

From: Ocampo, Virginia
Sent: Monday, February 12, 2018 2:42 PM
To: Ocampo, Virginia
Subject: FW: MD Anderson BLA

From: Degheidy, Heba
Sent: Monday, February 12, 2018 9:04 AM
To: Ocampo, Virginia <Virginia.Ocampo@fda.hhs.gov>
Cc: Quagraine, Mercy <Mercy.Quagraine@fda.hhs.gov>
Subject: MD Anderson BLA

Dear Virginia,

Please see below the summary of the telecon that was held on Friday, February 9, 2018 at 12:15 pm. The sponsor will send their list of attendees to you.

FDA attendees: Mercy Quagraine; Heba Degheidy

MD Anderson Cord Blood Bank attendees (submitted by applicant): Elizabeth Shpall, MD, Jeff Wilson, Donna Reieux, Theresa Tompkins, Ankita Desai, Erin Eaton and Mil Fontenot

We discussed the following with the sponsor during the telecon:

1. Regarding their response to agency request to submit an action plan in case the currently validated cytometer will be down, we made the sponsor aware that they have the following options:

* Before using (b) (4) as a backup cytometer, they should submit a comparability protocol for our review and conduct a separate flow cytometry validation study for the backup cytometer. The validation study should include comparison of CD34 results between both flow cytometers and establish acceptance criteria for inter-instrument variances.

* Their proposed strategy to cryopreserve the cord blood sample in case the currently validated cytometer is broken and perform CD34 enumeration once the instrument is fixed is unacceptable. We made the sponsor aware that they should provide data demonstrating that the cryopreservation will not affect CD34 results during the proposed storage time before implementing the proposed change. In addition, you should establish an SOP describing in sufficient detail cryoprotectant to be used and its final concentration, the method for cryopreservation, volume of cryopreserved samples, condition of freeze, endpoint temperature of cooling, cooling rate, and storage temperature, steps for thawing and washing if applicable, containers and closures etc. and an action plan in case the storage time exceeds the validated time range.

* Currently, you cannot license any cord blood unit during the period of instrument breakdown until you fully validate the backup cytometer and provide an acceptable CD34 comparability data results between both cytometers.

2. Conditions for holding the formulated unit after (b) (4) thaw wash as part of cryoprotectant removal validation and instructions for use.

3. SOP for thawing (will be part of instructions for use)

4. Brief narrative of list of other samples retained (in addition to segment), containers stored in, and amounts stored, and conditions stored. e.g. serum, DNA and other. These samples are different from your reference samples

5. Instructions for use as a standalone document.