. Sponsor states that nursing personnel do not perform donor screening. Cord blood staff perform this task and their training to perform this function is described in another SOP. FDA responded we would look for the SOP and will request if we are unable to locate. Also, SOPs S 004.006.001 and S 016.002.001, for review of medical records, do not adequately describe the process for review of relevant medical records looking for clinical and physical evidence of relevant communicable diseases. The SOPs only contain general references to communicable disease risk factors with a few examples. **Sponsor agreed to revise and submit SOP.**

Cord Blood Processing:

The sponsor was walked through the processing SOP (CBB S.007.008.00) clarifications sought, including the following:

- Please specify the single-use kit that you use for processing on the (b) (4) **(sponsor: we use kit number (b) (4))**
- You indicate a final (b) (4) concentration of (b) (4) after adding to the cord blood but your stock (b) (4) is a (b) (4) solution. Please clarify. **(sponsor: this is an error; the final (b) (4) concentration is (b) (4). We will correct)**
- How long is the (b) (4) **(sponsor: (b) (4))**
- Please provide information about (b) (4) processing including (b) (4) total processing time and volume of buffy coat achieved, examples of potential errors and how resolved **(sponsor: will do)**
- You add (b) (4) of plasma to (b) (4) buffy coat and save as a retention sample. Please note this is not representative of your final product. Please comment.
- Please provide time limits to the DMSO addition step (you state DMSO is added at a duration greater than (b) (4))

- Please explain/clarify the freeze protocol parameters in 7.2.1 under cryopreservation and storage.
- Indicate what happens after (b) (4) is achieved/not achieved during product freezing.

The sponsor indicated that responses will be sent in an amendment to the BLA. The call was concluded.

Teleconference date and time: November 8, 2017 at 13:00 – 14:00

FDA attendees:

Mercy Quagraine, PhD, BLA Chair, Product Reviewer, CBER/OTAT/DCGT

Heba Degheidy, PhD, CMC (flow) Reviewer, CBER/OTAT/DCGT

The following were discussed during the above telecon:

Process validation:

- Please explain how the cord blood units used for process validation were collected, consecutively or cherry picked (**sponsor: we used all the collection form a (b) (4) block from our collection sites**)
- You have steps mentioned in the validation document that cannot be found in the document e.g. Step 10.1.3, and thus makes it difficult to understand what was done (**sponsor: we do have a validation plan document (validation protocol) which you do not have; we will submit this document to you**)
- Please confirm that all the cord blood units (CBUs) used for the validation were transported within (b) (4) temperature range. (**sponsor: yes all units were within this range**)
- Please explain your acceptance criterion for CBU weight of (b) (4) (**sponsor: (b) (4) = bag; anticoagulant = (b) (4) and the remainder is cord blood volume; the minimum cord blood volume processed is (b) (4) = Cord blood+ bag+ anticoagulant**)

The sponsor indicated that responses will be sent in an amendment to the BLA. The call was concluded.